SPECIAL REPORT The Medicaid expansion divide

Managed Healthcare Executive

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APRIL 2015

Payment Reform shifts to high gear

Public, private sectors commit to historic industry changes

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COVER STORY

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By **LISA SMITH** and **TRACEY WALKER**

COMMENTARY

SPECIAL REPORT

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formulary watch

[BLOG] First biosimilar approval may lead to easier access to biologic drugs for patients

FDA reached a milestone by approving the first biosimilar in the U.S. Biosimilars have potential to increase access to vital therapy for patients living with chronic and life-threatening conditions. **http://bit.ly/1CKnhun**

[BLOG] Best Practices between formulary managers, pharmacists address COPD readmissions challenges

Open communications between formulary managers and pharmacists foster a successful outcome for patients with COPD by encouraging optimal treatment availability and medication adherence. **http://bit.ly/19KN5eI**

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SIGNAL THROUGH THE NOISE

Using data to improve care quality, lower costs

The term Big Data describes how the exponentially growing amount of information that's available today is stored and analyzed, and it's especially important in healthcare. Today, or very soon, everything from our individual genome analysis, to the medical services we get, to our personal habits—healthy or not!—will be available to dissect and analyze, making Big Data a critical tool for increasing the quality and lowering the cost of care.

Such ground-breaking developments with predictive analytics raise the question: What if?

- **What if we could identify gaps in care and alert the patient's doctor in real-time?**
- **What if we could predict who was most likely to need hospitalization in the near future?**
- **What if we could prevent people from even getting sick in the first place?**

In fact, wisely used, sophisticated data analytics—capturing and transforming huge amounts of data into information that enables us to see micro and macro trends—allows one to predict what is going to happen, to intervene more precisely, and make changes when necessary.

As a healthcare organization that serves nearly 10 million people across 24 states and the District of Columbia, Independence is well-positioned to be a leader in so-called "Big Data." Every time one of our members visits the doctor, checks into the hospital, or fills a prescription, this gives us data that we can use to reshape the face of care. And that data connects us to all the key players in healthcare—doctors, hospitals, patients, pharma, employers, and the individual consumer. Working closely with all of these partners, we analyze data and take action.

For example, using claims data, medication lists, lab results, and insights from our personal health coaches, we calculate a "likelihood-of-hospitalization" score for our members who have serious chronic illnesses. If a member's score hits a certain threshold showing she is clearly at risk, our health coaches reach out to her and, if necessary, notify her doctor, who can then determine the best course of action for that patient.

We are also using data to help physicians identify gaps in care. Three years ago, we partnered with two other Blue insurers and a healthcare technology firm to purchase NaviNet, the nation's largest real-time, secure communication network for physicians and hospitals. Today, through NaviNet we can notify physicians in real time if patients they are about to examine need an immunization, a health screening, or other critical preventive care.

That means we send the office an alert to share with your doctor detailing any gaps in your care—a missed mammogram or colon cancer screening, for example—that your physician can address right away. We also provide your physician a complete clinical profile showing any care you received across our entire network of physicians and hospitals—an unprecedented 360-degree view of your care.

Then there's that question, "What if we could prevent people from even getting sick in the first place?

Eight percent of the U.S. population—25 million people—suffer from diabetes, a condition that is not only expensive, but potentially fatal. But what is more astounding is that an estimated 25% of Americans—79 million people—are on the verge of getting diabetes. Two years ago, we began collaborating with New York University and NYU Langone Medical Center to develop machine-learning algorithms that could use our claims data to spot cases of undiagnosed diabetes and to predict diabetes in patients. We see a future where data will be provided directly to the physician who then works with at-risk patients to take preventive measures to slow the rate of diabetes, not just in Philadelphia, but in the nation.

The challenges in healthcare are big and complex. At Independence, we are seeking—and implementing—innovations like data analytics that will revolutionize the entire system. And once we realize the full potential of these technologies and innovations, the question we'll ask ourselves won't be "What if?" It will be "What's next?"

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Daniel J. Hilferty is president and chief executive officer of Independence Blue Cross, one of the nation's leading health insurers, and a Managed Healthcare Executive editorial board member.

