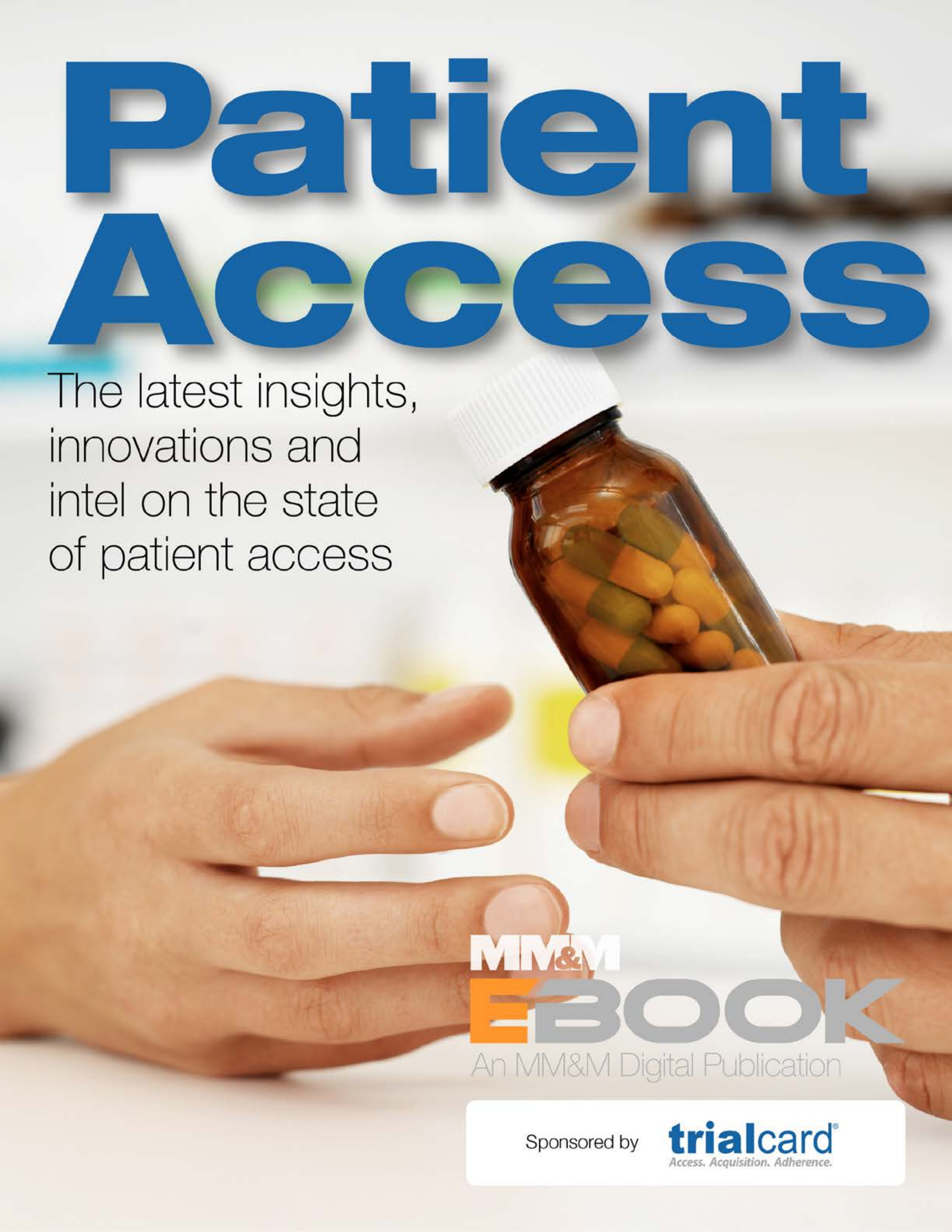
Patient Access

The latest insights, innovations and intel on the state of patient access



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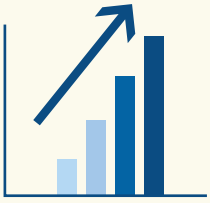
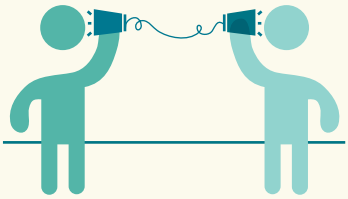


60% LIFT IN TRX

TrialCard Pulse Analytics determines the optimal offer to ensure brand therapy continues as prescribed.

20% INCREASE IN NRx

TrialCard Pulse Analytics' study of prescriber behavior, shows that NRx increases in the first three months of participation in our programs.



60% INCREASE OF SOV

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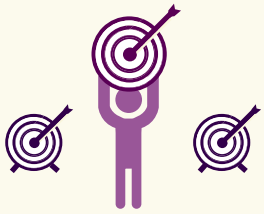
18% INCREASE IN ADHERENCE

Patients who utilize co-pay programs from TrialCard are 18% more adherent to their medications.



