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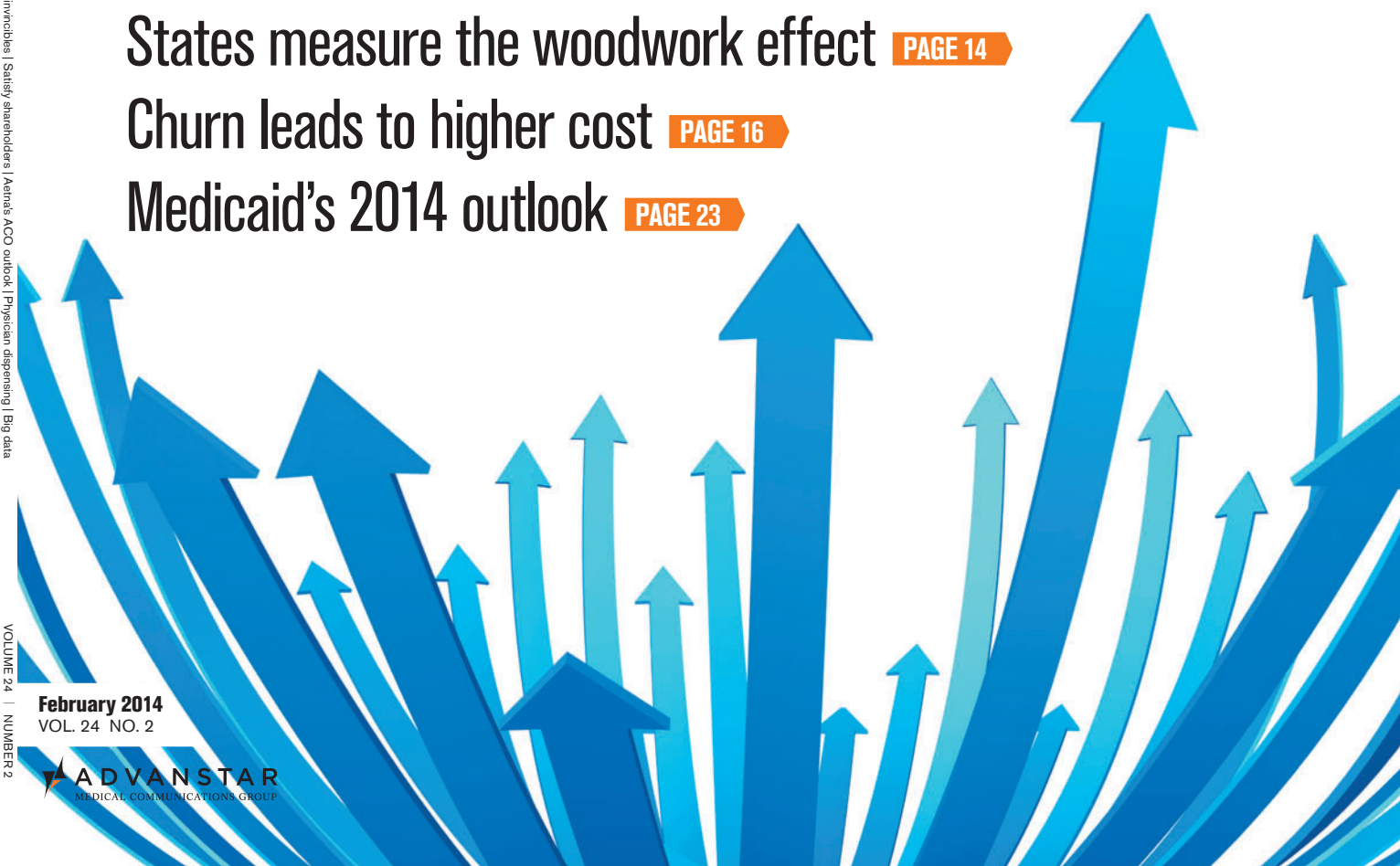
MEDICAID CHALLENGES BUDGETS

ACA DRIVES EXPANSION



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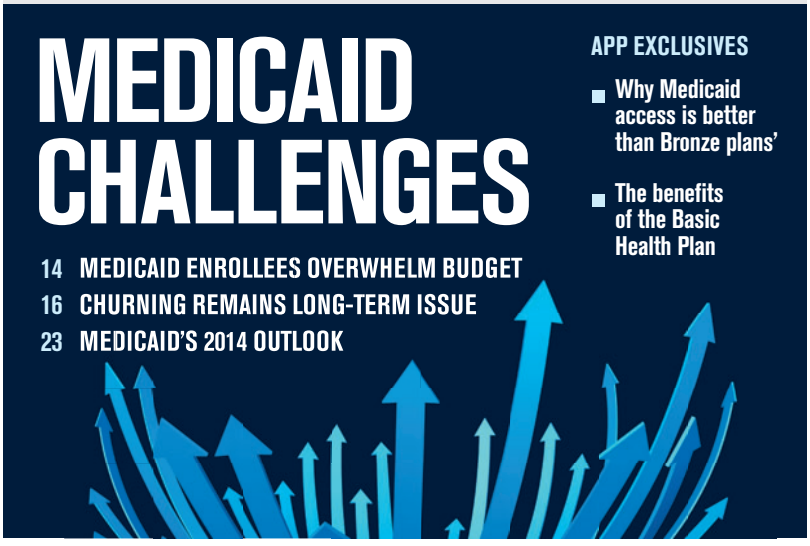
MEDICAID CHALLENGES

APP EXCLUSIVES

- Why Medicaid access is better than Bronze plans'
- The benefits of the Basic Health Plan



COMMENTARY

ESSENTIALS

SPECIAL REPORTS

Correction

Our January article "Concentrated efforts improve care coordination" should have reported that FAIR Health has a repository of more than 16 billion claims records. Read the full article: http://bit.ly/1iO69b8

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WE NEED MORE INNOVATION

Consumers expect more from healthcare as an industry

Customer experience in healthcare is slipping. Not that it was all that great to begin with, but it's slipping at a time when individual Americans are becoming more involved in health and interacting more often with the healthcare system.

According to PwC in its annual overview of the healthcare sector, all industry players could do a better job of innovating to meet the demands of the suddenly engaged consumers.

"We found that, indeed, these shoppers are price sensitive, but they are becoming more discerning," said Ceci Connolly, managing director of the Health Research Institute, in a conference call discussing the annual outlook.

With the industrywide focus on the consumer—specifically the consumer as an individual—money is moving differently. High-deductible health plans, increased out-of-pocket responsibility, transparent pricing and direct-to-consumer selling puts more market power in the hands of ordinary people who are restless and unimpressed with their healthcare experiences right now. From finding a health plan (on an exchange site or otherwise), enrolling, choosing a provider, scheduling an appointment and following up on care recommendations, consumers believe the experience is lacking.

For example, a busy mom doesn't want to fill out the same form with the same information about her family for each interaction she has with a payer or provider. She doesn't have to do that in other areas of her life, and shouldn't have to do it for her healthcare.

How to improve the experience

The PwC experts say that mobile health (mhealth) is one way to begin satisfying consumer wants while at the same time keeping up with added demand from 25 million new covered lives. Mhealth could include electronic communications between patients and providers, remote monitoring, virtual diagnosis and self-directed actions such as smart-phone apps for appointment scheduling.

Consumers are accustomed to these technologies for travel, banking and entertainment, and they perceive healthcare as being behind the times.

Chris Wasden, managing director for PwC, says the industry shouldn't wait for traditional technology creators to present products and services to healthcare, but rather, payers and providers should drive their own innovation and use mhealth and the cloud to fuse technologies into daily consumer activities.

It's telling when you consider that some of today's most popular wellness tools have come from outside healthcare, such as the electronic bracelets that so many Americans are wearing on their wrists to track exercise and calorie intake. Had the device originated on the healthcare side—rather than the consumer side—it would have no doubt suffered years of adoption barriers, not the least of which is price.

According to PwC research, 27% of physicians are encouraging their patients to use mhealth today, but sometimes it's the patients that are educating the physicians on what's available and how to use it. Almost 60% of physicians agree that mhealth is the way of the future.

Even though you're working at breakneck pace to keep up with consumerism, the demands are clearly growing faster. Consider creating a more versatile process to manage innovation separate from the model you currently have for your core business. ◘

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EXCHANGE VISITORS
Through Dec. 31, 2013

Source: Commonwealth Fund

Diabetes on the rise 10 / Exchanges still limping 11 / Plans fix formularies 12 / Time to rebrand 12

OIG VIEWS CUT-AND-PASTE SHORTCUTS IN EHRs AS FRAUD

DONNA MARBURY, MS
ADVANSTAR CONTRIBUTOR

NATIONAL REPORTS—The time-saving technique used by physicians known as "cloning" in electronic health records (EHRs) has drawn criticism from a top government report, which calls the practice the equivalent of fraud. However, those in the medical field have complained for years that lack of time and poorly designed systems are the real reasons for suspect billing errors.

A report by the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) calls out the Centers for Medicare and Medicaid Services (CMS) for failing to implement measures to prevent fraud. The *New York Times* reported last month that the federal government's $22 billion incentive program launched in 2009 to encourage EHR use in practices and hospitals may have encouraged "hundreds of millions of dollars" of fraudulent activity.

The OIG points the finger at "cloning"—the copy-and-paste function used in most EHR systems that allows the person inputting information to duplicate codes across different records. *"Inappropriate copy-pasting could facilitate attempts to inflate claims and duplicate or create fraudulent claims,"* the report stated. Also, the OIG blamed EHRs that auto-populate fields for *"suggesting the practitioner performed more comprehensive services than were actually rendered."*

CMS has long called fraud prevention a top priority.

The Health Care Fraud and Abuse Program's most recent report revealed that its efforts recovered $4.2 billion in fiscal year 2012. For every $1 spent on investigations, $7.90 is recovered, HHS says.

In the first half of 2013 alone, a Medicare strikeforce known as HEAT charged 148 fraudsters, saw 139 convictions and recovered $193.7 million.

DISABLE CUT-AND-PASTE

The OIG suggests that CMS make fraud prevention strategies clearer to providers and suggests disabling the copy-and-paste function on EHRs.

According to physicians and other medical professionals on social media who have commented about the controversy, they use the copy-and-paste functions in EHRs the same way that many people use it for other computer functions; to save time when they know they have to duplicate information.

Michele McGlynn, chair of the Health Information and Management Systems Society (HIMSS) EHR Association, says that more dialog between EHR companies, providers and others in healthcare needs to happen before new policies are made.

"We, of course, agree that providers should document accurately for both clinical and payment purposes, but feel that constraining technology features is not the solution," McGlynn says. "We feel strongly that CMS would benefit from the insights the EHR Association can bring to this discussion as to best practices, policies and recommendations regarding these features, having implemented and supported thousands of EHR systems collectively."

The issue of EHR fraud has been under scrutiny for years, gaining momentum as the Meaningful Use incentive program was launched. Medicare contractors, including National Government Services, reported in September 2012 that it would deny claims for what seemed to be cloned documents.

With the rise in demand for medical scribes to input EHR information for providers, it is unclear whether these extra hands on medical records will help deflate fraud claims or make the issue more complicated. ◘

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See the Office of the Inspector General's "Most Wanted Fugitives" list, featuring more than 170 people sought for charges related to healthcare fraud and abuse. http://1.usa.gov/1e7B0uE

PREVALENCE OF DIABETES ON THE RISE AMONG SUBPOPULATIONS

Consider tailored approaches for better health management

FRED GEBHART
MHE CONTRIBUTOR

NATIONAL REPORTS— If your health management program is seeing an increase in members with diabetes, you're not alone.

A study by the Health Care Cost Institute (HCCI) released in December 2013 found that the prevalence of diagnosed diabetes is rising across the country.

In 2012, 8.8% of individuals younger than 65 who had employer-sponsored health insurance had diagnosed diabetes, gestational diabetes or prediabetes. In 2008, the prevalence of diagnosed diabetes was 6.4%.

Even more alarming is the rate of diagnosed diabetes in specific subpopulations, says study co-author and HCCI Senior Researcher Amanda Frost, PhD. Only 0.6% of children covered by employer-supplied insurance had diabetes in 2012, but 11.6% of adults age 19 to 64 had diabetes. Greater than 10% of the overall study population in the Mid-Atlantic, South Atlantic and East South Central states had diabetes in 2012.

Women with diabetes outnumber men until age 44, but men with diabetes outnumber women in older cohorts. Overall, 76.6% of individuals with diabetes in the study were ages 45 through 64.

Prevalence: The percentage of a population that is affected with a particular disease at a given time.

Incidence: The rate of occurrence of new cases of a particular disease in a population being studied.

IN THE BRIEF, HCCI ESTIMATED PREVALENCE ONLY

"The subpopulations are not getting enough attention," Frost says. "Most people focus on the overall population numbers."

HCCI analyzed claims data weighted to be representative of the employer-sponsored insured population nationwide for 2007 to 2012. Claims data were based on ICD-9 codes as suggested by the Dictionary of Disease Management Terminology.

DIABETES PREVALENCE AMONG ESI INSUREDS, 2008-2012

	2008	2009	2010	2011	2012
Percent of ESI Population	6.4%	7.1%	7.8%	8.3%	8.8%
Diabetes per 1,000 Insured Months	64	71	78	83	88
Change from Prior Year	N/A	12.0%	9.2%	7.2%	5.4%

Source: Health Care Cost Institute
Note: All data weighted to reflect the national, younger than 65 ESI population.

Claims data showed that while the absolute number of individuals covered by employer-supplied insurance fell during the study period, the prevalence of diabetes within the insured population increased.

Researchers found an increase in the prevalence of diabetes in each year of the study within the overall population, as well as within each subgroup except children aged four and younger.

The greatest change in prevalence was in adults older than 25. In 2008, about 4.1% of adults aged 26 to 44 had diabetes compared to 6.1% in 2012. Over the same period, the percentage of adults aged 45 to 54 with diabetes increased from 10.1% to 14.3%. The oldest cohort, adults aged 55 to 64, showed the greatest increase in diabetes, jumping from 18.5% in 2008 to 24% in 2012. For all adults, the prevalence rates rose from 8.4% to 11.6% while the rate among children rose from 0.4% to 0.6%.

Diabetes in the insured population also varies geographically. States in the West showed the lowest rates of diabetes throughout the study period, while states in the South showed the highest prevalence.

According to co-author Carolina Herrera, MA, HCCI Director of Research, "There are clear implications in terms of population management of diabetes based on sex, age and geography."

@ More online

Read key findings from HCCI:
http://bit.ly/1fXcgfy

NAVIGATORS WORK AROUND CONTINUED GLITCHES

Ohio volunteer enrolls just two exchange members in three months

DAVID BENNETT
ADVANSTAR CONTRIBUTOR

CLEVELAND—Since she was hired as a navigator by the not-for-profit Parma Health Ministry last November, Dona Kiner has been stymied by the technical problems that persist with the federal insurance exchange website, *healthcare.gov*.

The problems haven't stopped Kiner from assisting local residents of this Cleveland suburb make sense of the new federal online insurance marketplace, however.

Adorned with a large shoulder bag, Kiner schedules presentations at local libraries, a community center and other public places where she conducts education for potential enrollees. It is also her job to walk applicants through enrollment forms.

Not that it's been easy.

"We're still dealing with glitches," Kiner says, referring to the lack of connectivity between the federal website and Ohio's Medicaid computer system, for example.

Kiner has become a practical expert in Ohio's new Medicaid enrollment procedures, helping dozens of individuals determine if they are eligible—delivering them directly into the state's growing Medicaid pool. She estimates that 95% of the people that she has assisted during the last few weeks are Medicaid eligible.

The first step in the Medicaid application process, Kiner says, is to bypass the *healthcare.gov* online exchange tool. It is still problem-plagued by her estimation, more than a month after federal officials announced it was working just fine for "the vast majority of visitors."

By using the federally operated exchange, Medicaid-eligible applicants risk falling into an administrative limbo they might not escape any time soon.

ENROLLMENT GROWS

Since Ohio's expanded Medicaid enrollment period began December 9, 2013, an estimated 65,000 Ohioans who have applied for Medicaid through *healthcare.gov* are still shut out of Ohio's system because the platform is unable to transfer data from individual applications onto state computers, says Samuel Rossi, spokesman for the Ohio Department of Medicaid.

"On December 28, representatives from *healthcare.gov* began calling those Ohioans who applied through the federal website for Medicaid and told them to reapply at the state level because the transfer is not going to be complete," Rossi says.

With the help of navigators like Kiner, and solicitation of state and federal officials, Ohio Medicaid applicants are reapplying at a fast clip, causing Ohio Medicaid enrollment figures to jump. Since December 9, 2013, Ohio has added 39,000 enrollees.

"Even if it takes 30 days or even a few more to get enrolled, it's still quicker than *healthcare.gov* at this point," Rossi says.

Ohio is one of 36 states using the federal online marketplace for enrollment. It also joins 25 states and the District of Columbia moving forward in expanding Medicaid under the Affordable Care Act (ACA). In October, the Centers for Medicare and Medicaid Services (CMS) approved a state plan amendment, extending Medicaid eligibility in Ohio.