ORAL ARGUMENTS IN KING V. BURWELL

ACA subsidy case pits judicial contextualists against conservative textualists

Oral arguments often poorly predict the outcome of Supreme Court cases. However, the argument in King v. Burwell, which will determine the viability of a central mechanism of the Affordable Care Act (ACA)—tax credit subsidies for economically-eligible citizens—provides useful information. Given the tone of Justices' questioning, it is likely that seven votes are set and the remaining two are looking for compromise. It is probable that at least one, maybe both, of the uncertain votes—those of the Chief Justice and Justice Kennedy—will create a majority to uphold the IRS subsidies in states that did not create exchanges.

The tax credits work in tandem with the individual mandate upheld in National Federation of Independent Business (NFIB) v. Sibelius, to allow lower-income persons to purchase health insurance and to avoid adverse selection that would drive up insurance costs. But NFIB also struck down, as unduly coercive on the states, a provision that would have required Medicaid expansion.

The tax code as amended by ACA provides for tax credit subsidies to individuals for health insurance coverage that is purchased through an "Exchange established by the State." The question here is whether the IRS may extend subsidies for coverage purchased through exchanges established by the federal government, in view of the fact that a substantial majority of the states have not established exchanges.

The case pits judicial "contextualists," who argue that the Court should not focus on a single provision at odds with the overall legislative scheme, against conservative "textualists," who believe in literal application statutory language.

Starting with the first question of Justice Breyer, it was clear that the Court's four judicial liberals—Justices Breyer, Ginsburg, Kagan and Sotomayor—will hold that "Exchange" is a term of art that means all exchanges, including those established by the federal government on behalf of the states. In their contextualist view, Congress had to have intended this because it inarguably wanted health insurance availability to be universal, and to allow the ACA to work as intended the subsidies had to be generally available as the tax code (amended by the ACA) makes clear.

Led by Justice Scalia, and likely joined by Justices Thomas and Alito, the strict textualists argue that the Court need go no further than the literal terms of the provision: "States" means "States." If this would hamstring the ACA program, it is up to the Congress, not the Court, to repair the statute.

The textualist/contextualist battle line having been drawn, Justice Kennedy, reminiscent of what the Chief Justice did to craft a majority in NFIB, suggested a "conservative" way out. Harkening to NFIB's holding that the states couldn't be compelled to expand Medicaid, Kennedy suggested that if the plaintiffs won in King, in order to protect their citizens, the states would be forced to do the very thing they had been unable to do, i.e., establish exchanges. Kennedy invoked the doctrine of "constitutional avoidance" which would support the administration. Thus, it is not unlikely that Justice Kennedy will see a public need to save the ACA's insurance subsidies, avoid the public disruption reversal would cause, and create a majority to affirm. Given what he did in NFIB, the Chief Justice may follow.

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Stuart M. Gerson is a member of Epstein Becker Green's Litigation and Health Care & Life Sciences practices.

Payment Reform shifts to high gear

Public, private sectors commit to historic industry changes

By **LISA SMITH** *and* **TRACEY WALKER**

After several years of uneven progress, the pace of healthcare payment reform shifted into high gear in January when the U.S Department of Health and Human Services (HHS) announced plans to tie 30% of traditional, or fee-for-service, Medicare payments to quality or value alternative payment models by the end of 2016, and 50% by the end of 2018.

With the idea of volume to value reimbursement now an expectation, HHS quickly followed up with plans to help the healthcare community achieve the goal, starting with the formation of the Health Care Payment Learning and Action Network.

On the 5th anniversary of the Affordable Care Act (ACA), Network members met for the first time in Washington D.C. to begin their work. Payers, providers, employers, consumers and non-profit leaders listened as a steady stream of government figures framed the challenge.

"For years, we've felt the effects of a healthcare system that…incentivizes the quantity of tests over quality of care, that prioritizes volume over value, that addresses conditions… instead of patients," said HHS Secretary Sylvia M. Burwell.

"After countless internal and external conversations looking at the data of what works [and] where the evidence will drive us, we determined that to get to a better care model… we would need to change the way that we pay providers," said Karen B. DeSalvo, M.D., M.P.H., MSc., acting assistant secretary for HHS.

Getty Images/iStock/Getty Images Plus/nadia

"The alignment on alternative payment models such as ACOs (accountable care organizations) or bundled payments or advance primary care is critical to moving our nation forward," said Patrick Conway, M.D., MSc., chief medical officer of the U.S. Centers for Medicare and Medicaid Services (CMS).

Finally, President Obama himself took the stage, recalling a main goal of the law that's taken a back seat to the uninsurance rate. "A lot of the attention has been rightly focused on people's access to care, and that obviously was a huge motivator to us passing the Affordable Care Act…but what was also a central notion of the Affordable Care Act was that we had an inefficient system with a lot of waste..." said President Obama. "We don't want the incentives to be skewed so that providers feel obliged to do more tests, we want them to do the right tests."