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Overview
The state of patient access

The average consumer benefits from ACA rules increasing the number of zero co-pays on prescription drugs and the availability of more low-cost generics, while specialty drug patients see costs and obstacles rise. **Marie Griffin** reports

Patient access to pharmaceuticals in 2014 is a tale of two worlds. For the world of the majority of patients, access has improved measurably. Prescription drug costs are declining and more drugs are available for no out-of-pocket cost, health insurance affordability has increased as a result of the Affordable Care Act (ACA), and seniors on Medicare are receiving help paying for branded drugs when they fall into the "donut hole," the price gap in which pharmaceutical costs are not covered by the program.

The situation is much more complicated, though, for the small minority of patients who have conditions requiring specialty medications. On the positive side, pharmaceutical companies are investing more in R&D to develop drugs that will be used by smaller patient populations. Seventeen new orphan drugs were launched in 2013 and a total of 53 have been launched over the past five years, in comparison to only 29 in the prior five years (IMS Institute for Healthcare Informatics).

On the downside, patients on specialty medications are asked to pay a higher proportion of their medication costs than other Americans—and the cost of these new specialty drugs can be sky high. One headline-grabbing case in point is Sovaldi, the Gilead Sciences treatment for chronic hepatitis C that was approved in December. The price for each pill is set at $1,000 and the cost adds up to $84,000 for a 12-week course—which is touted as a cure.

Gilead has instituted a program called Support Path that assists "eligible" hepatitis C patients who do not have insurance, are underinsured or who otherwise need financial assistance to gain coverage for or access to the drug, according to the company website.

The program includes dedicated case managers who can help patients and physicians with insurance issues, a 24/7 nursing support service line, and the Sovaldi Co-pay Coupon Program. "Most patients will pay no more than $5 per co-pay," according to the site. Gilead is also supporting the non-profit Patient Access Network Foundation, which assists eligible patients in covering out-of-pocket drug costs.

Generics and specialty drugs anchor price poles

The April "Medicine Use and Shifting Costs of Healthcare" report by the IMS Institute detailed how generics, which accounted for 86% of dispensed prescriptions in 2013, and no-cost preventative care drugs drove costs down for the average consumer. "Prescription drug costs for most patients are actually declining, with more than half of all prescriptions costing less than $5, and 23% now available with zero out-of-pocket costs," the IMS Institute reported.

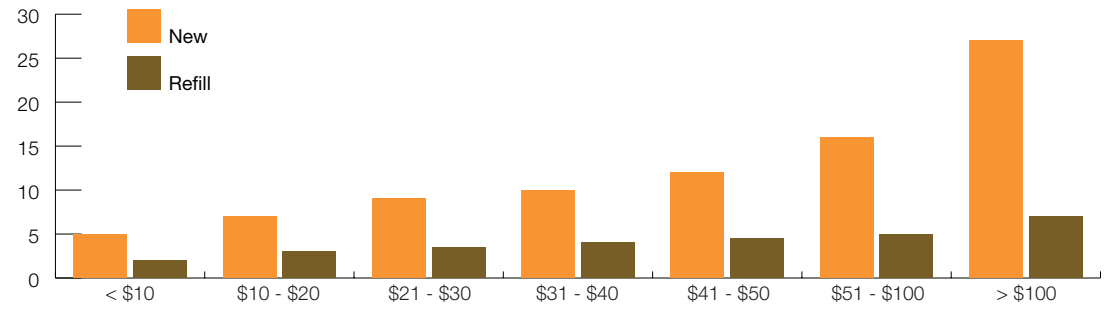
Americans with insurance picked up 207 million prescriptions without co-pays in 2013, and saved an

"You say, 'Well, if you're spending $100,000 for an oncology therapy, of course you'd expect some services.' But it didn't matter, regardless of disease state or type of drug."

—Tony Romito, *managing director, Accenture's Life Sciences Practice*

Abandoned prescriptions increase as co-pays increase, especially for new claims

Percent of claims by co-payment range for new vs. refill



New and refill commercial claims only, days supply ≤ 30, branded products only, 2009
Source: Wolters Kluwer Pharma Solutions

22%

of non-adherent patients said 'trying to save money' was a major reason for not filling a medication

Source: "MedicationAdherence in America, A National Report Card," National Community Pharmacists Association

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The state of patient access

average of $0.63 on each prescription they filled in 2013 compared to 2012. Women benefitted from new ACA rules on contraceptives, which resulted in the share of patients with zero co-pay rising from 20% in 2012 to 50% in 2013.

Spending on specialty medications, meanwhile, has averaged 10% growth in the last five years, and grew 9% in 2013. Specialty medications accounted for 29% of all drug spending in 2013, up from 23% five years earlier. As a result, 30% of patient prescription out-of-pocket costs were put toward just 2.3% of prescriptions. Five medical conditions—oncology, antidiabetes, mental health, respiratory and pain—are responsible for more than one-third of drug spending, the IMS Institute said.

Specialty medications accounted for 29% of drug spending in 2013

Access barriers are rising for patients who need specialty drugs, as PBMs and plan sponsors increasingly employ such PBM tactics as strict formularies, prior authorization and step edits. Earlier this year, *MM&M* commissioned a patient survey fielded by WEGO Health using the Truvio mobile research platform and database of health activists. Patients ranked cost, distribution and red tape as their three biggest obstacles. Sixty-two percent said they occasionally or frequently dealt with prior authorization or were asked to try cheaper alternatives before gaining access to the more costly drugs their doctors had prescribed, a tactic called step edits.