The move also provides Ohio $2.5 billion in federal funds through ACA.

Expansion of the Ohio program is expected to add about 366,000 uninsured residents to the rolls by 2015, including 231,000 children, parents and seniors who are now eligible, but who are not yet enrolled.

TWO EXCHANGE SIGN UPS

Since November, Kiner has successfully helped just two people navigate through *healthcare.gov*. Packing her bag as she prepares to leave the Parma Public Library, Kiner says it remains a work in progress.

Some fixes already implemented have resulted in improved performance of *healthcare.gov*. At the end of 2013, more than 2 million people had signed up for coverage, with about half of that number enrolling through the federal exchange, according to government estimates.

OHIO MEDICAID
POTENTIAL NEW ENROLLMENT

Newly eligible below 138% FPL	365,616
Previously eligible above 138% FPL*	90,863
Net new enrollment at 138%	**274,753**
Currently eligible, not enrolled	230,792
Total new enrollment	**505,545**

FPL= Federal Poverty Level
*Those eligible will seek coverage on the exchange
Source: Ohio Medicaid

CMS hired Accenture, a consulting and technology services company, in early January to fix the functionality of *healthcare.gov*. When the technical problems are finally resolved, it should be easier to steer consumers through the marketplace, Rossi says.

"I will say once the federal website is working well, their website and our website will be connected so the data will be able to be transferred in real time," Rossi says. ■

PLANS UNDER PRESSURE TO BALANCE FORMULARIES

More products on non-covered list

TRACEY WALKER
ADVANSTAR CONTRIBUTOR

Express Scripts and CVS Caremark are expected to expand their list of non-covered drugs for the 2015 plan year, leading to challenging pricing negotiations between branded pharmaceutical companies and pharmacy benefit managers (PBMs). Given the Affordable Care Act (ACA), industry watchers are not surprised.

"Narrowing pharmacy networks and limiting pharmacy risk exposure has become more important under ACA-compliant benefit offerings," according to F. Randy Vogenberg, PhD, RPh, principal, Institute for Integrated Healthcare, Greenville, S.C. "That creates obvious conflicts with select branded firms particularly in the traditional pharmaceuticals arena making contract negotiations high-pressured."

For managed care and health-system decision-makers this could mean more pressure on balancing network issues between clinical performance and economic impact, according to Vogenberg.

"For example, limited drug choice for patient use or increased risk sharing from a PBM shifts cost exposure to the provider versus the payer," he says.

Express Scripts moved 48 products to "not covered" status for its 2014 National Preferred Formulary, which is the selected formulary for approximately 30% of its members, according to David Whitrap, Express Scripts spokesman. In doing so, the company is able to save its clients more than $700 million this year, he says.

The excluded medications represent about 1% of all of the products currently on the PBM's formulary, and "nearly all of them have copay cards that drive up the overall cost of care," he says.

Also, the CVS Caremark Preferred Drug List (PDL) reflects the PBM's recommendations to provide comprehensive coverage and reduce overall costs, according to CVS Caremark spokeswoman Christine Cramer.

"A number of the drugs removed from the PDL for 2014 are high-cost, non-preferred drugs with very low utilization," she says. ■

CONSUMER FOCUS CHANGES PLAN BRANDING STRATEGY

Focus on local healthcare when rebranding your plan

JULIA BROWN
CONTENT SPECIALIST

SUNRISE, FLA.—With the start of 2014, more plans are rebranding to market to consumers under the Affordable Care Act.

Sunshine State Health Plan, a subsidiary of Centene Corperation—a national government-program-focused health insurer with health plans in 18 states—has undergone a statewide rebranding effort in order to increase exposure of the multiple managed care services it offers in Florida. The plan officially launched its new logo, marketing materials and name, Sunshine Health, on January 1.

"We believe very strongly in local branding and putting our employees in the local markets," says Beth Nunnally, vice president of external relations at Sunshine Health. "We want the states that we serve to know that our employees are hired locally, that they live locally and that we understand the communities, our providers and our members across the products."

Florida itself recently went through a large procurement process and is now transitioning its Medicaid program into a fully managed-care system. Instead of being a health plan entity, Florida will now be mainly a regulatory administrative entity.

"We were a large winner because there's a natural transition in the program in Florida," Nunnally says. "We wanted to go ahead and do the rebranding at the same time as we transitioned to the new program so there was a very clear delineation between the old program."

When founded 25 years ago, Centene offered only Medicaid-focused health plans. Over the past 10 years, the organization has expanded its portfolio. For example, not only is Sunshine Health a Medicaid health plan, but it also offers long-term care plans, child welfare through a foster care plan, Medicare Advantage, a nursing home diversion and a State Children's Health Insurance Program (S-CHIP) called Healthy Kids.

Nunnally says that with the rebranding, the plan wanted to focus on simplifying the healthcare process from a corporate, member and provider perspective.

"Overall, our purpose was not to just get a new look, but it was to stress the fact that as an organization, healthcare should be simple," she says. "So with our brand, our logo, and all our communication, we've tried very hard to simplify the process so healthcare's not intimidating."

Nunnally emphasizes the importance of a plan to brand locally, so that it can take ownership of the state in which it resides. For example, Centene's Sunshine Health, Peach State and Buckeye State health plans are easily identified as Florida, Georgia and Ohio plans. This makes it easier overall for employees, providers, members and the state itself, she says. ■

PLANS DRAW FIRE FOR NARROWING NETWORKS

Patients and insurers weigh tradeoffs between lower premiums, fewer doctors

Under pressure to control costs in a rapidly changing and uncertain healthcare market, insurers are slimming down provider networks in plans offered through federal and state exchanges and by Medicare Advantage (MA) plans. Similarly, plans and pharmacy benefit managers are establishing "preferred" pharmacy networks to control outlays on prescription drugs.

Doctors and hospitals have been fighting back, claiming that patients will lose choice and access to quality care. Officials in Maine and New Hampshire went after Anthem Blue Cross Blue Shield last fall for marketing exchange plans that excluded certain state hospitals. In Washington state, several insurers were kept off the exchange initially due to "inadequate" provider networks. Similar issues emerged in South Dakota, Pennsylvania and Mississippi, where legislators cited "any willing provider" laws requiring insurers to include any provider that accepts its terms.

Cuts in providers covered by MA plans have also drawn protests and legal action. Physicians in Connecticut filed suit in December to block UnitedHealthCare from dropping more than 2,000 doctors from its MA plan in that state. State medical societies in Ohio, New York and Florida weighed similar action against plans moving to cancel or change contracts with doctors and hospitals. The network changes in Connecticut drew attention on Capitol Hill, prompting a Senate hearing and proposals to require notice in advance of the annual MA open enrollment period of provider network changes.

Insurers say that slimmer networks are a way to maintain low premiums and copays in the face of major reductions in MA rates. Private Medicare plans have to meet clear "network adequacy" standards, they emphasize, noting that their aim is to establish "high value" and "high performing" provider networks that offer quality care.

Costs vs. coverage

Many consumers and payers accept the trade of limits on provider access for lower premiums. A December poll of small employers found the majority willing to offer plans with narrow networks if that means reduced costs.

Anxious to avoid "sticker shock" when consumers began shopping for coverage, the Obama administration approved many lower-cost Bronze plans with more limited provider rolls. As Qualified Health Plans can't exclude less healthy individuals and must offer minimum essential benefits, a way to keep a lid on premiums, deductibles and copays is to establish narrow or "ultra-narrow" networks.

Former HHS Secretary Mike Leavitt explained in a recent interview with Kaiser Health News that some consumers prefer to have fewer choices in providers and to assume added risk if that means lower premiums. While the tradeoff is not good for everyone, Leavitt emphasizes that "you can't constrain costs" unless insurers have the ability to narrow networks over time. "If you require everyone to have everything, then costs will continue to go up."

Steering beneficiaries to restricted networks is nothing new. Kaiser Permanente has long had a limited cadre of doctors and hospitals employed by the Kaiser system, and perennially earns high marks for quality and access.

Ironically, Congressional Republicans, who otherwise might agree with Leavitt's argument, seized on provider curbs as another opportunity to attack President Obama for promising Americans that his program would let them keep their doctors, as well as their current plans.

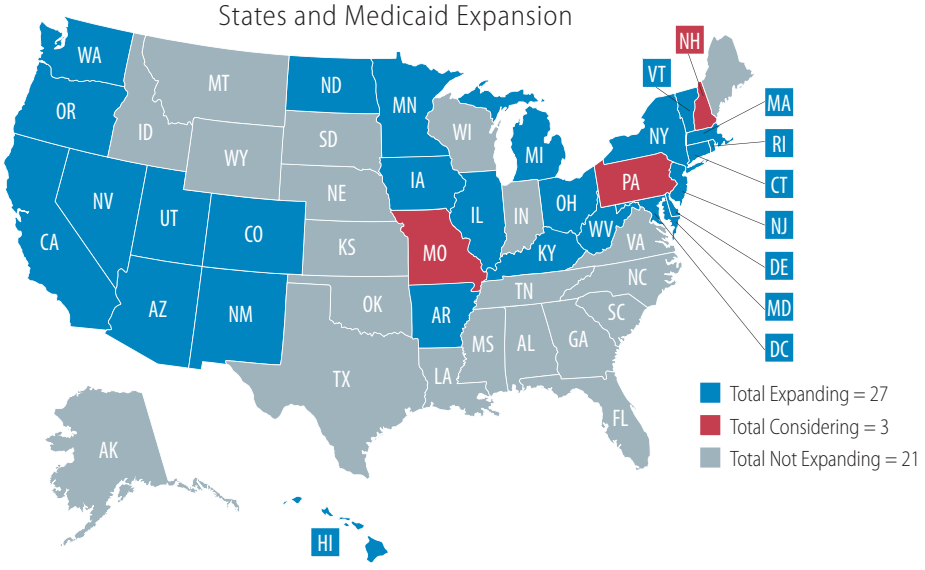
The idea that plans can save money by managing networks more tightly is supported by greater transparency in hospital and provider rates that reveal huge differences in charges for common procedures—with little correlation to quality. ■

ABOUT THE AUTHOR

Jill Wechsler, a veteran reporter, has been covering Capitol Hill since 1994.

MEDICAID ENROLLEES CHALLENGE BUDGETS

STATES EXPECTING THE WOODWORK EFFECT



Thinkstock/iStockphoto/Levente Janos Map Source: The Advisory Board Company, January 24, 2014

By **JENNIFER BYRNE**

ALTHOUGH THE DISSEMINATION OF FEDERAL funds to states opting into Medicaid expansion has only recently begun, increased enrollment was seen as early as October, when the exchanges first opened.

According to Emma Sandoe, spokesperson for the Centers for Medicare and Medicaid Services (CMS), 3.9 million people enrolled in Medicaid in October and November 2013, including people who are newly eligible under the Affordable Care Act's (ACA) expansion, and those who were eligible under prior law, she says.

The emergence of new Medicaid enrollees from among those previously eligible may be explained in part by the "woodwork effect," a phenomenon in which increasing general awareness of Americans' coverage options brings large numbers of the uninsured "out of the woodwork."

"We know that at any given point in Medicaid's history, there has always been

a significant number of people who are eligible, but just aren't on the program, for various reasons," says Matt Salo, executive director of the National Association of Medicaid Directors. "So, the expectation [was] that when January 2014 rolls around and the expansion happens and the exchanges go live—and the culmination of all the outreach and information and education about the program gets out—a lot of these people will start showing up."

Salo says in some cases, previously eligible individuals were not aware of the program, or might have been repelled by the stigma of receiving "handouts."

"An analogous situation was when the Children's Health Insurance Program (CHIP) program was created in 1987, as an add-on to the Medicaid program for kids," Salo says. "We did a lot of very different advertising for it, and it was billed as: 'This is not Medicaid; this is private insurance for kids.' And in a lot of states, what people found was that for every kid who came onto the program, there were sometimes two, three or four kids who were actually Medicaid eligible."

NO ACA FUNDS FOR WOODWORK POPULATION

While bringing more of the uninsured into the Medicaid program is ostensibly the goal of the expansion, the woodwork effect could be financially overwhelming to states if not immediately in 2014 then in years to come. The existing Federal Medical Assistance Percentages (FMAP) are one source of funding for state Medicaid populations—matching state expenditures with federal dollars—while new federal dollars under ACA are meant to pay for the expanded population.

"The people in the new expansion group, the newly eligible, will have 100% of their care paid for by the federal government, but anyone in this woodwork-effect group—those who were previously eligible—they don't get any enhanced match at all," Salo says. "If you're in New York, for example, maybe it's 50/50, or if you're in West Virginia, it's 70/30. And if that population turns out to be sizable, that does pose a possible financial impact to states."

According to Sara R. Collins, vice president of Healthcare Coverage and Access for the Commonwealth Fund, the Congressional Budget Office is projecting about 9 million new Medicaid enrollees this year, and about 12 million by 2015.

"This would include those who come into the program because they were already eligible," she says.

Salo says in terms of successfully managing a potential woodwork effect influx at the state level, much will depend on anticipating the numbers and budgeting for them.

"Part of the question is, how many of these folks will show up?" he says. "You know it's going to be factor, but you don't know how much of a factor it's going to be. You might budget expecting 10% of these people to show up, or you might budget expecting 90% of them to show up. This is what state budgeting does—you make assumptions about behavior, and they're often wrong. You can't predict the future."

Another important factor for states to consider, Salo says, is the demographics and the health status of new enrollees.

"Is it the 28-year-old waiter or waitress who is young and healthy, but just doesn't have a lot of money? That's easy; these people don't cost a lot of money," he says. "Or are these people who are off the grid, with co-occurring mental health disorders or substance abuse problems? Are they homeless? These people are very expensive."

COVERAGE GAP

Conversely, in states that have opted out of the Medicaid expansion, Collins says there is the coverage gap affecting many of those who would have been newly eligible. She says this gap will affect about 5 million of the uninsured.

"If your state doesn't expand the Medicaid program and your income is under 100% of federal poverty level, then you are often not eligible for the tax credits," Collins says. "States have varying levels of eligibility in their current Medicaid programs, mostly for very low income parents; most don't have coverage for adults. So people are going to fall into this gap where their incomes, perversely, aren't high enough to get a subsidy."

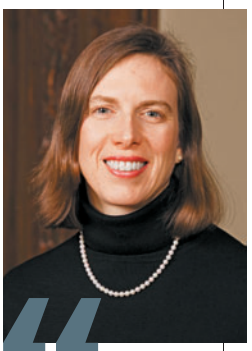
The motivations for choosing not to expand Medicaid vary from state to state. However, Collins says she doesn't believe that pure financial reasons would be a legitimate factor.

"It's hard to understand the economic rationale for not expanding," she says. "States can choose to ex-

Continued on page 16

EXECUTIVE VIEW

- States won't get ACA funds for previously eligible Medicaid enrollees.
- A few states are requesting waivers for private-market expansion models.



"States can choose to expand next year, but opt not to participate the following year. But they are losing a substantial amount of federal dollars by not participating."

—SARA R. COLLINS
THE COMMONWEALTH FUND

pand next year, but opt not to participate the following year. But they are losing a substantial amount of federal dollars by not participating."

She says particularly from the perspective of the hospitals, which will now have reimbursement for a lot of people who were previously uninsured, expansion makes sense. It's better to have patients with a source of coverage than to chalk up higher percentages of bad debt and charity care.

Salo says for many states, political or ideological concerns are the motivating factors for choosing not to expand Medicaid.

"In states where governors or state legislators have been, in essence, running against Obama as aggressively as possible for four years, for them to turn around and say, 'oh, I'd like a second helping of that please,' is a political nonstarter," he says.

He says it's not fair to characterize Republican-led states as not caring about poor populations, but rather it's that they're concerned that their only options are to expand the program as it is, or do nothing.

THE 'PRIVATE OPTION'

There has been some movement toward alternative Medicaid expansion models outside of what's described in ACA. Salo says the CMS approval of Arkansas' "private option"—which uses federal Medicaid resources to purchase private health insurance for low-income residents of the state—has spurred similar initiatives in other states. So far, four states have sought alternative models, with stipulations such as lifetime limits on coverage, mandatory job searches or drug testing for beneficiaries.

"The administration has been kind of coy in its willingness to broaden this to a lot of other states," Salo says. "But in the past couple of weeks, we've seen Iowa and Michigan get approval for variations of the Arkansas approach."

He says states want other options besides all or nothing, and the administration miscalculated the states' willingness to accept federal funding at the cost of their politics.

"In a lot of state houses, there's more concern about the direction the federal government is taking and the debt it is accruing," he says. "So, they are holding out. It's like Kabuki theater, or a game of chicken: waiting to see who is going to blink first."

Collins maintains that for the residents of the states, the expansion is bound to be beneficial, even with those who appear from the woodwork.