While there's long been discussion about payment reform, this latest effort represents a level of consensus and collaboration not before seen. The Network's 2,800 members include seven of 10 of the county's largest private payers. "If you put up CMS and the amount of people we insure plus these private payers, we already represent the majority of the American population," said Conway. "We are going to lead and catalyze from the public sector, but the public/private partnership here is critical and essential."

RAISING THE BAR

The HHS announcement marks the first time in the history of Medicare that the agency has set explicit goals for alternative payment models. Prior to 2012, virtually all Medicare payments were tied to fee-for-service models. In 2014, the agency says 20% of payments were linked to value initiatives.

Medicare and Medicaid are the largest health insurance programs in the world, and one in three Americans receives benefits from them.

PIPER

The announcement is a signal that HHS is serious about transitioning the system away from fee-for-service, says Kip Piper, MA, FACHE, advisor with Sellers Dorsey, a Medicaid consultancy in Washington, D.C.

"To the marketplace, both providers and other large purchasers such as state Medicaid agencies, employers, and health plans, [HHS] is signaling Medicare is throwing its imposing weight behind ending traditional fee-for-service payment and doing so on a fast track," Piper says. "This is very much in sync with the goals of most other buyers, particularly state Medicaid agencies, Fortune 500 employers, and innovative health plans in the Medicare, Medicaid, and commercial markets. They are all eager to end transitional fee-for-service and align provider payments with value."

For providers, the announcement "sends a clear message to adapt and help minimize uncertainty," says Piper, a former state and CMS official who advises states, health systems, and

Payment Reform Goals

U.S. Department of Health and Human Services
Tie 30% of Medicare payments to value-based care models by the end of 2016, and 50% by the end of 2018.

Health Care Transformation Task Force members
Tie 75% of operations to value-based contracts by 2010.

Aetna
Tie 50% of payments to vaue-based care models by 2018, and 75% by 2020.

CIGNA
Tie 90% of payments to value-based arrangements and 50% to alternative payment models by 2018.

Dignity Health
Tie 50% of its payments to ACOs by 2018, and 75% by 2020.

Humana
Tie 75% of Medicare Advantage members to ACOs by the end of 2017.

United HealthCare
Tie $65 million in payments to value-based care models by the end of 2018.

health plans. "Those providers who have been sitting back or taking a more cautious approach to innovation now have a clearer vision of the future of payment."

In recent years, Medicare has rolled out a "dizzying array" of performance measures and payment methods, says Piper. "In most cases, these have been tests or demonstrations. [This] initiative offers an actionable structure to take public and private innovations large-scale, nationwide."

Payment must be aligned with value to improve patient outcomes and the clinical and economic performance of care delivery, according to Piper. "While Medicare is a major player, to really drive change, all the largest purchasers—state Medicaid programs, self-insured employers, and health plans—must work together to leverage their buying power and align it with outcomes-based expectations.

"CMS can greatly benefit from the expertise and experience of the other purchasers and plans. Other buyers, notably innovative state Medicaid agencies, large employers, and health plans, are more experienced in payment reform than Medicare," Piper adds.

DEFINING VALUE

Close on the heels of the HHS announcement, a group of major providers and insurers launched the Health Care Transformation Task Force, with a goal to shift 75% of their operations to contracts designed to improve quality and lower costs by 2020. The coalition includes the nation's largest non-profit, Ascension Health, as well as Trinity Health, Partners HealthCare, Advocate Health Care, Aetna, the Health Care Services Corp. (HCSC), Caesars Entertainment and the Pacific Business Group.

The Task Force defines value-based payment arrangements as those that successfully incentivize and hold providers accountable for the total cost, patient experience and quality of care for a population of patients, either across an entire population over the course of a year or during a defined episode that spans multiple sites of care.

The group's first order of business, says David Lansky, chief executive officer of the Pacific Business Group, "is finding agreement and a shared understanding of how we are going to measure value." Different specialties, he notes, may have different ideals of what constitutes value.

Initial priorities also include improving the ACO model, developing a common bundled payment framework and improving care for high-cost patients. The Task Force will also develop policy and program design recommendations for the private sector, CMS and Congress; new delivery and payment models; and best-practice tools, benchmarks and approaches to implement them.