Poor adherence remains costly issue

The cost to the healthcare system of patients who do not take their prescriptions or do not take them correctly, known as nonadherence, has been estimated by various sources from slightly over $100 billion to almost $300 billion annually.

Progress is being made. For example, the IMS Institute reported that "medication adherence among large populations of patients with three of the most prevalent chronic diseases—hypertension, hyperlipidemia and diabetes—has improved since 2009 by about 3%." The institute also noted that out-of-pocket medication cost "is increasingly less of a factor" contributing to nonadherence for chronic conditions that can be treated with generic medicines.

Estimates of the percentage of patients that is nonadherent varies widely, partly because different researchers define the term differently. A November 2011 article, "Trouble Getting Started: Predictors of Primary Medication Nonadherence," published in the *American Journal of Medicine,* set out to measure primary nonadherence, prescriptions issued electronically and filled, but never picked up by the patient. Researchers found "nearly a quarter of patients given a new medication prescription by their doctor did not pick up their initial prescription, results that reflect slightly higher primary nonadherence figures than previous studies."

In "Medication Adherence in America, A National Report Card," a study commissioned by the National Community Pharmacists Association, nonadherence was studied at a more granular level. Based on a national sample of more than 1,000 adults age 40 and older who were taking a prescription medication for a chronic condition, NCPA found that 57% had missed a medication dose over the past 12 months, 28% did not refill their medication on time, 22% took a lower dose than prescribed, 20% did not fill a new prescription and 14% stopped taking their medication without discussing it with a physician.

Twenty-two percent of the nonadherent respondents said "trying to save money" was a major reason they did not fill a medication or did not take it as prescribed. Indeed, the higher the co-pay, the more likely it is that a prescription will go unfilled (see chart, previous page).

Pharma companies tackle adherence issues

There are many ways to improve adherence. Medication reminders can be sent to patient by text message or phone, or patients can use a medication reminder mobile app or use a simple plastic pill box with slots for each day of the week.

Pharmaceutical companies are addressing adherence issues when they formulate medications or prepare packaging for them. The classic wheel-shaped package for birth control pills with the days of the month displayed is one example of the packaging solution.

Formulating medications so that they can be taken less often—once a day rather than four times or once a month rather than weekly—has been found to improve both compliance and persistence in patients. Eight of the new drugs launched in 2013 were

Access barriers are rising for patients who need specialty drugs, as PBMs and plan sponsors employ strict formularies, prior authorization and step edits.

Overview
The state of patient access

formulated for easier dosing, the IMS Institute noted, "including an epinephrine auto-injector that talks the user through the process, once-daily formulations of diabetes drugs, an inhalable form of an antipsychotic drug, and a short three-day topical treatment for the prevention of skin cancer."

Co-pay assistance programs from pharma companies also contribute to the effort to improve medication adherence, various studies have found. A February IMS Insitute report, "Patient Savings Program Use Analysis," found that 14 million patients had received benefits from co-pay programs over the 12-month period studied. Authors concluded that "this study suggests that Patient Savings Programs play a selective

> **Co-pay programs also contribute to better medication adherence**

and meaningful role in addressing patient concerns about co-pay levels and out-of-pocket costs, enabling them to receive the benefits from medicines prescribed by their healthcare professional."

In another survey conducted for *MM&M*, this one by MDLinx.com/M3 Global Research, 71% of doctors strongly or somewhat agreed that co-pay assistance programs improved access to treatment, and 66% agreed strongly or somewhat that the card programs assisted adherence. Sixty-five percent of the patient advocates interviewed by WEGO Health strongly or somewhat agreed that co-pay assistance programs had an impact on adherence, as well.

The patients also made it clear that they wanted more than co-pay assistance from pharma when WEGO Health asked. Patients said information and assistance services were also important and highly valued. As one patient put it, "Loyalty programs can definitely be improved through more multi-dimensional and meaningful educational resources, in addition to co-pay assistance. Patients really need health-related information such as health and wellness tips, counseling and support, therapy, guidance, reminders, and other health education resources in addition to just lowering the cost of the medication."

These responses jive with what Accenture found when it surveyed 2,000 patients to find out what they wanted and expected from pharma companies. In a report titled, "Great Expectations: Why Pharma Companies Can't Ignore Patient Services," Accenture outlined the large gap between what consumers would like from pharma and what they get.

Although 63% of patients would like reward programs, only 10% say they had received them; 53% want product information, but only 48% have received it; and 51% want financial assistance, although only 10% say they have received it.

Seventy-six percent said they don't just want more services from pharmaceutical companies; they expected them, and the percentage was consistent across diseases and drugs.

"You say, 'Well, if you're spending $100,000 a year for an oncology therapy, of course you'd expect some services to come with that,'" explained Tony Romito, managing director of Accenture's Life Sciences practices, at *MM&M*'s Skill Sets Live event in June. "But it didn't matter, regardless of disease state or type of drug. It's a ubiquitous finding."

Interest in financial assistance is higher for patients taking medications for chronic conditions, at 57%. Overall, the most important services to patients, they said, are product information (73%), financial assistance (64%), reward programs (60%), and physician referrals (55%).