CHURNING REMAINS A LONG-TERM ISSUE

Coverage gaps lead to 40% higher costs

By **JULIE MILLER**

Interruptions in Medicaid coverage, widely known as "churn," cause gaps in care for members as well as substantial administrative burdens for all stakeholders. And the Affordable Care Act (ACA) doesn't solve the problem.

Medicaid health plans have been concerned about the issue of churning since the Medicaid program began, says Margaret A. Murray, CEO of the Association for Community Affiliated Plans (ACAP) and an editorial advisor for *Managed Healthcare Executive*. ACAP is a national association representing 58 not-for-profit safety-net health plans.

"It's not a simple as it should be to keep people on Medicaid," Murray says. "Sometimes people go to the pharmacy, and they think they're covered, but they're not. And then they can't get their maintenance drugs."

LOSING COVERAGE

According to ACAP, enrollment in Medicaid—unlike private insurance or Medicare—is like a sieve: Every year millions of people enroll, only to subsequently lose their coverage for a variety of reasons. Those who lose coverage often find their way back into the system, and then churn out of it again.

Even with the exchange marketplaces directing individuals and families to Medicaid when they qualify:

- **Administrative and technical problems can delay or halt the Medicaid enrollment process when a member does not have information or fails to complete the application correctly.**
- **Short-term enrollment periods require frequent re-enrollment that members might not be aware of.**

Continued on page 22

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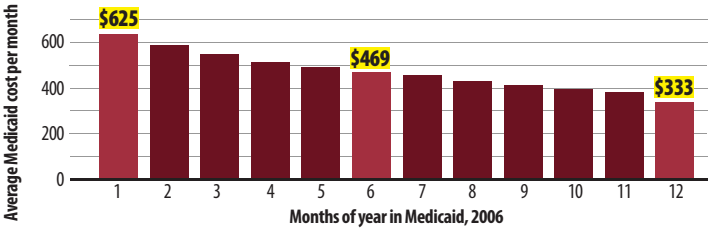
ManagedHealthcareExecutive.com

Average Monthly Medicaid Costs for Adults



Source: Analyses of 2006 Medical Expenditure Panel Survey, controlling for age, gender, health status, disability, pregnancy, income, education, etc. Ku, et al. 2009

Continued from page 16

- **Temporary changes in income can cause individuals or families to lose eligibility for Medicaid and experience a gap in coverage while they seek new coverage or default to being uninsured.**

Gaps in coverage can span from several months to years. The average person who qualifies for Medicaid is only covered and has use of benefits for 9.7 months of the year, Murray says. For a non-disabled adult, it's only 8.7 months of the year.

"Texas is most egregious state in that way," she says. "An eligible adult in Texas is only on Medicaid for half of the year—well below the national average."

Children fare better, however. About half the country has state laws that guarantee 12-month continuous coverage for children, and they have an enrollment continuity of 82%, meaning the population has continuous enrollment for an average of 82% of a full year.

Murray says ACAP would like to see a requirement for all states for 12-month enrollment.

At the federal level, an April 2013 bipartisan bill sponsored by Reps. Gene Green and Joe Barton of Texas would require 12-month continuous enrollment guarantees for all Medicaid beneficiaries to reduce churn in the population. Murray says 19 representatives have sponsored the bill in the House, and Senate introduction is expected soon.

CHURNING INTO EXCHANGES

While ACA aims to drive healthcare coverage for all Americans through increased Medicaid eligibility and financial assistance in the commercial market for those who don't qualify, churning still occurs between coverage situations.

"Now we're concerned because people's income might change, and they'll no longer be eligible for Medicaid, so they'd go to the exchanges and be eligible for subsidies," Murray says.

She says a significant number of individuals will be crossing the Medicaid/exchange line multiple times a year. A 2011 study in *Health Affairs* estimates that within a six-month period more than 35% of all adults with family incomes below 200% of the Federal Poverty Level will either lose Medicaid coverage and transition into an exchange, or vice versa.

Murray says having the same plans in Medicaid and in the exchanges could help ensure continuity of care for members. For example, members that stay with the same health plan, even though they might be moving from Medicaid coverage to commercial coverage, could maintain their preferred doctors and stay on their care regimens, she says.

"We did a study that showed of all the health plans that are in an exchange, 41% are also in Medicaid," Murray says.

ACAP's study found 117 of 287 Qualified Health Plans in the federal and state-based exchanges operate managed-care Medicaid plans in the same state.

COST SAVINGS

Research proves there are cost savings associated with continuous Medicaid enrollment.

A George Washington University report released by ACAP late last year, "The Continuity of Medicaid Coverage: An Update" used new data to calculate the average monthly costs for Medicaid enrollees. It found that the average monthly cost to the Medicaid program is $345 for adults enrolled in Medicaid for 12 months of the year, compared with $597 for those who are enrolled for just one month—a difference of more than 40%.

Researchers found significantly lower costs for children who are continuously enrolled, with an average monthly cost of $110 for children enrolled in Medicaid for 12 months of the year, versus monthly costs of $151 for those enrolled for just one month, a difference of more than 25%.

Additionally, there are long-term consequences to consider. Churn also interferes with efforts to measure outcomes. Most quality measures such as those used by the National Committee on Quality Assurance require continuous enrollment for 12 months for a patient's data to count toward a specific quality measure. Full-year enrollment would provide for more stable measurement.

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SMOOTH THE TRANSITION

In the meantime, plans are launching unique programs to help smooth the transition for members who might experience churn. For example, AmeriHealth Caritas offers high-touch services to help its Medicaid members re-enroll as required.

"We have a couple of units that focus on those members whose eligibility period is coming to an end," says Karen Michael, vice president of corporate medical management for AmeriHealth Caritas Family of Companies.

During the transition, the plan also offers downloadable clinical summaries to reduce care gaps.

"Members can go online and see their medical history that's gathered out of our claim data, and they can print that and take that with them if they experience a coverage change or a churn period where they're starting over with a new physician or primary care provider," Michael says.

Data includes office visits, hospital stays, pharmacy claims, diagnoses and high-level radiology information, she says. The program began just over a year ago and adoption is increasing across the 15 states AmeriHealth Caritas serves.

@ More online

See ACAP's state-by-state outline of enrollment continuity here

http://bit.ly/1aLaqqy

2014 MEDICAID OUTLOOK

1 Populations are Expanding

While Medicaid managed care plans have traditionally been employed by states to care for children, parents and pregnant moms, Robin Arnold-Williams, partner for Leavitt Partners, says states are going to the private market for other populations as well.

"We do continue to see the expansion of Medicaid managed care across the country where you see states that have not gone in that direction previously, now going that way," Arnold-Williams says. "We see it as well in states that for many years used Medicaid managed care as the vehicle to deliver Medicaid for the traditional populations of kids now also looking to integrate all of the Medicaid populations."

For example, the elderly who also qualify for Medicare are now being enrolled in pilot projects to manage their care with a blended funding stream. The Centers for Medicare and Medicaid Services (CMS) is especially interested in demonstrating cost savings by integrating care for dual eligibles.

California's Medi-Cal program and CMS are partnering to launch a three-year demonstration in eight counties beginning this year—Cal MediConnect—which aims to create a seamless service delivery experience for dual eligible beneficiaries, with the ultimate goals of improved care quality and a more efficient delivery system. Fourteen other states have similar demonstration projects planned, each receiving up to $1 million in funding.

2 The Private Market is Viewed as a Type of Reform

"Medicaid managed care is viewed as a private market solution, and that why it's retained its attractiveness," Arnold-Williams says. "It's viewed as 'reform' for traditional Medicaid especially in more conservative states that did not expand."

For example, Kansas is moving more individuals into managed Medicaid while the governor continues to lean away from expanding Medicaid under ACA rules.

3 Managed Care Can Control Costs

From a legislator's perspective, managed care can provide more predictability and is one of the best options for cost control.

"It brings certainty to your Medicaid budget," she says. "Whereas, with a fee-for-service model, you don't have the ability to control all the different variables. The factor you would predict is enrollment which is better than predicting fee-for-service costs."

4 Plans Must Prove They Can Care for the Populations

Arnold-Williams says with expansion of managed care comes skepticism of commercial carriers' effectiveness in handling high-need populations, such as the elderly or disabled. In fact, CMS put a project on hold that was supposed to begin January 1 in Kansas because of concerns over home-care services for the disabled.

— Julie Miller

Reducing waste requires collaborative effort

Avoidable costs amount to more than $1 trillion

by JILL SEDERSTROM

Waste in the American healthcare system is both rampant and costly—but experts say collaborative approaches between payers and providers to reduce waste and identify the best patient interventions could help drive costs down and improve overall care.

Reports detailing exactly how much wasteful spending exists in the American health system vary, but one report from PwC's Health Research Institute found that wasteful spending accounts for up to $1.2 trillion of the $2.2 trillion spent on healthcare in the United States. The largest area of waste was attributed to defensive medicine: redundant, inappropriate, or unnecessary tests and procedures.

To combat this wasteful spending, Brett Hickman, a partner in PwC's Health Industries Advisory Practice says payers and providers have adopted strategies that run the full gamut of integration, whether its non-integrated attempts to individually address medical management through utilization reviews or quality assurance, full integration, or something in between such as shared savings arrangements.

"Across the country, you have the understanding or realization that there is a lot of waste, a lot of inefficiency, a lot of duplication, and the savings is not in rates. The savings is in how well care is managed or not managed, and it's really in utilization," Hickman says.

TOP 3 AREAS OF WASTED SPENDING

$210 billion
Defensive medicine

$210 billion
Inefficient claims processing

$200 billion
Care for preventable conditions related to weight/obesity

Source: PricewaterhouseCoopers' Health Research Institute, 2013

New payment models

Payers are trying to reduce healthcare costs and cut out unnecessary or wasteful spending by changing payment models, increasing the focus on evidence-based medicine and sparking competition between providers.

While fee-for-service payment models once dominated the industry, some health plan executives say it isn't the best model to reduce unnecessary spending and address patient needs.

"In the provider community, we look to work toward risk based contracts with our provider groups and in so doing, they have a stronger stake in the game," says Paul Kasuba, MD, chief medical officer for Tufts Health Plan. "They are going to be more incentivized or aligned to think about the kind of care they are providing and do it in a more effective fashion."

Profit-sharing can create a necessary financial incentive for physicians to restructure

their ideas on patient care, according to Dr. Kasuba.

"It probably accelerates the changes," he says. "Most physicians out there want to practice using evidence-based medicine and want to do what's right, but often it takes some time for things to be adopted."

Bruce Nash, MD, MBA, chief medical officer for Capital District Physicians' Health Plan (CDPHP), agrees that to reduce overall waste in the system, health plans need to take the initiative to move away from fee-for-service structures. As part of the plan's enhanced primary care program, which includes more than 200 practices and 200,000 of CDPHP's members, primary care physicians are no longer paid on a fee-for-service structure and instead are heavily reimbursed based on how well they improve the patient experience, enhance the overall population health and reduce costs.

"We actually pay them more for the sicker patient, so they can spend more time for better outcomes," he says.

Dr. Nash says once physicians in the plan commit to the patient-centered model, they receive an increase in their base pay of 15% to 20% in addition to incentive dollars which can be an additional 20% on top of that.

"They are getting additional revenue into their practices so they can modify how they are practicing, in some cases seeing fewer patients per hour and spending more time with the appropriate patients or for that matter blocking off a couple hours a week to think about and work as a team within the practice to improve their care delivery," he says.

Dr. Nash says the plan is still waiting for further analysis to determine how effective their efforts were in 2012, but says data from an initial pilot showed improvements in 15 out of 18 HEDIS measures and saw cost reductions due to less hospital utilization and fewer emergency room visits.

Revenue reduction?

Even with incentive payments, a shift from fee for service could mean less income for providers, however experts say the current healthcare system is

HOW PROVIDERS USE CHECKLISTS TO CUT COSTS

Choosing Wisely rallies physicians around evidence

by **JILL SEDERSTROM**

Momentum is growing for the Choosing Wisely program. The initiative challenges national medical organizations to identify five tests or procedures that are potentially overused in their speciality. The lists are being incorporated into clinical settings in an effort to cut wasted spending in the United States.

It's a welcome development for payers—organizations that have long been at the table of stakeholders advocating for real-world cost reduction in the system overall.

When Choosing Wisely rolled out in 2012, it had the support of nine organizations, but now boasts 60 participating medical societies, according to Richard J. Baron, chief executive officer and president of the American Board of Internal Medicine (ABIM) and the ABIM Foundation, who launched the initiative.

"It's been going wonderfully well in any direction you could name," Baron says.

The ABIM Foundation funds some of the administrative functions of the initiative such as branding and trade marking, but Baron says the majority of funding comes from the medical organizations that participate in the effort.

Society checklists

Each society has developed its own list of recommendations derived from concrete, evidence-based studies to guide physicians practicing in the field. For example, the American College of Radiology suggests not doing imaging for uncomplicated headaches and not doing a computed tomography (CT) for children suspected of appendicitis until an ultrasound is considered.

Experts say the Choosing Wisely recommendations carry greater weight with physicians because they were developed by their own professional societies and aren't dictated by payers for the purpose of reducing costs.

"The drivers are quality and what's right for the patient, and the key person in charge is actually the front-line workers who are delivering care," says Kulleni Gebreyes, MD, a director with PwC's health industries practice.

Joseph Flood, MD, FACR, president of the American College of Rheumatology (ACR), says the ACR used a thorough process to identify services that may be overused or needing re-evaluation, including a recommendation not to use anti-nuclear antibody (ANA) subserologies without a positive ANA test first.

"Those expensive tests were thought by us to be really low-hanging fruit where we could save the system a lot of money through the recommendation," says Dr. Flood.

Quick adoption

Since the initiative rolled out, Dr. Gebreyes says academic medical centers and multihospital health systems have used Choosing Wisely as a springboard when developing their own clinical initiatives to reduce costs and improve the quality of care.

"We particularly see it used with systems that are investing heavily in population health management and are involved in risk sharing contracts," she says.

Data are limited about the effect the campaign has had on utilization but Dr. Gebreyes says the most significant cost implications of the campaign will likely be from reductions in hospital stays.

"On the inpatient side, reducing the number of tests may not reduce your costs in a significant way but what we have found is the coordination and the communication that goes around a campaign that also improves appropriate utilization decreases length of stay," she says.

Payers have worked to boost awareness of the campaign among providers. Paul Kasuba, MD, chief medical officer for Massachusetts-based Tufts Health Plan, says it has held provider forums around Choosing Wisely to help promote its implementation in the community.

"We've got a community here that understands that there is inefficiency and waste in the system and are looking for effective ways of taking that out and part of it is by being better-educated orderers of tests and also consumers of healthcare," he says.

Baron says payers haven't been directly involved with the effort because the campaign's focus is centered on the best patient care practices from a medical perspective.

"The idea behind the initiative is really professionalism in action, and we don't advocate for these things to be hard-coded into prior authorization rules," he says.

unsustainable as it is and needs to evolve to continue to function.

"Is there enough gain in the risk sharing to offset the revenue reduction? The answer is probably not," Joseph Fifer, president and chief financial officer of Healthcare Financial Management Assn., says. "But it's better than the alternative."

Sharing financial risks and rewards isn't the only tactic health plans are using to curb unnecessary tests and procedures. The healthcare community as a whole has also been placing a greater emphasis on evidence-based medicine and creating standards and recommendations to guide patient care.

CDPHP has instituted specific programs to guide utilization of areas of healthcare that are associated with high cost and variation, such as certain imaging procedures. They also run a medical therapy management program to highlight the latest pharmaceutical studies and findings with network physicians.

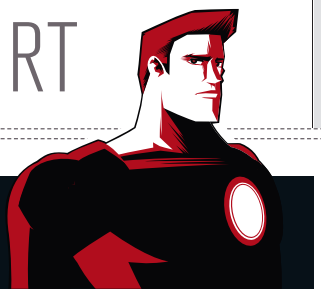
"We have invested heavily in our informatics capabilities in recent years so now we can give targeted information to specific practices in the area of pharmaceuticals for example," Dr. Nash says.

Placing a greater emphasis on the latest medical evidence can reduce variation, increase buy-in from physicians and aid in patient discussions.

"If I am a patient, I am going to rely on that physician's judgment with that evidence-based medicine to create the best care protocol for me, but in doing that you just eliminated lots of variation, you've created a high-quality environment, and a by-product to all of that is you've reduced your cost," Fifer says.

Health plan executives say report cards can also be an effective way to get providers and physicians to think differently about how they provide care in the future. Payers and providers may already be taking steps to reduce waste in the system, but experts say it's also important to note that meaningful change won't happen overnight.

Jill Sederstrom is a freelance writer based in Kansas City.



4 ways to attract YOUNG INVINCIBLES

Reach 18 to 34 year olds through social media and innovative products

by **JULIA BROWN**

Young invincibles are a vital ingredient to the long-term survival of the exchange plans under the Affordable Care Act (ACA). But the term "young invincibles"—used to describe 18 to 34 year olds—also pinpoints an attitude that insurers must try to override: *I don't need insurance, so why buy it?*

According to 2010 Census data, there are 73.7 million people ages 18 to 34 in the United States. Out of the 45 million uninsured nationwide, young adults make up the largest portion at about 19 million.