"The biggest challenge," says Lansky, "is we don't really know what works. In a very large, pluralistic environment, it's easy to state something, but to apply it in this environment is difficult."


LANSKY

Lansky said that, from a purchasing perspective, "we think the bar could be higher for quality outcomes. We're interested in higher standards." On the cost side, "we don't have very good measures on the total cost of care across the continuum. Just because a patient is enrolled in a value-based program doesn't ensure quality outcomes."

The second challenge, he says, "is changing the cultural legacy of healthcare, changing the way doctors practice medicine, changing patient expectations. It's going to take some time."

The Task Force already released its first consensus recommendations on how best to design the next generation ACO model for commercial, Medicare and Medicaid programs. "There is a great readiness and a motivation to help with work flow change," says Lansky. The group, he adds, wants payment transformation to move as quickly as possible so that providers don't have to straddle two payment systems.

Task Force member Stephen Ondra, M.D., senior vice president and chief medical officer at HCSC, which runs five state Blue Cross plans, says the status quo is not an option. "The current reimbursement system is not sustainable. Fee-for-service reimbursements have led to the situation we find ourselves in today, when we as a country get only average outcomes for the high costs we pay for healthcare. We must shift from a system that rewards volume to one that rewards quality.


ONDRA

"In an era during which everyone from the federal government down to each individual person must operate within the confines of limited resources, we all must focus on getting the most value from the dollars spent on care," says Ondra.

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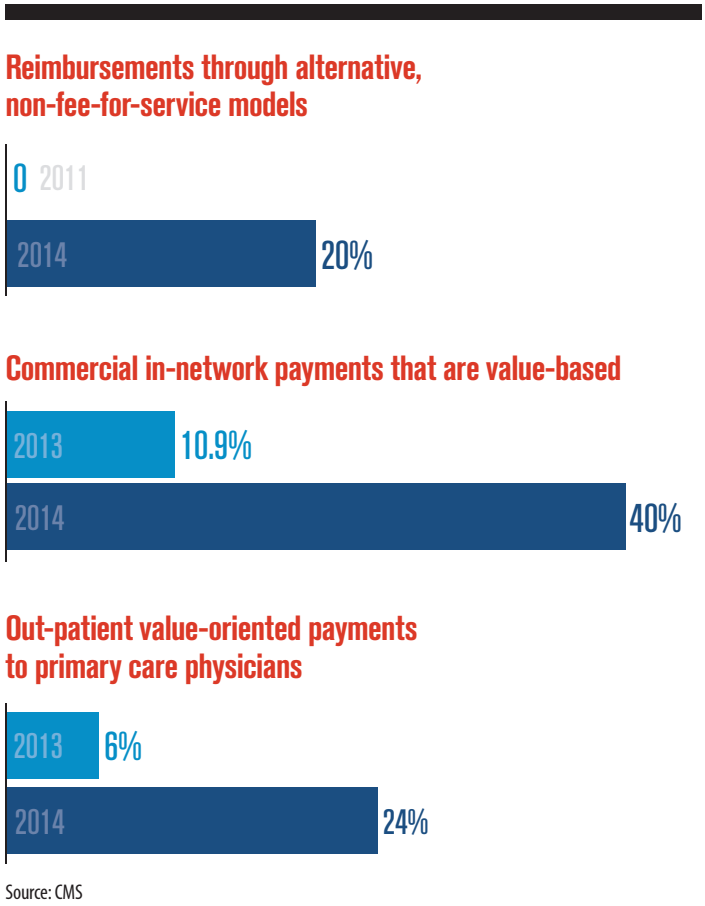
THE TIPPING POINT

While the Task Force set a goal of transitioning 75% of operations to value-based models, many organizations are already well on their way to hitting that benchmark.

UnitedHealthcare, the nation's largest insurer, recently announced that it had shifted 11 million individual, employer-sponsored, Medicare and Medicaid plan participants into value-based programs, and plans to increase payments tied to value-based arrangements to $65 billion by the end of 2018. It currently contracts with about 520 ACOs and plans to contract with 250 new ACOs in 2015.

Cigna says it will double revenues in the next seven to eight years due in part to the shift to value-based care contracts. More than 24 million Blue Cross/Blue Shield members in 2014 received care through value-based programs, according to the Blue Cross/Blue Shield Association, while Aetna reports that 3.2 million of its members are under value-based models.



Source: CMS

Currently 28% of all Aetna claims payments are for value-based care, and the company wants to increase that number to 50% by 2018 and 75% by 2020.