Payers are particularly keen to see assistance programs from pharma companies that go beyond co-pay discounts. In yet another survey commissioned by *MM&M* and conducted by MediMedia Managed Markets, payers tended to agree (42% of respondents) with the statement "improving adherence requires not only co-pay assistance, but also patient education and services."

In a newly released study, "Taking the Pulse, Formulary Decision Makers 2014," Manhattan Research found that formulary decision makers are taking notice of patient-support programs, with 87% of hospital, 43% of MCO and 47% of PBM formulary decision makers indicating that pharma-provided patient support or resources would positively impact or have boosted a treatment's formulary placement. ■

43%
of MCOs say patient-support prorams would impact formulary placement

Source: "Taking the Pulse, Formulary Decision Makers 2014," Manhattan Research

Barriers to Access

Costs rise for branded, specialty drugs

While generic usage is driving down costs for commonly used pharmaceuticals, co-pays and cost-sharing in both employer-sponsored and ACA exchange insurance programs is driving up costs for third- and fourth-tier brands

Patients may need help in accessing medications for a variety of reasons, including physical disability, language and educational barriers, and geographic proximity to pharmacy services, but the largest hurdle of all is cost. The good news on the cost front is that patients in general are benefitting from the ever-growing use of lower-cost generics, fueled by the fact that a number of the most commonly used "blockbuster" drugs, such as Pfizer's cholesterol-lowerer Lipitor and Bristol-Myers Squibb's blood thinner Plavix, have come off patent in recent years.

According to the IMS Institute for Healthcare Informatics' April 2014 report "Medicine Use and Shifting Costs of Healthcare," free prescriptions represented 23% of all prescriptions filled at retail pharmacies in 2013, and 78.6% of prescriptions cost patients $10 or less. (See chart below.)

At the same time, though, access for the minority of patients who need branded pharmaceuticals that have been declared non-preferred brands (tier 3) by their insurers or high-priced specialty medications are being hit hard by cost increases.

For consumers with employer-sponsored pharmacy benefits, non-preferred drugs moved further out of reach between 2012 and 2013. The Pharmacy Benefit Management Institute's (PBMI) 2013-2014 Prescription Drug Benefit Cost and Plan Design Report, which surveys employer-sponsored health plans, reported that the average co-pay for a 30-day prescription of a preferred-brand drug at retail was $29.17 in 2012; that rose by a modest 3.6% to $30.21 in 2013. The average co-pay for a non-preferred brand in 2012 was $53.10, but non-preferred brand co-pays climbed 5.7% to $56.12 in 2013.

The Affordable Care Act (ACA) was designed to enable more US citizens to access healthcare insurance, and the plans offered in the health insurance exchanges (HIX) are required to offer pharmacy benefits. However, benefit designs vary widely and the plans can reach government-mandated affordability targets in multiple ways. This may include prioritizing the affordability of medical services over pharmaceuticals, and, as a result, many people with HIX plans still won't be able to afford their prescribed drugs, according to the findings of a report published by Avalere Health in June 2014, "Analysis of Benefit Design in Silver Plan Variations." (The Pharmaceutical Research and Manufacturers of America, PhRMA, funded the research.)

"Consumers who qualify for financial assistance could pay the same cost-sharing for a prescription drug as higher income consumers who do not qualify for such assistance," the Avalere report stated.

Avalere's conclusions were based on analysis of one plan category, the Silver level, of the four levels offered within the exchanges, and those plans were within the federally facilitated marketplace (FFE) that covers 34

"Consumers who qualify for financial assistance could pay the same as higher income consumers who do not."

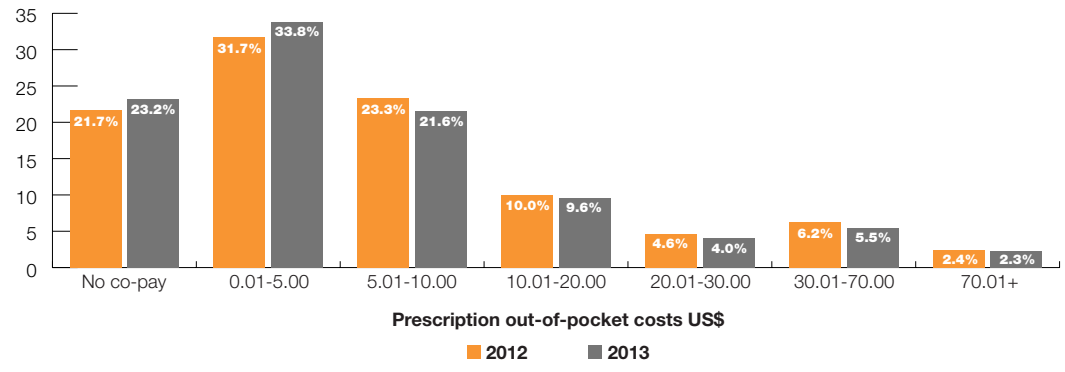
—Avalere Health, June 2014 report

4.95

Average rating (out of 9) patients give drugmaker efforts at working with MCOs to ensure drug access

(Source: *MM&M* and WEGO Health, 2014)

Percent of retail dispensed prescriptions by out-of-pocket costs US$



Source: IMS Health, Xponent PlanTrak Co-pay 2013

Barriers to Access

Costs rise for branded, specialty drugs

states. For ACA plans that offer tiered co-pays, the gap between preferred and non-preferred brands was even wider than in the employer-sponsored plans studied by PBMI. For the Standard Silver plan, Avalere found preferred brand co-pays averaged $49 and co-pays for non-preferred brands averaged $87, a difference of $38 as compared to $26 in the PBMI research.