Nearly a quarter of the 2.2 million people who have enrolled in health coverage through the federal and state exchanges so far are young adults, according to a January report by the Department of Health and Human Services (HHS). That's below the 38% estimate the Obama administration has given for ensuring that premiums stay low.

The Congressional Budget Office estimates that 7 million people will sign up during open enrollment, including about 2.7 million young adults. While administration officials say they are satisfied with current numbers, they hope to increase young adult enrollment before the March 31 deadline.

Millions of young adults have already gained coverage through the ACA's provision allowing family-plan dependence until age 26, and there is still a potential market of 18 to 34 year olds for the exchanges. Kentucky and Washington estimated that more than one-third of early enrollments in their respective exchanges were within the 18-to-34 age group.

Using Massachusetts' health reform as an example, older and sicker people signed up first, while others primarily waited until the end of the six-month enrollment period. ACA enrollment is following in a similar pattern, which allows plans a last-minute opportunity to catch the attention of the younger demographic, according to experts.

Before open enrollment comes to an end, acquire a well-balanced risk pool and ensure your plan's sustainability by attracting young invincibles with these best practices.

1/ PRIORITIZE MEMBER ENGAGEMENT

A start-up health plan co-founded by three technology entrepreneurs has been sparking a lot of interest in New York. The three friends behind Oscar Health plan are looking to compete in the marketplace. With its market niche, the industry has dubbed it the plan for young people, the founders say.

"We designed a new kind of health insurance that is simple, guides members through a complex healthcare system, and makes them feel like they have a doctor in

Getty Images/iStock Vectors/Tomacco

52%

of young adults cite cost as the primary reason for not having coverage.

the family," says co-founder Mario Schlosser. "We are observing that the simplicity and utility of our product speaks for itself."

Oscar prioritizes member engagement by offering an interactive experience that focuses on ease of use. The plan also offers value-added services, such as free 24/7 telemedicine through a partnership with Teledoc with the ability to have a physician on the phone within an hour of a member's request. Most importantly, the plan is reinventing the typical healthcare process by having the member seek out the health plan prior to the visit.

Oscar also provides free generic drugs, one-click refills through a Twitter-like interface, online rate comparisons and other web-based tools, such as an interactive map of in-network providers.

"Everyone deserves member-friendly health insurance," says Schlosser. "Our product is useful and affordable so that everyone, no matter what age or background, will want to sign up."

The co-founders have compared their product to Google in the way that customers can search the site and get an answer.

"Plans should speak their members' language and offer products that operate like the rest of the Internet and the most consumer-friendly applications and gadgets out there," he says. "The best marketing strategy won't be able to gloss over poor usability, counter-intuitive processes and other product failures."

2/ MICRO-TARGET DIFFERENT POPULATION SEGMENTS

Just because young people share commonalities, experts say that it's a mistake to approach all 18 to 34 year olds the same way. It's important to develop a refined strategy that micro-targets the subsegments of the young adult population, such as ethnic groups. This is something that the Covered California exchange has done well, according to Aaron Smith, co-founder and executive director of Young Invincibles, a national nonprofit advocating for the voice of young adults on issues like healthcare.

"Whether it's young Latinos or young African Americans, young professionals or young students, these are all slightly different demographics that have slightly different economic interests and health needs," he says.

Young Invincibles recently teamed up with Univision on a mobile app to reach a young Latino audience. It also has a partnership with a hip-hop radio station in Los Angeles, which has integrated healthcare advertisements into all of its concerts.

One mistake for insurers to avoid is assuming that all young people are going to pick the same type of health plan: a high deductible, low premium plan. Young people are attracted to all different levels of plans, Smith says, and many who have enrolled with the help of Young Invincibles have opted for more robust, comprehensive coverage.

According to HHS, the majority of enrollees overall have purchased Silver plans (60%) as opposed to Bronze (20%), Gold (13%) and Platinum (7%). Purchase preferences for 18 to 34 year olds have not been released.

3/ THINK OUTSIDE THE BOX

It helps to get creative when reaching out to young people, especially on social media.

"A lot of people think [ACA] is very complicated. And there is a certain complexity, but the main thing is breaking down the barriers so that people realize they can sign up and there's coverage out there," says Ted Goldman, veteran legal affairs writer and editor in Washington, D.C., and lead author of a recent *Health Policy* brief on young adults and the ACA.

YouTube videos are a great place to start. Rocky Mountain Health Plan created an entire site dedicated to a leaked "zombie apocalypse" video that urges people to sign up for coverage before it's too late. The video has received more than 44,000 views.

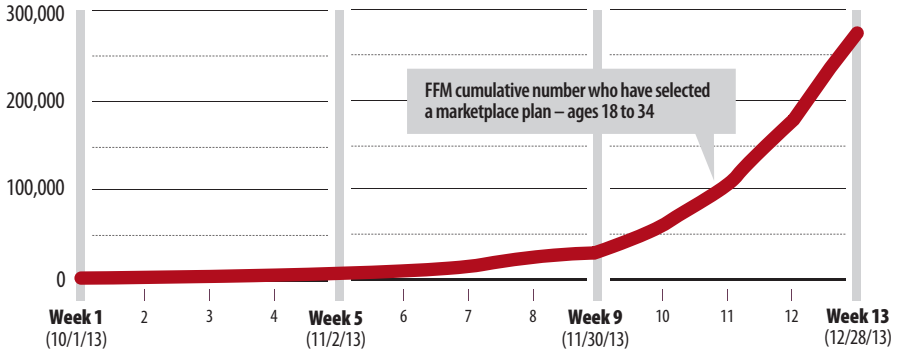
"Tell a Friend—Get Covered," a national campaign led by Covered California in collaboration with other state exchanges and Enroll America, has been using an online social presence to raise awareness about health reform among young people. The campaign actively uses the Obama administration's hashtag *#GetCovered* with all of their media.

In January, the campaign hosted a six-hour live YouTube event, which aimed to inform young people about how to obtain coverage. Featuring policy makers and celebrities, the event also promoted wellness.

In partnership with the campaign, a number of videos geared toward young adults that feature celebrities have been released by *Whitehouse.gov* as well as Funny or Die, a popular comedy video website. In contrast to these efforts, the organization Generation Opportunity is taking its "Creepy Uncle Sam"

OCTOBER 1 - DECEMBER 28, 2013

Young adults who selected a plan through the federally-facilitated marketplace



Source: Centers for Medicare & Medicaid Services, as 1-9-2014

ad campaigns to platforms like YouTube and SnapChat, a popular photo messaging application, to encourage young adults to opt-out of coverage. Views on YouTube for the ad have reached more than 2 million.

4/ PROVE WHY COVERAGE IS FINANCIALLY SOUND

A survey by the Kaiser Family Foundation found that 52% of young adults cited cost as their primary reason for not having coverage as opposed to not needing coverage (17%).

Although the initial mentality might be to simply sell a product, plans should prioritize explaining to young people why purchasing coverage is a good financial decision.

"It's not about selling young people on some idea or slick marketing campaign," Smith says. "For many, health insurance has been a tough financial decision because they don't make very much money, they have jobs that don't provide benefits and there's skepticism about whether the product is going to be affordable and whether it's going to cover them when they need it. But young people are pretty hungry for unbiased, just-the-facts information."

According to a December, 2013 *Health Affairs* policy brief, young adults are two to four times more likely to forgo treatment for medical problems.

Young people also go to the emergency room more than any other age group and 15% have chronic conditions, according to Smith. He says polls have shown that young adults want health insurance, they just haven't been able to afford it. The idea of paying a penalty and getting nothing for it verses purchasing coverage and receiving services in return is an important message to convey.

"You get health insurance for more reasons than just to avoid a catastrophic crisis," says Goldman. "If you end up with a high deductible plan, you're still going to pay a negotiated rate even if you have to pay out of pocket. If you get an MRI, it'll be $500 or $600 instead of $1,500 or $2,000, which is what you'd get if you walked in off the street without coverage. It may be a bit archaic, but it's pretty important."

Young Invincibles estimates that some 9 million young adults with incomes 133% to 400% of the Federal Poverty Level will be eligible for a premium tax credit that will reduce or eliminate the price paid for coverage through the exchanges, but many aren't even aware. A survey by PerryUndem showed that 69% of uninsured adult respondents did not realize financial help was available through the exchanges.

Nonprofit advocacy groups and some health insurers are working hard to get the word out and are pointing to helpful tools, such as subsidy calculators. Another useful tool is Blue Cross Blue Shield of Michigan's Text 4 Subsidy resource, which allows consumers to initiate a back and forth exchange detailing their subsidy eligibility. The text-messaging-based tool is available to most young people daily.

WHAT DEATH SPIRAL?

With all the technological setbacks and glitches of *healthcare.gov* at the end of 2013, and the clock ticking on open enrollment, concerns about low enrollment of the young and healthy have been abundant.

However, a recent study by the Kaiser Family Foundation (KFF) addressed concerns that low enrollment of young adults might lead to a "death spiral."

The study stated that under a worst-case scenario in which only 25% of enrollees are age 18 to 34, insurers would have to raise premiums by 2.5% in 2015. Similarly, if young adults represent 33% of enrollees, premiums would be raised by 1.1%.

With the addition of ACA transitional policies that allow insurers risk adjustment mechanisms during the first three years while the risk pool settles, it's unlikely that premiums will spiral in 2015, according to KFF. Find out more:

http://bit.ly/1k2FQi2

— Julia Brown

STOCKHOLDERS EXPECT PLAN INVESTMENT IN 2014

Invest in efficiency and consider big data

by **DONNA MARBURY**

It is no surprise that health plans have been overperforming on Wall Street for the past few years during the rollout of the Affordable Care Act (ACA). Overall, healthcare stocks have outperformed the S&P 500 by 15 percentage points since the ACA was passed.

"And they are going to do just fine in the next year also. When the dust settles with ACA, they will all end with new customers," says economist and author J. D. Kleinke, who is also an MHE editorial advisor.

Many of the new enrollees will be subsidized by the federal government. And enrollment numbers for 2014 and beyond are more than what the typical market would support.

"Wall Street knows this and understands that this is growth for a bunch of mature companies," Kleinke says. "Especially when it comes to the new laws surrounding pre-existing conditions. Health plans' stocks aren't going to do anything but get better."

He also says the influx in new members from the individual market will be a healthy boost to bottom lines for years to come; the key is to be able to manage the risk for the newly insured.

"The pathway to growth is the young, sick and the reluctant, and many of those will need Medicaid or managed care. As more people end up with Medicaid, there will be managed care tools, and health plans will get bigger, but will also have to be smarter," Kleinke says.

Plans will need strategies to deal with high-risk patients and the frequent visitors to the emergency departments (ED). Many in the newly insured population are in the habit of accessing the ED for routine care.

"Unmanaged Medicaid is going to be the struggle, and big health plans don't know how to manage it," he says. "When you add 100 people to the ACA, at least 50 of them will need to be managed. It won't net the biggest profits, but there will be enough top-line growth to make a difference."

However with so many new members, there will be uncertain risk. Health plans cannot rely on ACA-related membership growth in the long term, says Scott Pickens, managing director of Arlington Healthcare Group.

"If you define growth as increased operating margins or profit then you are dealing with a whole different set of challenges," he says. "For example, many if not most health plans competing on the public health exchanges set first year premiums assuming they will initially lose money while the associated risk pools settle out and actuarial experience can be more accurately applied to premium calculations. Further, with minimal medical loss ratios now being set by law and regulation, health plans have much less wiggle room to squeeze out a stock-market acceptable operating margin when medical costs vary upward."

Pickens says many have begun diversifying their revenue streams. Particularly the large national plans have for years been evolving away from being pure payers and claim processors to being integrated providers of a variety of health related and industry supporting services.

"These include everything from health data and information services, population health, occupational health, to full integrated care management utilizing business combinations with hospitals and health-plan-owned physician networks," Pickens says. "The stock market sees opportunity for those health plans that are becoming full service providers of both direct and administrative health related services to their members."

Is big data worth it?

Big data is a buzzword that has many healthcare investors either excited or running scared. With mountains of claims data, many see this as the time to start investing in ways to repurpose the data. Though smaller plans may find it harder to invest in proprietary data mining software and services, Pickens says that larger companies will be able to develop the technology that integrates clinical science, care coordination and cost sensitivity.

"Larger health plans—especially those integrated with some provider capabilities—are arguably the best suited to address this emerging ecosystem. They have the core skills, the executive and managerial expertise, and the scale required," he says, adding that products addressing population health, chronic disease management, episodic care, and rehabilitation that require new levels of data integration will be the most costly, yet quite profitable.

Short-term attention

Though Kleinke agrees that more pinpointed managed care will provide profits, he says that the hype over big data will fade in the upcoming years.

"Health plans have been trying to make money off of information for years. They have always tried and never been any good at it," Kleinke says. "There's too much competition with businesses that are really good at it."

Small businesses and independent data companies sell their analytical services and products to several industries as a core competency. Health plans generally don't do well selling to their competitors, he says.

Kleinke also says that health plans would have to invest more money and effort into creating industry-standard big data products and will ultimately jump ship after a lack of profits.

"The typical shareholder may not have been around 10 years ago when health plans tried to sell data before. Two or three years from now, everyone will be rushing back out of the data business, it's just the organic nature of the market," he says.

But the return on big data will come from long-term efforts, Pickens adds. "Health plan stockholders will need patience to see the benefits of investments in big data. And the benefits—while I believe very real—may be difficult to attribute directly to big data investments as separated from other contributing factors," he says.

Investing in efficiency

Health plans will also have more opportunities to manage government-subsidized programs. An increase in members without experience in the healthcare system might cause a spike in costs that could slim profits. That's another place big data comes in, according to Pickens.

"The return on investment will manifest as lower healthcare costs as illness is avoided, treatments are more effective more quickly, and the enormous waste from less-than-effective treatment is gradually diminished," Pickens says. "Therefore the impact on health plan revenue stream may be somewhat hidden, and the greater impact will show up in operating margin."

Kleinke says finding ways to manage primary and maternity care are areas where health plans can maximize efficiency.

"People are skittish, and this issue flies under the radar, particularly with Medicaid" Kleinke says. "It is the number one reason women go to the hospital: to deliver a baby. There are way too many C-sections and induced births and a lack of prenatal care. And nobody manages it well. It doesn't get a lot of attention, because people don't see it as problematic, and there is hesitancy because there are a lot of cultural and political issues surrounding maternity care. Actually, basic prenatal care will yield better outcomes, healthy, happy members and lower healthcare costs. It's like the Holy Grail."

The likely winners

As the healthcare industry continues to diversify into more information and clinical technology, experts agree that many companies have an opportunity to capitalize on developments. Though insurers are excelling, biotechnology companies were up 60% in 2013 on the S&P 500, according to *CNNMoney.com*.

"These new concepts are not coming from health plans," says Kleinke. "They are coming from entrepreneurs, technology and more community-based care. This kind of care can happen on an iPhone."

Pickens says that although 2014 and 2015 will see the largest influx of new members, an increase in high-deductible plans may also slow operations and cash flow for health plans.

"Many health plans are [often intentionally] underestimating adverse selection when setting premiums as they try to enter the competition for new members under the ACA with the intent of making it up later as the new risk pools stabilize and are better understood," Pickens says.

Ultimately, new revenue streams in development now and the past few years will be the best way for health plans and stockholders to combat the potential bottleneck.

"I expect that those plans that are farther along in development and marketing of these services to benefit as they are early to a very large potential market," he says. ■

Donna Marbury *is an Advanstar Content Specialist.*

5 STRATEGIES FOR HEALTH PLANS TO IMPROVE THEIR BOTTOM LINE

Four are easy, but one is not so easy

by **JULIE MILLER**

DeltaSigma Healthcare Consulting in Littleton, Colo., has found the most-overlooked opportunities for plans to boost their margins in healthcare's changing landscape. Growth can come from several market strategies, but plans must keep in mind that diversity is becoming increasingly important.

1

Maximize Medicare

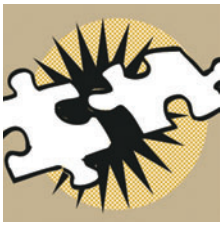
Review your Medicare risk scores and compare them to the actual risks presented. You might be missing out on revenue. Plans that close the gap between actual and potential capitation could realize Risk Adjustment Factor increases. Also, assess the 2014 CMS blended model to determine the impact on your risk score, which translates to future revenue. Have an outside risk adjustment firm review your claims to make the match against your data. Consider home visit assessments to identify the needs of high-risk members, which is especially effective when integrated with care management outreach.

2

PBM contract review

It's likely your pharmacy benefit has hidden savings, even if you've just completed your contract with your pharmacy benefit manager (PBM). The marketplace for PBMs is extremely dynamic with frequent changes in discounts, trends and formulary management. A thorough contract review can identity potential cost savings prior to any engagement. Look for metrics to ensure the PBM is performing at its fully contracted terms and is bringing clinical and pharmacy trend management strategies to the table. Your PBM should be providing cost-saving ideas on a regular basis.