Co-pays and co-insurance

Further, HIX plans were more likely than employer-sponsored plans to use co-insurance rather than co-pays, which requires patients to pay a percentage of the drug's retail cost rather than a fixed co-pay. The average co-insurance rate was 30% for tier-2 drugs and 36% for tier-3 drugs.

> **Patients who need brands declared 'non-preferred' are being hit hardest**

In many cases, the plans integrated co-pays and co-insurance, using co-payments for lower tier drugs and co-insurance rates for higher tier drugs. "Despite receiving cost-sharing subsidies, low-income consumers may face barriers accessing brand-name drugs due to high cost-sharing requirements, which are particularly prevalent on higher formulary tiers," the study's authors concluded.

For specialty drugs, patients face higher access barriers because of the higher costs of these medications. In four-tier benefit plan designs, which represented 15% of the plans included in PBMI's 2013-2014 Prescription Drug Benefit Cost and Plan Design Report, the average retail co-pay for specialty drugs (tier 4) grew from $88.75 in 2010 to $106.97 in 2013, an increase of over 20%.

Earlier this year, *MM&M* commissioned a survey of patients from the rare and specialty disease communities to understand their experience obtaining and paying for specialty medications. *MM&M*'s survey partner Truvio by WEGO Health contacted 24 health activists belonging to the WEGO Health social network. When asked to rate the effectiveness of specialty drugmakers in working with MCOs to ensure patients have access to medications, the average rating was a middle-of-the-road 4.95 out of 9.

For their part, payers are increasingly employing traditional pharmacy benefit management tools to keep escalating specialty drug expenditures in check. According to PBMI's 2014 Specialty Drug Benefit Report, the top strategies in order of use in 2013 were prior authorization, preferred products/formularies, clinical care management programs, step therapy and limiting the supply of specialty drugs to 30 days. (See chart below.) Although prior authorization was the most commonly used benefit management tool from 2011 through 2013, both preferred product/formulary plan designs and step therapy saw the greatest increase in use, by 17 and 14 percentage points, respectively. ■

Money managers

The top-five management strategies in pharmacy benefits for specialty drugs in 2013.

Percent of plans using strategy

	2011	2012	2013
Prior authorization	82%	84%	90%
Preferred products/formulary	68%	73%	85%
Clinical care management programs	81%	74%	82%
Step therapy	60%	68%	74%
Limit specialty products to 30-day supply	57%	67%	65%

SOURCE: Pharmacy Benefit Management Institute's 2014 Specialty Drug Benefit Report*
*Survey sample comprised 337 employers covering an estimated 14.3 million enrollees, including active employees, retirees and their dependents.

Leveraging Data
Patient-level insights

Pharma companies and their partners are beginning to mine the enormous amount of data collected across the healthcare continuum. Within that vast data pool lie the answers to endless questions about patient access

The pharmaceutical industry has a long history of working with voluminous data, but "big data" is still new. The term big data as it is commonly used today does not refer to how much data is gathered; rather, it refers to technologies that have recently emerged to allow businesspeople to analyze and gain insights from data more quickly and economically.

With big-data tools, the time has come for pharmaceutical companies, payers, healthcare providers and pharmacies to make better use of the great volume of data that flows through their enterprises every day.

A mindboggling amount of data, usually de-identified, is generated by just one consumer's interaction with retail pharmacy, including names of all prescribers, all the drugs the patient has taken, which of those drugs were brands or generic, how many times each drug was refilled and the time that elapsed between refills, the patient's insurer and the patient's share of the prescription cost, any and all co-pay discount cards that were used, which prescriptions were rejected by insurers and why, and more, as well as information on the patient such as gender, age and household income.

Within the vast data pool of drug and pharmacy information lie the answers to endless questions about patient access. What is the co-pay price sensitivity and walkaway rate for each branded medication, and what are the variables associated with it? Is there an age group, gender or income level that makes a patient more likely to abandon a prescription? What tactics can pharmaceutical companies and payers do to enhance adherence at an almost patient-specific level?

The IMS Institute for Healthcare Informatics dove into this data to get disease-specific answers, which formed the basis of its June 2013 report "Avoidable Costs in US Healthcare." The institute estimated that $213 billion in avoidable costs could be eliminated from the US healthcare system through more responsible use of medicines.

Nonadherence represents approximately half of the avoidable cost, which the institute pegged at $105 billion, with a range of $68 billion to $146 billion. IMS focused on six medical conditions that result in high morbidity and are major drivers of healthcare costs—hypercholesterolemia, diabetes, hypertension, osteoporosis, HIV and congestive heart failure—and used big data to analyze medication costs in light of the cost of medical services, providing proof with real-life data that while correct pharmaceutical adherence raises costs in the pharmacy benefit, it saves more money in the long run by lowering medical costs.

"Of the $105 billion wasted due to medication therapy nonadherence in 2012, 69% is spent on hospitalizations," the report said. All told, the IMS Institute estimated that better medication adherence would lead to a net healthcare savings of $44 billion for hypercholesterolemia, $24.6 billion for diabetes, $18.6 billion for hypertension, $15.5 billion for osteoporosis, almost $2 billion for HIV and $1 billion for congestive heart failure.

Big data a vast opportunity

Pharma is considered to be late to the big-data party

Insights help Sanofi win favorable reimbursement

"The 'big data' revolution in healthcare," published by McKinsey & Co. in January 2013, presented one example of how pharma companies have used big data to improve access. In Germany, a major payer, G-BA, would not include Sanofi's premium-priced diabetes drug Lantus (pictured) in its formulary.

Sanofi conducted a study that compared the effectiveness of Lantus to human insulin using data from IMS Health's Disease Analyzer. Lantus was shown to have a 17% higher persistence rate and findings suggested the use of Lantus might also delay the need for higher-priced therapy in the future.

As a result, "G-BA reversed its position. Sanofi has now secured contracts with more than 150 individual payors in Germany, covering about 90% of the German population," according to McKinsey.

"Not a lot of work has been done linking the front and back of the store, but we could get a great deal of insight into consumer behavior."

—Paul LeVine, *VP, analytic services, TrialCard*

67%
of life science firms use big data in marketing and intelligence efforts

Source: Cutting Edge Information, 2013

in comparison to other industries, and early efforts are being put toward big-data projects with big potential payoffs, such as the new product pipeline and providing clinical evidence for reluctant payers.

A recent study by consulting firm Cutting Edge Information shows that 67% of surveyed life science companies already use big data in their marketing and market intelligence efforts. The top ways pharma companies are using big data are, one, to assess the performance of existing products and therapies (73% of companies), and—tied for second place with 67% of companies—to characterize disease states and patient populations, and to target products and services.

A notable example of using so-called real-world data was AstraZeneca's PATHOS study, published in 2013, which showed that patients treated with AZ's Symbicort Turbohaler are significantly less likely to be hospitalized for COPD than those treated with GlaxoSmithKline's Seretide, and the company is using the study with payers, *MM&M* reported in March 2014.

> **Pharma companies are using big data for better formulary placement**

As drilling down into these kinds of data becomes a bigger priority for companies, vendors are also putting their resources toward big-data services that can bring a host of useful information to the surface.

Paul LeVine, VP, analytic services, for TrialCard, explained that his company is doing more and more proprietary data analysis for clients of its co-pay assistance and other patient-access products. He noted that a good co-pay assistance program requires a delicate balance between providing access to people who can benefit from lowered drug co-pays—which are linked to improved compliance and persistence with drug therapies—and taking a shotgun approach to marketing that will simply waste money.

Co-pay assistance programs provide a bridge between the patient and the pharma company that is difficult to accomplish due to HIPAA regulations. Patients signing up for the programs can opt in to share personal information and allow themselves to be contacted by the pharma.

Once that consumer-TrialCard connection is made, numerous new big-data opportunities open up. One example would be finding patterns in patient behavior between the pharmacy and other departments in a food, drug or mass merchandise store. "Not a lot of work has been done linking the front and back of the store," LeVine noted, "but we could get a great deal of insight into consumer behavior."

A new program from TrialCard called Prescriber Feedback is an effort to give consumers a reason to become more engaged with TrialCard, although, from the consumer's view, they are interfacing with a particular pharma brand. "We invite a consumer using a co-pay card to take a couple of surveys about his or her experience before and after using a product," LeVine said.

"When the patient opts in, we are able to give that information on the patient's experience with the drug to the doctor."

This information is particularly valuable with a new drug. "Patients typically only contact their doctor when a drug isn't working," LeVine pointed out. "So, in a case where a doctor wouldn't ordinarily hear of good experiences, we now have a vehicle to send that message." ■

$105B
was wasted in 2012 due to non-adherence to medications

Source: IMS Institute for Healthcare Informatics, 2013

Innovations in Access

Technology revolutionizes care

Mobile, wearable, ingestible, intelligent and interconnected devices become the building blocks for groundbreaking new ways to help patients with chronic conditions stay compliant

As health and medication data is increasingly digitized and mobile devices become more intimately integrated into the lives of consumers and healthcare providers, the opportunities for technological innovations in areas related to patient access and patient care management abound.

By the end of the first quarter of 2014, there were more than 100,000 health-related mobile apps available on the iOS and Android operating systems, a number that had more than doubled over the past two-and-a-half years, according to the Fourth Annual Study on mHealth App Publishing by mobile app ecosystem research and advisory firm research2guidance.

Publishers of mobile health applications primarily targeted chronically ill patients (31%) and consumers interested in fitness and health (28%). Physicians were targeted by 14% of app developers.

"Adherence-oriented programs harness mobile and web for reminders, education

Several pharmaceutical companies have developed mobile apps designed to improve adherence through reminders and education, but more and more companies are developing comprehensive disease-specific programs that incorporate mobile devices and Web-based tools, as well as a host of supportive services.