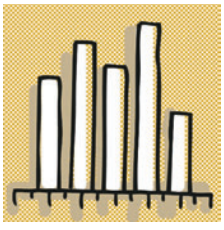
3



Integrated care management

AResearch has demonstrated behavioral health issues have a direct effect on separate outcomes for comorbid conditions. A significant number of health plans still maintain separate medical and behavioral protocols. Integrated programs offer powerful synergy and can result in return on investment of 2-to-1 or more. Those with multiple chronic illness and behavioral health issues might only represent 10% of a population but often account for 35% of the spending or more. Members might be difficult to identify and engage, especially with new Medicaid enrollment in 2014. Make sure your plan is prepared to engage members in care management.

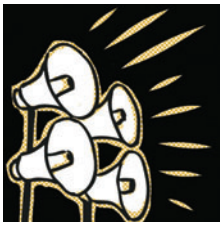
4



Benchmark your performance

Compare your medical and administrative costs to similar plans. A benchmarking assessment can be an effective evaluation approach to identify issues that are unique to your plan, your community or your market. Many of your competitors take advantage of operational benchmarks, MLR benchmarks, staff performance and productivity assessments. Don't forget to analyze your IT, as data is increasingly becoming a competitive advantage. Look for opportunities to improve your efficiency and optimize administrative processes..

5



Create a sales culture

This strategy is a bit more difficult than the other four. For a surprising number of plans, the idea of "selling" is relegated to the marketing department. While it's important to grow membership, the separation ignores the importance of creating an organizational culture in which growing and retaining membership is part of your firm's DNA. A comprehensive approach starts with a meaningful description of what your plan stands for. From there, embed your mission and vision into every aspect of the organization from job descriptions to marketing materials. A sales culture is not high-pressure sales, but rather it's "walking the talk."

INVOKANA™ is the #1 branded therapy prescribed by endocrinologists when adding or switching non-insulin type 2 diabetes medications*

ENVISION NEW **POSSIBILITIES**

Invokana™
canagliflozin tablets

*Data on file. Based on NBRx data sourced from IMS NPA Market Dynamics Database, weekly data through 9/20/13.

INVOKANA™ (canagliflozin) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

INVOKANA™ is not recommended in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

IMPORTANT SAFETY INFORMATION

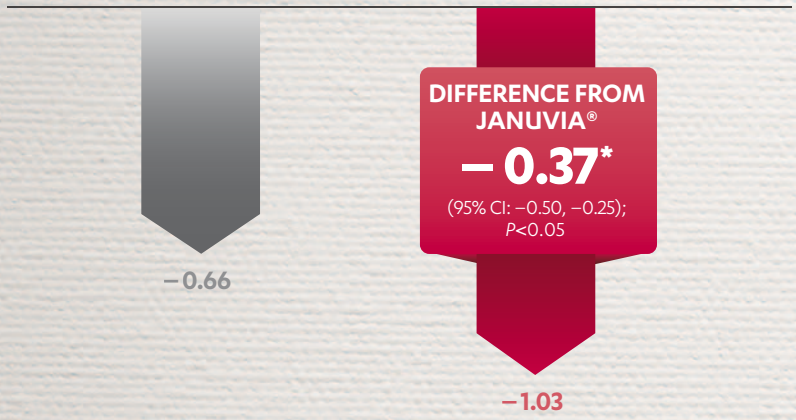
CONTRAINDICATIONS

- History of a serious hypersensitivity reaction to INVOKANA™.
- Severe renal impairment (eGFR <30 mL/min/1.73 m^2), end stage renal disease, or patients on dialysis.

Please see additional Important Safety Information and brief summary of full Prescribing Information on the following pages.

INVOKANA™ 300 mg demonstrated greater reductions in A1C vs Januvia® 100 mg at 52 weeks...

Adjusted Mean Change in A1C From Baseline (%): INVOKANA™ 300 mg vs Januvia® 100 mg, Each in Combination With Metformin + a Sulfonylurea[1]



Incidence of Hypoglycemia

With metformin + a sulfonylurea over 52 weeks: INVOKANA™ (canagliflozin) 300 mg: **43.2%**; Januvia® 100 mg: **40.7%**[1]

- Insulin and insulin secretagogues are known to cause hypoglycemia. INVOKANA™ can increase the risk of hypoglycemia when combined with insulin or an insulin secretagogue[1]

Convenient Once-Daily Oral Dosing[1]

- Recommended starting dose: INVOKANA™ 100 mg
- Dose can be increased to 300 mg in patients tolerating 100 mg who have an eGFR ≥60 mL/min/1.73 m^2 and require additional glycemic control

*INVOKANA™ + metformin is considered noninferior to Januvia® + metformin because the upper limit of the 95% confidence interval is less than the prespecified noninferiority margin of 0.3%.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS and PRECAUTIONS

- **Hypotension:** INVOKANA™ causes intravascular volume contraction. Symptomatic hypotension can occur after initiating INVOKANA™, particularly in patients with impaired renal function (eGFR <60 mL/min/1.73 m^2), elderly patients, and patients on either diuretics or medications that interfere with the renin-angiotensin-aldosterone system (eg, angiotensin-converting-enzyme [ACE] inhibitors, angiotensin receptor blockers [ARBs]), or patients with low systolic blood pressure. Before initiating INVOKANA™ in patients with one or more of these characteristics, volume status should be assessed and corrected. Monitor for signs and symptoms after initiating therapy.
- **Impairment in Renal Function:** INVOKANA™ increases serum creatinine and decreases eGFR. Patients with hypovolemia may be more susceptible to these changes. Renal function abnormalities can occur after initiating INVOKANA™. More frequent renal function monitoring is recommended in patients with an eGFR below 60 mL/min/1.73 m^2.
- **Hyperkalemia:** INVOKANA™ can lead to hyperkalemia. Patients with moderate renal impairment who are taking medications that interfere with potassium excretion, such as potassium-sparing diuretics, or medications that interfere with the renin-angiotensin-aldosterone system are more likely to develop hyperkalemia. Monitor serum potassium levels periodically after initiating INVOKANA™ in patients with impaired renal function and in patients predisposed to hyperkalemia due to medications or other medical conditions.

*COVERED FOR >**75%** OF COMMERCIALLY INSURED PATIENTS WITHOUT PRIOR AUTHORIZATION*[3]

...as well as greater reductions in body weight† and systolic blood pressure (SBP)†

Change in Body Weight†

Significant reductions in body weight at 52 weeks, each in combination with metformin + a sulfonylurea (*P*<0.001)[1]

- Difference from Januvia®‡:
  300 mg: **–2.8%**

Change in SBP†

Significant lowering of SBP at 52 weeks, each in combination with metformin + a sulfonylurea (*P*<0.001)[2]

- Difference from Januvia®‡:
  300 mg: **–5.9 mm Hg**

INVOKANA™ is not indicated for weight loss or as antihypertensive treatment.

†Prespecified secondary endpoint.

‡Adjusted mean.

INVOKANA™ provides SGLT2 inhibition, reducing renal glucose reabsorption and increasing urinary glucose excretion.[1]

Adverse Reactions

In 4 pooled placebo-controlled trials, the most common (≥5%) adverse reactions were female genital mycotic infection, urinary tract infection, and increased urination.[1§]

References: 1. INVOKANA™ [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; 2013. **2.** Schernthaner G, Gross JL, Rosenstock J, et al. Canagliflozin compared with sitagliptin for patients with type 2 diabetes who do not have adequate glycemic control with metformin plus sulfonylurea: a 52-week randomized trial. *Diabetes Care*. 2013;36(9):2508-2515. **3.** Data on file. Janssen Pharmaceuticals, Inc., Titusville, NJ. Data as of 9/17/13.

SGLT2 = sodium glucose co-transporter-2.

§Included 1 monotherapy and 3 add-on combination trials with metformin, metformin + a sulfonylurea, or metformin + pioglitazone.

Learn more at **INVOKANAhcp.com/journal**

- **Hypoglycemia With Concomitant Use With Insulin and Insulin Secretagogues:** Insulin and insulin secretagogues are known to cause hypoglycemia. INVOKANA™ can increase the risk of hypoglycemia when combined with insulin or an insulin secretagogue. Therefore, a lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with INVOKANA™.
- **Genital Mycotic Infections:** INVOKANA™ increases the risk of genital mycotic infections. Patients with a history of genital mycotic infections and uncircumcised males were more likely to develop genital mycotic infections. Monitor and treat appropriately.
- **Hypersensitivity Reactions:** Hypersensitivity reactions (eg, generalized urticaria), some serious, were reported with INVOKANA™ treatment; these reactions generally occurred within hours to days after initiating INVOKANA™. If hypersensitivity reactions occur, discontinue use of INVOKANA™; treat per standard of care and monitor until signs and symptoms resolve.
- **Increases in Low-Density Lipoprotein (LDL-C):** Dose-related increases in LDL-C occur with INVOKANA™. Monitor LDL-C and treat per standard of care after initiating INVOKANA™.
- **Macrovascular Outcomes:** There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with INVOKANA™ or any other antidiabetic drug.

Please see additional Important Safety Information and brief summary of full Prescribing Information on the following pages.

ENVISION NEW
POSSIBILITIES

Invokana™
canagliflozin tablets

IMPORTANT SAFETY INFORMATION (cont'd)

DRUG INTERACTIONS

- **UGT Enzyme Inducers:** Rifampin: Co-administration of canagliflozin with rifampin, a nonselective inducer of several UGT enzymes, including UGT1A9, UGT2B4, decreased canagliflozin area under the curve (AUC) by 51%. This decrease in exposure to canagliflozin may decrease efficacy. If an inducer of these UGTs (eg, rifampin, phenytoin, phenobarbital, ritonavir) must be co-administered with INVOKANA™ (canagliflozin), consider increasing the dose to 300 mg once daily if patients are currently tolerating INVOKANA™ 100 mg once daily, have an eGFR greater than 60 mL/min/1.73 m^2, and require additional glycemic control. Consider other antihyperglycemic therapy in patients with an eGFR of 45 to less than 60 mL/min/1.73 m^2 receiving concurrent therapy with a UGT inducer and requiring additional glycemic control.
- **Digoxin:** There was an increase in the area AUC and mean peak drug concentration (C_{max}) of digoxin (20% and 36%, respectively) when co-administered with INVOKANA™ 300 mg. Patients taking INVOKANA™ with concomitant digoxin should be monitored appropriately.

USE IN SPECIFIC POPULATIONS

- **Pregnancy Category C:** There are no adequate and well-controlled studies of INVOKANA™ in pregnant women. Based on results from rat studies, canagliflozin may affect renal development and maturation. In a juvenile rat study, increased kidney weights and renal pelvic and tubular dilatation were evident at ≥0.5 times clinical exposure from a 300-mg dose.

  These outcomes occurred with drug exposure during periods of animal development that correspond to the late second and third trimester of human development. During pregnancy, consider appropriate alternative therapies, especially during the second and third trimesters. INVOKANA™ should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- **Nursing Mothers:** It is not known if INVOKANA™ is excreted in human milk. INVOKANA™ is secreted in the milk of lactating rats, reaching levels 1.4 times higher than that in maternal plasma. Data in juvenile rats directly exposed to INVOKANA™ showed risk to the developing kidney (renal pelvic and tubular dilatations) during maturation. Since human kidney maturation occurs in utero and during the first 2 years of life when lactational exposure may occur, there may be risk to the developing human kidney. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants from INVOKANA™, a decision should be made whether to discontinue nursing or to discontinue INVOKANA™, taking into account the importance of the drug to the mother.
- **Pediatric Use:** Safety and effectiveness of INVOKANA™ in pediatric patients under 18 years of age have not been established.
- **Geriatric Use:** Two thousand thirty-four (2034) patients 65 years and older, and 345 patients 75 years and older were exposed to INVOKANA™ in nine clinical studies of INVOKANA™. Patients 65 years and older had a higher incidence of adverse reactions related to reduced intravascular volume with INVOKANA™ (such as hypotension, postural dizziness, orthostatic hypotension, syncope, and dehydration), particularly with the 300-mg daily dose, compared to younger patients; more prominent increase in the incidence was seen in patients who were ≥75 years of age. Smaller reductions in HbA1C with INVOKANA™ relative to placebo were seen in older (65 years and older; -0.61% with INVOKANA™ 100 mg and -0.74% with INVOKANA™ 300 mg relative to placebo) compared to younger patients (-0.72% with INVOKANA™ 100 mg and -0.87% with INVOKANA™ 300 mg relative to placebo).
- **Renal Impairment:** The efficacy and safety of INVOKANA™ were evaluated in a study that included patients with moderate renal impairment (eGFR 30 to <50 mL/min/1.73 m^2). These patients had less overall glycemic efficacy and had a higher occurrence of adverse reactions related to reduced intravascular volume, renal-related adverse reactions, and decreases in eGFR compared to patients with mild renal impairment or normal renal function (eGFR ≥60 mL/min/1.73 m^2); patients treated with INVOKANA™ 300 mg were more likely to experience increases in potassium.

  The efficacy and safety of INVOKANA™ have not been established in patients with severe renal impairment (eGFR <30 mL/min/1.73 m^2), with end-stage renal disease (ESRD), or receiving dialysis. INVOKANA™ is not expected to be effective in these patient populations.

Janssen Pharmaceuticals, Inc.

Canagliflozin is licensed from Mitsubishi Tanabe Pharma Corporation.

November 2013 004991-131021

»**Hepatic Impairment:** No dosage adjustment is necessary in patients with mild or moderate hepatic impairment. The use of INVOKANA™ has not been studied in patients with severe hepatic impairment and it is therefore not recommended.

OVERDOSAGE

»There were no reports of overdose during the clinical development program of INVOKANA™ (canagliflozin).

In the event of an overdose, contact the Poison Control Center. It is also reasonable to employ the usual supportive measures, eg, remove unabsorbed material from the gastrointestinal tract, employ clinical monitoring, and institute supportive treatment as dictated by the patient's clinical status. Canagliflozin was negligibly removed during a 4-hour hemodialysis session. Canagliflozin is not expected to be dialyzable by peritoneal dialysis.

ADVERSE REACTIONS

»The most common (≥5%) adverse reactions were female genital mycotic infections, urinary tract infections, and increased urination. Adverse reactions in ≥2% of patients were male genital mycotic infections, vulvovaginal pruritus, thirst, nausea, and constipation.

K02CAN13149

Please see brief summary of full Prescribing Information on the following pages.

Invokana™
canagliflozin tablets

janssen
PHARMACEUTICAL COMPANIES OF Johnson&Johnson

INVOKANA™

(canagliflozin) tablets, for oral use

Brief Summary of Prescribing Information.

INDICATIONS AND USAGE

INVOKANA™ (canagliflozin) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus *[see Clinical Studies (14) in full Prescribing Information]*.

Limitation of Use: INVOKANA is not recommended in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.

CONTRAINDICATIONS

- History of a serious hypersensitivity reaction to INVOKANA *[see Warnings and Precautions]*.
- Severe renal impairment (eGFR less than 30 mL/min/1.73 m^2), end stage renal disease or patients on dialysis *[see Warnings and Precautions and Use in Specific Populations]*.

WARNINGS AND PRECAUTIONS

Hypotension: INVOKANA causes intravascular volume contraction. Symptomatic hypotension can occur after initiating INVOKANA *[see Adverse Reactions]* particularly in patients with impaired renal function (eGFR less than 60 mL/min/1.73 m^2), elderly patients, patients on either diuretics or medications that interfere with the renin-angiotensin-aldosterone system (e.g., angiotensin-converting-enzyme [ACE] inhibitors, angiotensin receptor blockers [ARBs]), or patients with low systolic blood pressure. Before initiating INVOKANA in patients with one or more of these characteristics, volume status should be assessed and corrected. Monitor for signs and symptoms after initiating therapy.

Impairment in Renal Function: INVOKANA increases serum creatinine and decreases eGFR. Patients with hypovolemia may be more susceptible to these changes. Renal function abnormalities can occur after initiating INVOKANA *[see Adverse Reactions]*. More frequent renal function monitoring is recommended in patients with an eGFR below 60 mL/min/1.73 m^2.

Hyperkalemia: INVOKANA can lead to hyperkalemia. Patients with moderate renal impairment who are taking medications that interfere with potassium excretion, such as potassium-sparing diuretics, or medications that interfere with the renin-angiotensin-aldosterone system are more likely to develop hyperkalemia *[see Adverse Reactions]*.

Monitor serum potassium levels periodically after initiating INVOKANA in patients with impaired renal function and in patients predisposed to hyperkalemia due to medications or other medical conditions.

Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues: Insulin and insulin secretagogues are known to cause hypoglycemia. INVOKANA can increase the risk of hypoglycemia when combined with insulin or an insulin secretagogue *[see Adverse Reactions]*. Therefore, a lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with INVOKANA.