Merck, for example, offers the iChemoDiary app, which not only allows patients to track treatments but also to easily record their symptoms, such as nausea, pain and fatigue, that can be shared with doctors or loved ones.

AstraZeneca, which markets respiratory drug Symbicort, recently launched a program for patients suffering from chronic obstructive pulmonary disease (COPD) called Me&MyCOPD, which was developed in collaboration with Exco InTouch, a provider of digital patient engagement and data capture solutions for healthcare providers.

The AZ program addresses issues that have been shown to contribute to poor health outcomes, such as improper use of medications and failure to attend clinic visits, with mobile- and Web-based patient tools for patients. In addition, clinicians receive real-time access to enrolled patients' data, which gives them the ability to monitor adherence to treatment regimes.

Janssen Healthcare Innovation (JHI) is a group within Janssen R&D that has been tasked with the job of using cutting-edge technology and healthcare delivery solutions to improve patient outcomes. Under a consumer-facing Care4Today brand, JHI is developing programs focused on heart health, mental health and orthopedics, specifically for hip and knee replacement patients.

The technology at the center is JHI's Care4Today Mobile Health Manager, an iOS and Android mobile app with a secure digital messaging platform. The app allows consumers to set reminders for any prescription or OTC medications they choose, not only Janssen or other products from parent J&J.

Novel incentive

As a novel incentive for staying adherent, users can choose the Care4Charity feature that will allow them to earn 5 cents for each day they take their medications correctly and donate it to a charity. Users can track their donations and the combined donations of all users of the app.

While the pharma company programs have focused on specific patient groups, one new program from pharmacy chain Walgreens aims to improve the health habits of 81 million active members of its Balance Rewards customer loyalty program.

"Health trackers will interact with other wearables HCPs use, and when this happens, the power of the system will far exceed that of isolated wearables."

—Tim Chang, *managing director, Mayfield Fund, as quoted in TechCrunch*

31%

of mobile health apps target chronically ill patients

Source: Study on mHealth App Publishing (research2guidance)

In July, Walgreens introduced a new "Balance Rewards for healthy choices" initiative, which will reward the adoption of healthy choices—proven through connected devices—with loyalty points. To support consumers in their efforts, Walgreens is training select pharmacists and online Pharmacy Chat agents in the Tiny Habits method of behavior change developed by Dr. BJ Fogg, which encourages simple steps, or micro-habits, that lead to a healthier life.

Participants are able to earn points for activities like walking, running and biking when they track their activities with fitness devices and apps such as MapMyFitness, Lose It!, MyFitnessPal or RunKeeper and connect them to their Balance Rewards account. Walgreens also offers Balance Rewards points for participants who track their blood pressure and glucose levels at home using iHealth blood pressure and glucose monitors. Smoking cessation and nutritional behavior change programs are to be added to Balance Rewards for healthy choices in the coming months.

Digital health firms hold even greater promise for the near future

Meanwhile, new technology-based companies entering the digital health field hold even greater promise for the near future. One such company is Proteus Digital Health, which has developed an ingestible sensor that can be placed in a pill. The sensor sends a signal from within the body to a patch worn on the skin via Bluetooth.

The patch, which also tracks heart rate, body position and activity, transmits the various data to a mobile phone app where it can be stored, accessed and analyzed by the patient and, if given permission, healthcare professionals. Proteus, which raised $172 million in new funding in July, is conducting "private beta" tests with health systems in the US and UK to test the technology's utility for monitoring patient compliance and other purposes.

In a July 26 article for TechCrunch, "Startups Are Finally Hacking Healthcare," Tim Chang, managing director for the Mayfield Fund, suggested that "wearables," sensors and devices on skin and clothing or products like Google Glass will lead to another transformation.

"We'll see wearable [devices] expand to track continuous health data—heart rate, blood sugar, blood pressure, stress levels, respiration, brainwaves, posture, and even muscle activity. These trackers will also evolve from one-way passive reading to two-way reading and 'writing.' Further, these devices will interact with other wearable devices used by healthcare professionals and health services providers," Chang wrote.

"When this networked transformation happens," he added, "the power of the system will far exceed that of isolated wearables operating independently. Over time, this data can also be combined with confidential health-record data to provide truly personalized medical updates and a comprehensive view of your health and habits."

Another startup, Omada Health, has found a way to replicate the key elements of face-to-face therapy in Web-based programs for such conditions as type 2 diabetes, smoking cessation and insomnia. Omada has been able to demonstrate the clinical effectiveness of its programs so decisively that healthcare providers such as Blue Shield Louisiana, Kaiser Permanente and Stanford Hospital are willing to pay for them.

WellDoc is a developer of interactive disease management programs delivered via mobile or desktop app. Its type 2 diabetes interactive management program has been shown in a randomized clinical trial to produce a decline in blood sugar levels. One of the investors in WellDoc's recent $20-million funding round was Merck Global Health Innovation Fund. ■

$172M
of capital was raised by smart-pill company Proteus in its latest funding round this past July

Case Study
Co-pay trial yields data

Co-pay assistance programs can provide a manufacturer with information beyond that of a rebate program. This data may help with the marketing and overall sales of a product, as seen in the following case study

A small Southeastern-based pharmaceutical company specializing in GI products had been distributing a discount rebate for patients for its chief product, a one-time-use medication that is used in conjunction with a diagnostic testing procedure. The company is working with TrialCard on its patient-access programs, but the company declined to be named for confidentiality reasons.

The company's branded GI product competes in a mature, highly competitive market. Although there is not an AB-equivalent generic for this medication, there is a significant presence of generic products in the drug's class.

Although the pharma company was able to find out when, where and how often its rebate coupon was used by patients, the binary nature of the coupon—the voucher is either used or not, but no further information is gathered from the patient—prevented the company from gaining insights that would help with the marketing and overall sales of this mature product.

"The patient access programs that we operated on behalf of this product have had the limitation that they are not able to contribute much learning as to the behavior of patients or prescribers," said Paul LeVine, VP, analytic services, for TrialCard.

The TrialCard representative set up a test of a co-pay assistance program that would provide the manu-

37%
more new scripts for the target drug were written by prescribers in the co-pay program

Study on co-pay assistance debunks PCMA claims

A February 2014 report from the IMS Institute for Healthcare Informatics showed that patient access, patient assistance or patient savings programs—different names for the same proposition—do indeed lower patients' cost for the highest-price branded pharmaceuticals and that 14 million patients benefitted from these programs in 2012, the year studied.

The IMS Institute study also debunked earlier claims made in a November 2011 report from the Pharmaceutical Care Management Association (PCMA) titled "How Co-pay Coupons Could Raise Prescription Drug Costs By $32 Billion Over the Next Decade."

Visante, the healthcare consulting firm that conducted the study on PCMA's behalf, came up with the $32 billion sum based on assumptions and projections because, as the authors explained, the details of co-pay coupon programs are invisible to payers and PBMs because they occur after the adjudication of the prescription.

In contrast, the IMS Institute researchers had access to prescription data from IMS Health that came directly from retail pharmacies and included data related to co-pay cards that was not reported to payers.

Visante had "conservatively" estimated that 11% of brand prescriptions were associated with coupons in 2010 and projected that number would increase approximately 15% per year. Using that math, 14% to 15% of brand prescriptions should have been discounted with a manufacturer's co-pay program by 2012.

However, based on actual pharmacy transactions between November 1, 2011, and October 31, 2012, IMS Institute researchers found that only 6.1% of branded prescriptions and 1.2% of total prescriptions had co-pays paid in part by a manufacturer's co-pay assistance program. Among all prescriptions dispensed during those 12 months, the report noted, 80.4% were dispensed as generics and 18.4% were branded pharmaceuticals not associated with a prescription savings program.

The linchpin of PCMA's estimate of a $32 billion increase in drug costs over 10 years was the idea that co-pay assistance programs "reduce or eliminate the incentive to use generics." However, of the 526 programs the IMS Institute analyzed, almost nine in 10 (459 programs) were for brands that did not have an AB-equivalent generic.

Co-pay reduction programs did not eliminate the incentive for patients to use generic versions of branded drugs in the same therapeutic class, either. The IMS Institute found that, on average, patient savings programs reduced the consumer's co-pay by $40 and patients ended up paying $26 out of pocket.

According to the Prescription Drug Benefit Cost and Plan Design Report 2013-2014, published by the Pharmacy Benefit Management Institute (PBMI), the average co-pay for a 30-day supply of a generic drug in a three-tier plan configuration in 2012 was $10.64, making a branded drug co-pay, even with a manufacturer discount, almost 2.5 times as much as the generic.

But one key PCMA claim did hold up. The Visante report said co-pay reduction programs eliminated the cost advantages of payers' preferred drugs (tier 2). In 2012, according to PBMI data, the average co-pay for a 30-day supply of a preferred-brand drug at retail was $29.17, $3.17 (12%) more than the average co-pay for a branded drug with a manufacturer-supported co-pay discount program.

The data clearly indicates that manufacturers use co-pay assistance programs to make their non-preferred brand products more financially attractive to consumers. More research is required to discover the impact of that strategy on payers, patients and the American public.

facturer with additional value that the rebate program could not. The co-pay program would measure the amount of "spillover" prescribing from doctors participating in the program and help the company's sales team identify prescribers most likely to produce ROI for the brand through a prescriber targeting initiative.

> **The voucher is used or not, but no further information is gathered**

In the first four months of the new co-pay assistance program, 4,000 prescribers and 24,000 patients participated. In conjunction with IMS Health Consulting, TrialCard conducted an analysis to help the pharma company understand the financial impact of the program and found that:

- Prescribers in the new co-pay program wrote 37% more new prescriptions for the target drug than did statistically matched prescribers from the IMS database not exposed to the program.
- Physicians who were new prescribers of the product were writing 86% more prescriptions than matched prescribers who were not exposed to the program.
- Three months into the trial of the co-pay assistance program, about half of all participating prescribers were generating "net spillover prescriptions." These are the number of prescriptions purchased by patients of participating physicians at full, unsubsidized co-pay amounts that are higher than would be expected based on purchasing habits of patients of matched, unexposed prescribers.
- Through its prescriber targeting analysis, TrialCard was able to identify about 6,000 prescribers who were statistically likely to be strong contributors to brand growth, including 3,500 from the brand's original target list that had not been actively pursued. ■