Genital Mycotic Infections: INVOKANA increases the risk of genital mycotic infections. Patients with a history of genital mycotic infections and uncircumcised males were more likely to develop genital mycotic infections *[see Adverse Reactions]*. Monitor and treat appropriately.

Hypersensitivity Reactions: Hypersensitivity reactions (e.g., generalized urticaria), some serious, were reported with INVOKANA treatment; these reactions generally occurred within hours to days after initiating INVOKANA. If hypersensitivity reactions occur, discontinue use of INVOKANA; treat per standard of care and monitor until signs and symptoms resolve *[see Contraindications and Adverse Reactions]*.

Increases in Low-Density Lipoprotein (LDL-C): Dose-related increases in LDL-C occur with INVOKANA *[see Adverse Reactions]*. Monitor LDL-C and treat per standard of care after initiating INVOKANA.

Macrovascular Outcomes: There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with INVOKANA or any other antidiabetic drug.

ADVERSE REACTIONS

The following important adverse reactions are described below and elsewhere in the labeling:

- Hypotension *[see Warnings and Precautions]*
- Impairment in Renal Function *[see Warnings and Precautions]*
- Hyperkalemia *[see Warnings and Precautions]*
- Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues *[see Warnings and Precautions]*
- Genital Mycotic Infections *[see Warnings and Precautions]*
- Hypersensitivity Reactions *[see Warnings and Precautions]*
- Increases in Low-Density Lipoprotein (LDL-C) *[see Warnings and Precautions]*

Clinical Studies Experience: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to the rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

Pool of Placebo-Controlled Trials: The data in Table 1 is derived from four 26-week placebo-controlled trials. In one trial INVOKANA was used as monotherapy and in three trials INVOKANA was used as add-on therapy *[see Clinical Studies (14) in full Prescribing Information]*. These data reflect exposure of 1667 patients to INVOKANA and a mean duration of exposure to

INVOKANA™ (canagliflozin) tablets

INVOKANA of 24 weeks. Patients received INVOKANA 100 mg (N=833), INVOKANA 300 mg (N=834) or placebo (N=646) once daily. The mean age of the population was 56 years and 2% were older than 75 years of age. Fifty percent (50%) of the population was male and 72% were Caucasian, 12% were Asian, and 5% were Black or African American. At baseline the population had diabetes for an average of 7.3 years, had a mean HbA1C of 8.0% and 20% had established microvascular complications of diabetes. Baseline renal function was normal or mildly impaired (mean eGFR 88 mL/min/1.73 m^2).

Table 1 shows common adverse reactions associated with the use of INVOKANA. These adverse reactions were not present at baseline, occurred more commonly on INVOKANA than on placebo, and occurred in at least 2% of patients treated with either INVOKANA 100 mg or INVOKANA 300 mg.

Table 1: Adverse Reactions From Pool of Four 26–Week Placebo-Controlled Studies Reported in ≥ 2% of INVOKANA-Treated Patients*

Adverse Reaction	Placebo N=646	INVOKANA 100 mg N=833	INVOKANA 300 mg N=834
Female genital mycotic infections†	3.2%	10.4%	11.4%
Urinary tract infections‡	4.0%	5.9%	4.3%
Increased urination§	0.8%	5.3%	4.6%
Male genital mycotic infections¶	0.6%	4.2%	3.7%
Vulvovaginal pruritus	0.0%	1.6%	3.0%
Thirst#	0.2%	2.8%	2.3%
Constipation	0.9%	1.8%	2.3%
Nausea	1.5%	2.2%	2.3%

* The four placebo-controlled trials included one monotherapy trial and three add-on combination trials with metformin, metformin and sulfonylurea, or metformin and pioglitazone.

† Female genital mycotic infections include the following adverse reactions: Vulvovaginal candidiasis, Vulvovaginal mycotic infection, Vulvovaginitis, Vaginal infection, Vulvitis, and Genital infection fungal. Percentages calculated with the number of female subjects in each group as denominator: placebo (N=312), INVOKANA 100 mg (N=425), and INVOKANA 300 mg (N=430).

‡ Urinary tract infections includes the following adverse reactions: Urinary tract infection, Cystitis, Kidney infection, and Urosepsis.

§ Increased urination includes the following adverse reactions: Polyuria, Pollakiuria, Urine output increased, Micturition urgency, and Nocturia.

¶ Male genital mycotic infections include the following adverse reactions: Balanitis or Balanoposthitis, Balanitis candida, and Genital infection fungal. Percentages calculated with the number of male subjects in each group as denominator: placebo (N=334), INVOKANA 100 mg (N=408), and INVOKANA 300 mg (N=404).

Thirst includes the following adverse reactions: Thirst, Dry mouth, and Polydipsia.

Abdominal pain was also more commonly reported in patients taking INVOKANA 100 mg (1.8%), 300 mg (1.7%) than in patients taking placebo (0.8%).

Pool of Placebo- and Active-Controlled Trials: The occurrence of adverse reactions was also evaluated in a larger pool of patients participating in placebo- and active-controlled trials.

The data combined eight clinical trials *[see Clinical Studies (14) in full Prescribing Information]* and reflect exposure of 6177 patients to INVOKANA. The mean duration of exposure to INVOKANA was 38 weeks with 1832 individuals exposed to INVOKANA for greater than 50 weeks. Patients received INVOKANA 100 mg (N=3092), INVOKANA 300 mg (N=3085) or comparator (N=3262) once daily. The mean age of the population was 60 years and 5% were older than 75 years of age. Fifty-eight percent (58%) of the population was male and 73% were Caucasian, 16% were Asian, and 4% were Black or African American. At baseline, the population had diabetes for an average of 11 years, had a mean HbA1C of 8.0% and 33% had established microvascular complications of diabetes. Baseline renal function was normal or mildly impaired (mean eGFR 81 mL/min/1.73 m^2).

The types and frequency of common adverse reactions observed in the pool of eight clinical trials were consistent with those listed in Table 1. In this pool, INVOKANA was also associated with the adverse reactions of fatigue (1.7% with comparator, 2.2% with INVOKANA 100 mg, and 2.0% with INVOKANA 300 mg) and loss of strength or energy (i.e., asthenia) (0.6% with comparator, 0.7% with INVOKANA 100 mg and 1.1% with INVOKANA 300 mg).

In the pool of eight clinical trials, the incidence rate of pancreatitis (acute or chronic) was 0.9, 2.7, and 0.9 per 1000 patient-years of exposure to comparator, INVOKANA 100 mg, and INVOKANA 300 mg, respectively.

In the pool of eight clinical trials with a longer mean duration of exposure to INVOKANA (68 weeks), the incidence rate of bone fracture was 14.2, 18.7, and 17.6 per 1000 patient years of exposure to comparator, INVOKANA 100 mg, and INVOKANA 300 mg, respectively. Upper extremity fractures occurred more commonly on INVOKANA than comparator.

In the pool of eight clinical trials, hypersensitivity-related adverse reactions (including erythema, rash, pruritus, urticaria, and angioedema) occurred in 3.0%, 3.8%, and 4.2% of patients receiving comparator, INVOKANA 100 mg and INVOKANA 300 mg, respectively. Five patients experienced serious adverse reactions of hypersensitivity with INVOKANA, which included 4 patients with urticaria and 1 patient with a diffuse rash and urticaria occurring within hours of exposure to INVOKANA. Among these patients, 2 patients discontinued INVOKANA. One patient with urticaria had recurrence when INVOKANA was re-initiated.

Photosensitivity-related adverse reactions (including photosensitivity reaction, polymorphic light eruption, and sunburn) occurred in 0.1%, 0.2%, and 0.2% of patients receiving comparator, INVOKANA 100 mg, and INVOKANA 300 mg, respectively.

Other adverse reactions occurring more frequently on INVOKANA than on comparator were:

Volume Depletion-Related Adverse Reactions: INVOKANA results in an osmotic diuresis, which may lead to reductions in intravascular volume. In clinical studies, treatment with INVOKANA was associated with a dose-dependent increase in the incidence of volume depletion-related adverse reactions (e.g., hypotension, postural dizziness, orthostatic hypotension, syncope, and dehydration). An increased incidence was observed in patients on the 300 mg dose. The three factors associated with the largest increase in volume depletion-related adverse reactions were the use of loop diuretics, moderate renal impairment (eGFR 30 to less than 60 mL/min/1.73 m^2) and age 75 years and older (Table 2) *[see Dosage and Administration (2.2) in full Prescribing Information, Warnings and Precautions, and Use in Specific Populations]*.

Table 2: Proportion of Patients With at Least one Volume Depletion-Related Adverse Reactions (Pooled Results from 8 Clinical Trials)

Baseline Characteristic	Comparator Group* %	INVOKANA 100 mg %	INVOKANA 300 mg %
Overall population	1.5%	2.3%	3.4%
75 years of age and older†	2.6%	4.9%	8.7%
eGFR less than 60 mL/min/1.73 m^2†	2.5%	4.7%	8.1%
Use of loop diuretic†	4.7%	3.2%	8.8%

***** Includes placebo and active-comparator groups

† Patients could have more than 1of the listed risk factors

Impairment in Renal Function: INVOKANA is associated with a dose-dependent increase in serum creatinine and a concomitant fall in estimated GFR (Table 3). Patients with moderate renal impairment at baseline had larger mean changes.

Table 3: Changes in Serum Creatinine and eGFR Associated with INVOKANA in the Pool of Four Placebo-Controlled Trials and Moderate Renal Impairment Trial

			Placebo N=646	INVOKANA 100 mg N=833	INVOKANA 300 mg N=834
Pool of Four Placebo-Controlled Trials	Baseline	Creatinine (mg/dL)	0.84	0.82	0.82
		eGFR (mL/min/1.73 m^2)	87.0	88.3	88.8
	Week 6 Change	Creatinine (mg/dL)	0.01	0.03	0.05
		eGFR (mL/min/1.73 m^2)	-1.6	-3.8	-5.0
	End of Treatment Change*	Creatinine (mg/dL)	0.01	0.02	0.03
		eGFR (mL/min/1.73 m^2)	-1.6	-2.3	-3.4
			Placebo N=90	**INVOKANA 100 mg N=90**	**INVOKANA 300 mg N=89**
Moderate Renal Impairment Trial	Baseline	Creatinine (mg/dL)	1.61	1.62	1.63
		eGFR (mL/min/1.73 m^2)	40.1	39.7	38.5
	Week 3 Change	Creatinine (mg/dL)	0.03	0.18	0.28
		eGFR (mL/min/1.73 m^2)	-0.7	-4.6	-6.2
	End of Treatment Change*	Creatinine (mg/dL)	0.07	0.16	0.18
		eGFR (mL/min/1.73 m^2)	-1.5	-3.6	-4.0

***** Week 26 in mITT LOCF population

In the pool of four placebo-controlled trials where patients had normal or mildly impaired baseline renal function, the proportion of patients who experienced at least one event of significant renal function decline, defined as an eGFR below 80 mL/min/1.73 m^2 and 30% lower than baseline, was 2.1% with placebo, 2.0% with INVOKANA 100 mg, and 4.1% with INVOKANA 300 mg. At the end of treatment, 0.5% with placebo, 0.7% with INVOKANA 100 mg, and 1.4% with INVOKANA 300 mg had a significant renal function decline.

In a trial carried out in patients with moderate renal impairment with a baseline eGFR of 30 to less than 50 mL/min/1.73 m^2 (mean baseline eGFR 39 mL/min/1.73 m^2) *[see Clinical Studies (14.3) in full Prescribing Information]*, the proportion of patients who experienced at least one event of significant renal function decline, defined as an eGFR 30% lower than baseline, was 6.9% with placebo, 18% with INVOKANA 100 mg, and 22.5% with INVOKANA 300 mg. At the end of treatment, 4.6% with placebo, 3.4% with INVOKANA 100 mg, and 3.4% with INVOKANA 300 mg had a significant renal function decline.

In a pooled population of patients with moderate renal impairment (N=1085) with baseline eGFR of 30 to less than 60 mL/min/1.73 m^2 (mean baseline eGFR 48 mL/min/1.73 m^2), the overall incidence of these events was lower than in the dedicated trial but a dose-dependent increase in incident episodes of significant renal function decline compared to placebo was still observed.

Use of INVOKANA was associated with an increased incidence of renal-related adverse reactions (e.g., increased blood creatinine, decreased glomerular filtration rate, renal impairment, and acute renal failure), particularly in patients with moderate renal impairment.

In the pooled analysis of patients with moderate renal impairment, the incidence of renal-related adverse reactions was 3.7% with placebo, 8.9% with INVOKANA 100 mg, and 9.3% with INVOKANA 300 mg. Discontinuations due to renal-related adverse events occurred in 1.0% with placebo, 1.2% with INVOKANA 100 mg, and 1.6% with INVOKANA 300 mg *[see Warnings and Precautions]*.

Genital Mycotic Infections: In the pool of four placebo-controlled clinical trials, female genital mycotic infections (e.g., vulvovaginal mycotic infection, vulvovaginal candidiasis, and vulvovaginitis) occurred in 3.2%, 10.4%, and 11.4% of females treated with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively. Patients with a history of genital mycotic infections were more likely to develop genital mycotic infections on INVOKANA. Female patients who developed genital mycotic infections on INVOKANA were more likely to experience recurrence and require treatment with oral or topical antifungal agents and anti-microbial agents *[see Warnings and Precautions]*.

In the pool of four placebo-controlled clinical trials, male genital mycotic infections (e.g., candidal balanitis, balanoposthitis) occurred in 0.6%, 4.2%, and 3.7% of males treated with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively. Male genital mycotic infections occurred more commonly in uncircumcised males and in males with a prior history of balanitis or balanoposthitis. Male patients who developed genital mycotic infections on INVOKANA were more likely to experience recurrent infections (22% on INVOKANA versus none on placebo), and require treatment with oral or topical antifungal agents and anti-microbial agents than patients on comparators. In the pooled analysis of 8 controlled trials, phimosis was reported in 0.3% of uncircumcised male patients treated with INVOKANA and 0.2% required circumcision to treat the phimosis *[see Warnings and Precautions]*.

Hypoglycemia: In all clinical trials, hypoglycemia was defined as any event regardless of symptoms, where biochemical hypoglycemia was documented (any glucose value below or equal to 70 mg/dL). Severe hypoglycemia was defined as an event consistent with hypoglycemia where the patient required the assistance of another person to recover, lost consciousness, or experienced a seizure (regardless of whether biochemical documentation of a low glucose value was obtained). In individual clinical trials *[see Clinical Studies (14) in full Prescribing Information]*, episodes of hypoglycemia occurred at a higher rate when INVOKANA was co-administered with insulin or sulfonylureas (Table 4) *[see Warnings and Precautions]*.

Table 4: Incidence of Hypoglycemia* in Controlled Clinical Studies

Monotherapy (26 weeks)	**Placebo (N=192)**	**INVOKANA 100 mg (N=195)**	**INVOKANA 300 mg (N=197)**
Overall [N (%)]	5 (2.6)	7 (3.6)	6 (3.0)
In Combination with Metformin (26 weeks)	**Placebo + Metformin (N=183)**	**INVOKANA 100 mg + Metformin (N=368)**	**INVOKANA 300 mg + Metformin (N=367)**
Overall [N (%)]	3 (1.6)	16 (4.3)	17 (4.6)
Severe [N (%)]†	0 (0)	1 (0.3)	1 (0.3)
In Combination with Metformin (52 weeks)	**Glimepiride + Metformin (N=482)**	**INVOKANA 100 mg + Metformin (N=483)**	**INVOKANA 300 mg + Metformin (N=485)**
Overall [N (%)]	165 (34.2)	27 (5.6)	24 (4.9)
Severe [N (%)]†	15 (3.1)	2 (0.4)	3 (0.6)
In Combination with Sulfonylurea (18 weeks)	**Placebo + Sulfonylurea (N=69)**	**INVOKANA 100 mg + Sulfonylurea (N=74)**	**INVOKANA 300 mg + Sulfonylurea (N=72)**
Overall [N (%)]	4 (5.8)	3 (4.1)	9 (12.5)
In Combination with Metformin + Sulfonylurea (26 weeks)	**Placebo + Metformin + Sulfonylurea (N=156)**	**INVOKANA 100 mg + Metformin + Sulfonylurea (N=157)**	**INVOKANA 300 mg + Metformin + Sulfonylurea (N=156)**
Overall [N (%)]	24 (15.4)	43 (27.4)	47 (30.1)
Severe [N (%)]†	1 (0.6)	1 (0.6)	0

Table 4: Incidence of Hypoglycemia* in Controlled Clinical Studies (continued)

In Combination with Metformin + Sulfonylurea (52 weeks)	**Sitagliptin + Metformin + Sulfonylurea (N=378)**		**INVOKANA 300 mg + Metformin + Sulfonylurea (N=377)**
Overall [N (%)]	154 (40.7)		163 (43.2)
Severe [N (%)]†	13 (3.4)		15 (4.0)
In Combination with Metformin + Pioglitazone (26 weeks)	**Placebo + Metformin + Pioglitazone (N=115)**	**INVOKANA 100 mg + Metformin + Pioglitazone (N=113)**	**INVOKANA 300 mg + Metformin + Pioglitazone (N=114)**
Overall [N (%)]	3 (2.6)	3 (2.7)	6 (5.3)
In Combination with Insulin (18 weeks)	**Placebo (N=565)**	**INVOKANA 100 mg (N=566)**	**INVOKANA 300 mg (N=587)**
Overall [N (%)]	208 (36.8)	279 (49.3)	285 (48.6)
Severe [N (%)]†	14 (2.5)	10 (1.8)	16 (2.7)

* Number of patients experiencing at least one event of hypoglycemia based on either biochemically documented episodes or severe hypoglycemic events in the intent-to-treat population

† Severe episodes of hypoglycemia were defined as those where the patient required the assistance of another person to recover, lost consciousness, or experienced a seizure (regardless of whether biochemical documentation of a low glucose value was obtained)

Laboratory Tests: *Increases in Serum Potassium:* Dose-related, transient mean increases in serum potassium were observed early after initiation of INVOKANA (i.e., within 3 weeks) in a trial of patients with moderate renal impairment *[see Clinical Studies (14.3) in full Prescribing Information]*. In this trial, increases in serum potassium of greater than 5.4 mEq/L and 15% above baseline occurred in 16.1%, 12.4%, and 27.0% of patients treated with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively. More severe elevations (i.e., equal or greater than 6.5 mEq/L) occurred in 1.1%, 2.2%, and 2.2% of patients treated with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively. In patients with moderate renal impairment, increases in potassium were more commonly seen in those with elevated potassium at baseline and in those using medications that reduce potassium excretion, such as potassium-sparing diuretics, angiotensin-converting-enzyme inhibitors, and angiotensin-receptor blockers *[see Warnings and Precautions]*.

Increases in Serum Magnesium: Dose-related increases in serum magnesium were observed early after initiation of INVOKANA (within 6 weeks) and remained elevated throughout treatment. In the pool of four placebo-controlled trials, the mean change in serum magnesium levels was 8.1% and 9.3% with INVOKANA 100 mg and INVOKANA 300 mg, respectively, compared to -0.6% with placebo. In a trial of patients with moderate renal impairment *[see Clinical Studies (14.3) in full Prescribing Information]*, serum magnesium levels increased by 0.2%, 9.2%, and 14.8% with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively.

Increases in Serum Phosphate: Dose-related increases in serum phosphate levels were observed with INVOKANA. In the pool of four placebo controlled trials, the mean change in serum phosphate levels were 3.6% and 5.1% with INVOKANA 100 mg and INVOKANA 300 mg, respectively, compared to 1.5% with placebo. In a trial of patients with moderate renal impairment *[see Clinical Studies (14.3) in full Prescribing Information]*, the mean serum phosphate levels increased by 1.2%, 5.0%, and 9.3% with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively.

Increases in Low-Density Lipoprotein Cholesterol (LDL-C) and non-High-Density Lipoprotein Cholesterol (non-HDL-C): In the pool of four placebo-controlled trials, dose-related increases in LDL-C with INVOKANA were observed. Mean changes (percent changes) from baseline in LDL-C relative to placebo were 4.4 mg/dL (4.5%) and 8.2 mg/dL (8.0%) with INVOKANA 100 mg and INVOKANA 300 mg, respectively. The mean baseline LDL-C levels were 104 to 110 mg/dL across treatment groups *[see Warnings and Precautions]*.

Dose-related increases in non-HDL-C with INVOKANA were observed. Mean changes (percent changes) from baseline in non-HDL-C relative to placebo were 2.1 mg/dL (1.5%) and 5.1 mg/dL (3.6%) with INVOKANA 100 mg and 300 mg, respectively. The mean baseline non-HDL-C levels were 140 to 147 mg/dL across treatment groups.

Increases in Hemoglobin: In the pool of four placebo-controlled trials, mean changes (percent changes) from baseline in hemoglobin were -0.18 g/dL (-1.1%) with placebo, 0.47 g/dL (3.5%) with INVOKANA 100 mg, and 0.51 g/dL (3.8%) with INVOKANA 300 mg. The mean baseline hemoglobin value was approximately 14.1 g/dL across treatment groups. At the end of treatment, 0.8%, 4.0%, and 2.7% of patients treated with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively, had hemoglobin above the upper limit of normal.

DRUG INTERACTIONS

UGT Enzyme Inducers: Rifampin: Co-administration of canagliflozin with rifampin, a nonselective inducer of several UGT enzymes, including

UGT1A9, UGT2B4, decreased canagliflozin area under the curve (AUC) by 51%. This decrease in exposure to canagliflozin may decrease efficacy. If an inducer of these UGTs (e.g., rifampin, phenytoin, phenobarbital, ritonavir) must be co-administered with INVOKANA (canagliflozin), consider increasing the dose to 300 mg once daily if patients are currently tolerating INVOKANA 100 mg once daily, have an eGFR greater than 60 mL/min/1.73 m^2, and require additional glycemic control. Consider other antihyperglycemic therapy in patients with an eGFR of 45 to less than 60 mL/min/1.73 m^2 receiving concurrent therapy with a UGT inducer and require additional glycemic control *[see Dosage and Administration (2.3) and Clinical Pharmacology (12.3) in full Prescribing Information]*.

Digoxin: There was an increase in the area AUC and mean peak drug concentration (C_{max}) of digoxin (20% and 36%, respectively) when co-administered with INVOKANA 300 mg *[see Clinical Pharmacology (12.3) in full Prescribing Information]*. Patients taking INVOKANA with concomitant digoxin should be monitored appropriately.

USE IN SPECIFIC POPULATIONS

Pregnancy: Teratogenic Effects: Pregnancy Category C: There are no adequate and well-controlled studies of INVOKANA in pregnant women. Based on results from rat studies, canagliflozin may affect renal development and maturation. In a juvenile rat study, increased kidney weights and renal pelvic and tubular dilatation were evident at greater than or equal to 0.5 times clinical exposure from a 300 mg dose *[see Nonclinical Toxicology (13.2) in full Prescribing Information]*.

These outcomes occurred with drug exposure during periods of animal development that correspond to the late second and third trimester of human development. During pregnancy, consider appropriate alternative therapies, especially during the second and third trimesters. INVOKANA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is not known if INVOKANA is excreted in human milk. INVOKANA is secreted in the milk of lactating rats reaching levels 1.4 times higher than that in maternal plasma. Data in juvenile rats directly exposed to INVOKANA showed risk to the developing kidney (renal pelvic and tubular dilatations) during maturation. Since human kidney maturation occurs *in utero* and during the first 2 years of life when lactational exposure may occur, there may be risk to the developing human kidney. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from INVOKANA, a decision should be made whether to discontinue nursing or to discontinue INVOKANA, taking into account the importance of the drug to the mother *[see Nonclinical Toxicology (13.2) in full Prescribing Information]*.

Pediatric Use: Safety and effectiveness of INVOKANA in pediatric patients under 18 years of age have not been established.

Geriatric Use: Two thousand thirty-four (2034) patients 65 years and older, and 345 patients 75 years and older were exposed to INVOKANA in nine clinical studies of INVOKANA *[see Clinical Studies (14.3) in full Prescribing Information]*.

Patients 65 years and older had a higher incidence of adverse reactions related to reduced intravascular volume with INVOKANA (such as hypotension, postural dizziness, orthostatic hypotension, syncope, and dehydration), particularly with the 300 mg daily dose, compared to younger patients; more prominent increase in the incidence was seen in patients who were 75 years and older *[see Dosage and Administration (2.1) in full Prescribing Information and Adverse Reactions]*. Smaller reductions in HbA1C with INVOKANA relative to placebo were seen in older (65 years and older; -0.61% with INVOKANA 100 mg and -0.74% with INVOKANA 300 mg relative to placebo) compared to younger patients (-0.72% with INVOKANA 100 mg and -0.87% with INVOKANA 300 mg relative to placebo).

Renal Impairment: The efficacy and safety of INVOKANA were evaluated in a study that included patients with moderate renal impairment (eGFR 30 to less than 50 mL/min/1.73 m^2) *[see Clinical Studies (14.3) in full Prescribing Information]*. These patients had less overall glycemic efficacy and had a higher occurrence of adverse reactions related to reduced intravascular volume, renal-related adverse reactions, and decreases in eGFR compared to patients with mild renal impairment or normal renal function (eGFR greater than or equal to 60 mL/min/1.73 m^2); patients treated with INVOKANA 300 mg were more likely to experience increases in potassium *[see Dosage and Administration (2.2) in full Prescribing Information, Warnings and Precautions, and Adverse Reactions]*.

The efficacy and safety of INVOKANA have not been established in patients with severe renal impairment (eGFR less than 30 mL/min/1.73 m^2), with ESRD, or receiving dialysis. INVOKANA is not expected to be effective in these patient populations *[see Contraindications and Clinical Pharmacology (12.3) in full Prescribing Information]*.

Hepatic Impairment: No dosage adjustment is necessary in patients with mild or moderate hepatic impairment. The use of INVOKANA has not been studied in patients with severe hepatic impairment and is therefore not recommended *[see Clinical Pharmacology (12.3) in full Prescribing Information]*.

INVOKANA™ (canagliflozin) tablets

OVERDOSAGE

There were no reports of overdose during the clinical development program of INVOKANA (canagliflozin).

In the event of an overdose, contact the Poison Control Center. It is also reasonable to employ the usual supportive measures, e.g., remove unabsorbed material from the gastrointestinal tract, employ clinical monitoring, and institute supportive treatment as dictated by the patient's clinical status. Canagliflozin was negligibly removed during a 4-hour hemodialysis session. Canagliflozin is not expected to be dialyzable by peritoneal dialysis.

PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (Medication Guide).

Instructions: Instruct patients to read the Medication Guide before starting INVOKANA (canagliflozin) therapy and to reread it each time the prescription is renewed.

Inform patients of the potential risks and benefits of INVOKANA and of alternative modes of therapy. Also inform patients about the importance of adherence to dietary instructions, regular physical activity, periodic blood glucose monitoring and HbA1C testing, recognition and management of hypoglycemia and hyperglycemia, and assessment for diabetes complications. Advise patients to seek medical advice promptly during periods of stress such as fever, trauma, infection, or surgery, as medication requirements may change.

Instruct patients to take INVOKANA only as prescribed. If a dose is missed, advise patients to take it as soon as it is remembered unless it is almost time for the next dose, in which case patients should skip the missed dose and take the medicine at the next regularly scheduled time. Advise patients not to take two doses of INVOKANA at the same time.

Inform patients that the most common adverse reactions associated with INVOKANA are genital mycotic infection, urinary tract infection, and increased urination.

Inform female patients of child bearing age that the use of INVOKANA during pregnancy has not been studied in humans, and that INVOKANA should only be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Instruct patients to report pregnancies to their physicians as soon as possible.

Inform nursing mothers to discontinue INVOKANA or nursing, taking into account the importance of drug to the mother.

Laboratory Tests: Due to its mechanism of action, patients taking INVOKANA will test positive for glucose in their urine.

Hypotension: Inform patients that symptomatic hypotension may occur with INVOKANA and advise them to contact their doctor if they experience such symptoms *[see Warnings and Precautions]*. Inform patients that dehydration may increase the risk for hypotension, and to have adequate fluid intake.

Genital Mycotic Infections in Females (e.g., Vulvovaginitis): Inform female patients that vaginal yeast infection may occur and provide them with information on the signs and symptoms of vaginal yeast infection. Advise them of treatment options and when to seek medical advice *[see Warnings and Precautions]*.

Genital Mycotic Infections in Males (e.g., Balanitis or Balanoposthitis): Inform male patients that yeast infection of penis (e.g., balanitis or balanoposthitis) may occur, especially in uncircumcised males and patients with prior history. Provide them with information on the signs and symptoms of balanitis and balanoposthitis (rash or redness of the glans or foreskin of the penis). Advise them of treatment options and when to seek medical advice *[see Warnings and Precautions]*.

Hypersensitivity Reactions: Inform patients that serious hypersensitivity reactions such as urticaria and rash have been reported with INVOKANA. Advise patients to report immediately any signs or symptoms suggesting allergic reaction or angioedema, and to take no more drug until they have consulted prescribing physicians.

Urinary Tract Infections: Inform patients of the potential for urinary tract infections. Provide them with information on the symptoms of urinary tract infections. Advise them to seek medical advice if such symptoms occur.

Active ingredient made in Belgium

Finished product manufactured by:
Janssen Ortho, LLC
Gurabo, PR 00778

Manufactured for:
Janssen Pharmaceuticals, Inc.
Titusville, NJ 08560

Licensed from Mitsubishi Tanabe Pharma Corporation

10282400

K02CAN13080B

janssen

DATA WILL DRIVE ACOs IN THE REAL WORLD

Q&A with Charles Kennedy, MD

by **JULIE MILLER**

Less than a week after Charles Kennedy, MD, the CEO of Accountable Care Solutions for Aetna, spoke to MANAGED HEALTHCARE EXECUTIVE about the company strategy in the ACO space, the plan announced yet another accountable care agreement. This time, Aetna forged a partnership with Valley Preferred, a PPO aligned with the Lehigh Valley Health Network in Allentown, Pa.

More than 1.3 million of the insurer's 44 million members could be served by the new ACO. And that's just one example of the pace at which the accountable-care model growing.

Q: What is the general outlook and the goals for Aetna's ACO strategy?

KENNEDY: To date, we've been able to put into play 32 ACO agreements with leading health systems. We have a very robust pipeline of over 200 and if you look at the service area that those delivery systems cover, that's about 60% of the U.S. population. We're on a path to really make accountable care a foundational component of what Aetna does and how Aetna creates or supports the attainment of the Triple Aim for its customers and patients and physicians nationwide.

Q: What is something that you've learned about ACOs and the dynamic between payers and providers? Because this is an emerging model, it really does change the negotiations.

KENNEDY: The most important thing we've learned is that the accountable care concept does something important for healthcare, which is change the underlying business model. Accountable care has become critically important to many of our customers because it represents a new way of being financial sustainable.


DR. KENNEDY

Second, the relationship we've formed with the delivery system is one based on collaboration, partnership and transparency. And, what we mean by that is traditionally the delivery system and the health plan would hoard data and not share data among one another. In our model, we share as much data as we possibly can because through our collaborative relationships, based on gain-share or risk-share contracts, it now makes all the sense in the world for a health plan to deliver all the claims data or other data that it can find because we are now in a collaborative relationship designed to achieve the Triple Aim, rather than a confrontational relationship designed to manage price.

The simplest way to think of what we do is: enablement and monetization. Enablement means we're going to deliver to our clinical partners the technology, care management programs and the consulting support to allow them to transition from a fee-for-volume to a value-based world. Monetization is providing the contractual relationship that allows you to be rewarded for achieving the Triple Aim as well as the **sale** and financial administrative infrastructure necessary for you to be successful.

Q: Are providers embracing the value based care idea? Or do you think they're reluctantly accepting it?

KENNEDY: Some of both. What you will typically see is that the ACO concept has been successful at improving the quality of care. What is much less well documented is the financial viability of these types of arrangements. And, if you look at the results that participants in the federal program have shared, many of the organizations did not save any money. A few did, and some actually were unsuccessful at becoming more efficient.

In the early stages, and in order to get physicians and delivery systems more on board with accountable care, we're going to have to develop more tools that allow the financial components

of the new business model to be more commonly realized.

Q: That's a big concern because the last thing you want is to create an ACO and hospitals end up going out of business because they can't make it financially viable.

KENNEDY: That's not a simple question because we all know that a lot of the savings are going to come out of the inpatient or hospital component of the overall healthcare delivery system.

Think about any business: the hardware business, a grocery store, anything. All of those businesses invest substantial amounts of money in understanding their customers. In the hospital and healthcare delivery system environment, that is not a common way of thinking.

One of the early things we do in many of our ACO relationships is to simply analyze our claim data and find "leakage" and "keepage" percentages. What percent of the dollars that those individuals are spending are staying within your system and what percent are going outside the system? And it's always a big eye opener to our delivery system customers how much care their patients are getting at other facilities.

Through applying techniques like managing leakage or promoting keepage, there are reasons to believe that this could be a sustainable financial model.

Q: You completed the Coventry acquisition last year. How does Coventry fit into your ACO strategy?

KENNEDY: Coventry has had a series of high-performance or narrow networks, types of contractual arrangements that have many similarities with our ACO strategy. We are assessing and actually putting in production ways of taking those narrow network relationships and extending them in full ACO relationships.

[*Editor's Note: Coventry added more than 5 million total members, including 1.5 million Medicare Part D members.*]

Q: Do you think ACOs are effectively controlling costs now, and what about for the long term? Is the ACO the way to bend the curve?

KENNEDY: I think the jury is still out on that, but I believe it is the best strategy that the healthcare industry has available to it. It's just too early to know.

What we are really trying to do with the ACO strategy is take delivery systems into a value-based world. That means new technology. Electronic medical records themselves don't promote value-based care. But you're going to see a next generation of tools come out over the next year that are more specifically focused on value-based care than volume-based care, which is really when electronic medical records got their start.

The technology's immature and will evolve, and I'm seeing substantial investments within organizations. We spent over $1 billion acquiring companies like Medicity, Active Health and others with a specific focus on having the technology to work with value-based care.

The other big requirement for value-based care is having successful care management programs. And, traditionally you've seen care management programs provided by large national health plans, where we've used claim data and programs that have not been integrated with what the delivery system is doing.

But, what has been a weak spot in these models is that that program isn't well coordinated with the day to day activities of your physician. And that's another innovation that accountable care provides. Now that we have shared economic interest and now that we have transparency, it begins to make a lot more sense. I do believe we'll see incremental value as that plays out.

Q: Do you see that health IT is getting a lot more attention for investment from providers?

KENNEDY: Not so much an increase in spending on health IT, you're likely to see a change in emphasis of spending. Instead of focusing as much on the electronic medical records, you're going to see organizations focus more on adjacent technologies that specifically enable ACOs for things like population analytics.

People use the term "big data" quite a bit to try and talk about using a wide variety of data streams and trying to understand behaviors and actions of patients in their interactions with the healthcare system. You'll see a switch more toward data-centric strategies than electronic medical records, which are more of a document centric infrastructure. ■

***Julie Miller** is Managed Healthcare Executive's Content Channel Director.*

ACO FACT FILE

Payer : Aetna Medicare Advantage
Provider : NovaHealth IPA
Population : 750 Medicare Advantage members
Assignment : Prospective

RESULTS

50% fewer hospital days per 1,000
45% fewer admissions
56% fewer readmissions than unmanaged Medicare populations in the state
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Source: Aetna Medicare Advantage

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STATES TAKE CLOSER LOOK AT PHYSICIAN DISPENSING

Drug prices show staggering markup

by **MARI EDLIN**

Physicians occasionally dispense drugs to injured employees under workers' compensation programs. Compared to medications dispensed through a pharmacy, medications given to patients during an office visit often have higher mark-up, adding to doctors' profits.

The Workers Compensation Research Institute (WCRI), a not-for-profit, public policy research organization in Cambridge, Mass., keeps tabs on the prevalence and costs of physician-dispensed drugs. A recent WCRI study not only indicates higher costs for drugs given to patients in physician offices, but also the effect of state legislation on modifying or preventing the practice.

The study has resulted in a reference book containing data from 24 states with more than 600,000 workers' compensation claims, accounting for 70% of total workers' compensation benefits paid in the United States.

These claims represent more than seven days of lost time and 4.8 million prescriptions for injuries occurring from Oct. 1, 2007 to Sept. 30, 2011, with prescriptions filled through March 31, 2012. WCRI developed its first large-scale benchmark study in 2010, and has added reports focusing on specific states as data become available.

Driving physician dispensing

One of the drivers of higher prices from drugs dispensed by physicians is repackaging, says Dongchun Wang, co-author of the study and an economist for WCRI.

Doctors purchase drugs in bulk, contract with a repackaging company to rebundle them into smaller containers for in-office dispensing and assign a new national drug code (NDC). Drugs dispensed at a pharmacy, however, are controlled by a fee schedule, Wang says.

Physicians reap the benefits of the higher costs because they can submit claims without any caps, and receive full reimbursement without any repercussions.

Pharmacies, however, often are part of a network established by a pharmacy benefits manager (PBM) that is able to negotiate pricing with manufacturers for discounts.

Jennifer Kaburick, Express Scripts vice president, product management for workers' compensation, points out that physician-dispensed drugs are priced 60% to 300% higher than identical drugs dispensed at a pharmacy for several reasons: Not only does a new NDC allow for a higher average wholesale price, but also physicians have no incentive to negotiate lower rates for these drugs with repackagers, thus enabling them to pass costs onto payers.

Generally, there are no out-of-pocket costs for injured employees and few incentives to question prices or shop around.

"The challenge facing workers' comp payers is that, depending on the state, injured workers are not required to use an in-network pharmacy or physician when seeking treatment for a work-related injury," Kaburick says. "It's very important that risk managers talk to their claims administrators to make sure they have the appropriate programs in place to help minimize the impact of physician-dispensed medications. This will help rein in costs and ensure safe utilization of drugs by injured workers."

Safety, Kaburick says, is an issue with physician dispensing because unlike at pharmacies, drugs available at offices could lack the point-of-sale safety edits that check for potential drug interactions, for example.

"A doctor—especially one that is not a primary care physician—may not have a complete view of an injured worker's prescription history or current regimen resulting in a higher risk of adverse effects," Kaburick says.

Express Scripts recently launched a product that relies on comprehensive pharmacy data to review physician-dispensed pharmacy claims and checks them against a client's formulary and plan design and against a script's

history. At that point, the PBM recommends appropriate payment in alignment with state guidelines to help payers control costs and minimize the impact of physician dispensing, while ensuring that injured workers have access to the medications they need.

Drugs have cost variation

WCRI studied five popular generics—hydrocodone, ibuprofen, meloxicam and tramadol HCL (all pain relievers) and cyclobenzaprine HCL (muscle relaxant)—and compared the costs of those dispensed by physicians and by pharmacies and in every case, the latter was less expensive, sometimes by as much as 134%.

Vicodin sells for $1.46 a pill when a doctor dispenses it, which is four times more than what a patient would pay at a pharmacy, according to WCRI. The markup on muscle relaxer Soma (carisoprodol) is 700%, according to research.

Today, 14.5% of workers' comp medical expenses are attributed to pharmacy, according to CompPharm, a consulting company. It asked insurers and third-party administrators what they considered to be the largest drivers of drug costs.

Opioids spring to the top of the list, followed by physician dispensing, which accounted for more than 35% of drug costs in 2012. CompPharm cited concerns about physician-dispensed drugs: no required drug utilization review; potential duplication of therapy; higher costs due to repackaging; unnecessary medications or those not related to a claimant's injury; extended disability duration; and higher overall medical costs.

The National Council on Compensation Insurance (NCCI), which collects workers' comp data, also has conducted studies on workers' compensation claims and while earlier reports showed that utilization, not price, was the culprit for rising costs, its latest information points to physician-dispensed drugs as the primary driver.

The average cost of physician-dispensed drugs grew about 25% between 2008 and 2009 and doubled by 2011. The average cost of prescriptions dispensed by others only rose 5% during the same period.

Also, the number of prescriptions per claim dispensed by a physician rose 14% between 2007 and 2011, while prescriptions from other sources only increased 8%.

Although NCCI reports the discrepancies in costs and alludes to physicians seeking higher revenue, it also recognizes why many drugs are dispensed in doctors' offices: Patients need an immediate and limited prescription before visiting a pharmacy; the physician is unsure of the patient's reaction to a drug giving the patient a chance to respond; and patients may not be able to access a pharmacy.

Lynn R. Webster, MD, president of the American Academy of Pain Medicine, says there are two reasons why physicians dispense medications in their offices.

"Many patients find it more convenient," she says. "But the primary reason is that it increases revenue to the practice."

She suggests drugs cost more in many physician offices because they don't have bulk discounts that pharmacies can command.

The National Community Pharmacists Assn. (NCPA) supports laws and regulations that prohibit dispensing of prescription legend drugs by individuals other than pharmacists.

"This practice erodes the traditional system of checks and balances inherent in the drug delivery system and is contrary to the best interests of the public," according to the organization.

NCPA believes that physician dispensing denies the patient the advantages of personal consultation with a pharmacist.

Effects of reform efforts

States have adopted a spectrum of reform initiatives to deal with what they see as higher costs for drugs dispensed at a physician's office. Six states—New York, Montana, Wyoming, Massachusetts, Texas and Utah—generally prohibit all physician dispensing. Fourteen states allow physician dispensing but have reforms that limit price mark-ups, while Florida and Louisiana prevent physician dispensing of Schedule II and Schedule III narcotics.

Although Wang says that prices for physician-dispensed drugs have dropped in states with reform efforts, the costs in most cases are still much higher than the same drugs dispensed by a pharmacy.

Most drug prices dropped 22% to 36% at physician offices, but still remained 20% to 40% higher than those dispensed at pharmacies.

Georgia has legislation that caps the reimbursement amount for physician-dispensed, repackaged drugs to the average wholesale price of the original product. WRCI says the intention is to lower drug costs, not prevent physician dispensing. ■

Mari Edlin *is a freelance writer based in Sonoma, Calif.*

HOW PLANS CAN LEVERAGE BIG DATA

Choose your goals before crunching numbers

by **JOANNE SAMMER**

The age of big data is here and many health plans have been building and leveraging their data analytics capabilities for some time. Plans that have not invested in the technology infrastructure and data building necessary to maximize the benefits of data analytics could soon find themselves lagging behind. Here are some ways health plans can start differentiating themselves by using big data.

1/ Build a foundation

Data analytics is only as powerful as the underlying data. That is why many health plans are investing heavily in upgrading their technology infrastructure and cleaning up and standardizing their data.

"Some plans are relatively sophisticated in using their data and others are struggling," says Pamela Peele, chief analytics officer for UPMC Insurance Services Division in Pittsburgh. "The constraining factor is how much investment health plans have in their IT infrastructure and that varies widely across health plans."

UPMC Health Plan, which has invested some $1.5 billion in its IT infrastructure, has created a large data source of what Peele calls "a harmonized, groomed layer of information holdings and data from multiple disparate sources."

UPMC Health Plan is using data analytics in a number of areas. For example, it focuses on reducing hospital readmissions before a member is even admitted rather than waiting until the patient is discharged. The plan has developed data models that calculate the probability of readmission among its entire health plan membership.

"Every month, we are predicting readmission probability based on whether a plan member who is admitted to the hospital today would be readmitted to the hospital within 30 days after discharge," says Peele. "When someone is admitted to one of our hospitals, that readmission risk is displayed on the opening screen." At that point, the hospital creates the authorization for the admission and also begins the work on reducing that readmission risk as much as possible.

2/ Set guidelines

Using data analytics to bolster existing priorities may be tempting, but doing so will not allow health plans to maximize their return on their investments. Ken Park, vice president of payer and provider solutions at WellPoint in Indianapolis, offers three suggestions that can serve as broad guidelines when using data analytics:

- **Don't bend the data in order to prove an ongoing hypothesis. Look at what the data is actually showing you.**
- **The focus should be on ways to deliver the highest quality healthcare at the most affordable prices rather than ways to provide the lowest cost healthcare regardless of the quality.**
- **The most effective data analytics focus on a valid clinical question that is not already answered by the academic literature, are relevant to the business and promise a significant business impact, and begin with a clear idea of how the organization will use the resulting information.**

3/ Learn from other industries

As health plans shift to more consumer-oriented business models, data analytics will become more important.

"Health plans need to learn to use data the same way that American Express, Disney, Harrah's and others have," says Jack Newsom, vice president of marketing analytics at Silverlink Communications, Inc. "This means understanding what motivates individuals and learning how to communicate with them in order to build trust and loyalty, and ultimately change behavior."

For example, UnitedHealthcare has leveraged its data analytics in an effort to increase colorectal

cancer screening rates among minority populations. This effort included analyzing the screening rates among 500,000 plan members in different ethnic groups to identify barriers to screening and to determine the most effective methods of encouraging specific groups to complete recommended screenings. Based on the results, UnitedHealthcare created customized outreach programs to increase screening rates. The analysis found that a phone call from a plan representative to one group of men increased cancer screening nearly 11% compared to another group who received a recorded call.

4/ Leverage multiple data sources

The more strong data in the system, the more powerful data analytics will be. Core claims data, member-provided information from health risk assessments and general marketing data can all support data analytics. For example, plans can use general marketing data to get information on household size, whether members use mail order and other standard marketing information. Plans can use this data to get a clearer picture of each member that can be important when trying to coordinate and improve access to care.

UPMC Health Plan relies on health risk assessment data to get a sense of the potential plan usage among new enrollees in Medicare Advantage plans during their first 12 months with the plan.

"With no usage data among newly eligible Medicare Advantage enrollees, we would have to wait and see who is going to require care coordination," says Peele. "We identify those members using a specific combination of answers on the health assessment survey and assign a care coordinator to that member before they have their first doctor's appointment."

UPMC Health Plan also receives daily data feeds from all of its vendors, including the provider of health risk assessments, labs and pharmacy benefit managers so that the plan does not have to wait for claims data before acting on that data.

Peele expects clinical outcomes data to be the next frontier in data gathering. Claims data can show productivity measures, such as how often members see a doctor and the exams or tests done. However, "we want to know the outcome of that care," she says. "If a diabetic patient sees a physician for a hemoglobin A1c test, outcomes-based data will show how effective that care has been in terms of actual clinical outcomes."

5/ Combine clinical and claims data

Data analytics do not have to focus solely on operations. WellPoint uses both claims and clinical data to evaluate medical policies and its drug formulary to see whether coverage for a certain drug is appropriate and to evaluate the effectiveness of different benefit designs and programs.

Another use for data analytics is to test and disseminate information on clinical care. For example, WellPoint's analytics can evaluate treatment patterns for children with chronic headaches to determine the prevalence of CT scans. A key concern is that use of CT scans in treatment and diagnosis exposes patients to unnecessary radiation at a young age.

"We examined the data to see if we needed to change policies or programs to avoid scans," says Park. "Upwards of one-quarter of children who identified with headaches had some type of imaging scan, most commonly a CT scan."

When the analytics identified emergency rooms as the setting where scans for this population are most likely to occur, WellPoint was able to adjust its policies and disease management interventions to reduce that number. In addition to using this information in its own operations, WellPoint also shares its findings in conjunction with groups like the American Academy of Pediatrics as a way to support more evidence-based medicine. ■

Joanne Sammer *is a Brielle, N.J.-based freelance writer.*

ADVERTISER INDEX

The following is a list of the advertisers in this issue. Although every effort is made to ensure accuracy, this publication assumes no liability for errors or omissions.

OLDER WORKERS WITHOUT EMPLOYER COVERAGE ARE MOST LIKELY TO BE UNINSURED

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TOTAL

Source: AARP

BUSINESS

Orlando Health Inc. has inked a deal with Florida Blue, Florida's Blue Cross and Blue Shield company, to form an accountable care organization designed to increase quality, enhance coordination of care between the two organizations and decrease costs in the Orlando area. Florida Blue has approximately 4 million members and serves 15.5 million people in 16 states through its affiliated company. Orlando Health has approximately 500 employed physicians and eight hospitals.

BUSINESS

WellPoint Inc. is selling online contact-lens site 1-800-CONTACTS, which it acquired in 2012 from Fenway Partners, to private equity firm Thomas H. Lee Partners LP to focus on building its insurance business. Financial terms of the transaction were not disclosed. WellPoint also plans to sell *Glasses.com*, part of the contact-lens retail operation, to Luxottica Group SpA.

PHARMACY

Walmart and Sam's Club pharmacies have been added to the preferred network of the Aetna CVS/pharmacy Prescription Drug Plan (PDP). The Aetna CVS/pharmacy PDP is available in 43 states and the District of Columbia. The plan's preferred pharmacy network comprises 4,200 Walmart, 580 Sam's Club and 7,500 CVS/pharmacy locations. The Aetna CVS/pharmacy PDP offers a median $32 monthly plan premium. Plan members will pay a $2 copayment for nearly 800 preferred generic drugs in most states and a $1 copayment in all states for certain generic drugs that are commonly used for treatment of hypertension, high cholesterol and diabetes.

HEALTH MANAGEMENT

UnitedHealthcare earned three Best in Biz Awards. myClaims Manager earned Gold in the Consumer Service of the Year category; Health4Me received Silver in the Consumer Product of the Year category; and UHC.TV took Bronze in the Website of the Year category. The latest consumer innovation, myEasyBook, is an online healthcare shopping service that makes it easier and more affordable for consumers to make appointments with local healthcare professionals, including same-day and next-day appointments. myEasyBook was a CES 2014 Editor's Choice Award winner from *USA Today*. Also, the company's Health4Me mobile application earned the 2013 eValue8 Innovation award for innovative programs that address critical healthcare issues. For more visit *www.uhc.com*.

ANALYSIS

Analysis from the Commonwealth Fund found that rising medical costs were the primary driver of recent rate increases by health insurers, accounting for three-quarters or more of the larger premium hikes requested between July 2012 and June 2013. The Affordable Care Act (ACA) requires health insurers to justify rate increases of 10% or more for nongrandfathered plans in the individual and small-group markets. Insurers attributed only a very small portion of these medical cost trends to factors related to the ACA. The ACA-related factor mentioned most often, but only in a third of the rate filings in this study, was the requirement to cover women's preventive and contraceptive services without patient cost-sharing. But, the insurers who point to this requirement or other ACA-related costs attributed only about 1 percentage point of their rate increases to the health reform law.

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