Humana already has about 50% of its members under value-based reimbursement models, and plans to have 75% of Medicare Advantage members under ACOs by 2017, according to Bruce Broussard, Humana's president and chief executive officer. Brousssard and other panelists at the Health Care Payment Learning and Action Network kick-off meeting shared what's working for their organizations.

Humana has seen the biggest impact from value models on chronic care, said Broussard. "Chronic care is not one and done, it is a lifestyle change. When we have a conversation with a member about their health and prevention and ensuring that they're adhering to their prescriptions and ensuring that they're walking, it makes a big impact," he noted. Payment reform "has wrapped the conversation around the journey of someone's health as opposed to treatment."

Dignity Health, one of the nation's largest delivery networks with care sites in 21 states, started an ACO even before the passage of the ACA, noted Lloyd Deen, chief executive officer. "We recognized…that cost escalations that historically were happening in our country were not sustainable." Dignity's partnership with the California Public Employees' Retirement System "resulted in a model that improved care, saved money, but most importantly, saved lives."

Caesar's Entertainment Group's Chief Executive Officer Gary Loveman shared the success the company has had with a bundled care pilot in Reno, Nevada. The program "encourages those facing joint replacement decisions to consider a bundled offering…that combines orthopedic surgeons, rehab services as well as the in-hospital portion of the experience under a capitated cost structure that [results] in substantially lower out-of-pocket costs," for employees, said Loveman.

HHS has also seen promising results from alternative payment models, realizing a combined savings of $417 million to Medicare due to existing ACO programs. It said it expects those models to continue to contribute to the recent slowdown in healthcare spending.

PROVIDING SUPPORT

As value-based alternative payment models evolve, some physicians are wondering where

resources will come from to help acclimate to different programs and metrics.

A recent joint study by the RAND Corporation and the American Medical Association found that physicians reported needing help in managing the increasing amounts of data and programs in use.

"We found that changing the payment system probably isn't enough to ensure that patient care will improve," said Mark W. Friedberg M.D., senior natural scientist at RAND, and the study's lead author. "For alternative payment methods to work best, medical practices also need support and guidance. It's the support that accompanies a new payment model, plus how well the model aligns with all of a practice's other incentives, that could determine whether it succeeds."

The disparity of data systems is something HCSC's Ondra has seen in the field. "We see a great diversity of providers in the five states we serve, in terms of their integration, technological capabilities and ability or willingness to share risk. We try to meet providers where they are with the right models and support.

"HCSC is working to lead the way to streamline and refine quality measurement," says Ondra. "Together with CMS, NQF (National Quality Forum), and our fellow payers at AHIP (America's Health Insurance Plans), we have convened a collaborative working group with providers to reduce quality measure variability across payers and programs, refine measurement to be less resource-intensive, and relate the measures to patient outcomes." The NQF is a non-profit, nonpartisan, membership-based organization that advises the federal government and private sector payers on optimal measures for specific payment and accountability programs.

Part of the work of the Health Care Payment Learning and Action Network will be to develop scalable, standardized value-base payment models, said HHS' DeSalvo. "We want to add certainty to the marketplace so that everyone, including providers, knows what business model to build for optimal care delivery," DeSalvo said at the Network's first meeting.

Some payers are also rolling out resources directly to help providers. The Texas Medical Association (TMA) and Blue Cross and Blue Shield of Texas (BCBSTX) recently launched a resource initiative to assist independent physicians with providing accountable care. TMA's membership includes more than 48,000 Texas physicians and medical students. BCBSTX serves more than 5 million members in all 254 Texas counties.

VALUE IN THE PATIENT'S EYES

At the end of the road, improving patient outcomes is the ultimate goal of payment reform, says Miles J. Varn, M.D., chief medical officer of PinnacleCare. "Where the benefit of volume to value really lies is, we need more personalized, physician-based care. If [we] save patients from surgeries, that's a huge benefit for the patient…it starts with treatment recommendations, and transparency focused on treatment options."

NESS

For patients, healthcare reform is "the promise of really being able to have a primary care provider with whom you have a trusted relationship, that knows you and takes [you] into account," noted Debra L. Ness, president of the National Partnership for Women & Families, speaking at the Health Care Payment Learning and Action Network kick-off.

"We've talked a lot about access to care. But people…have to believe and trust that what they're getting is better. If we want them to make decisions that are value-based, we have to let them see information about quality and costs," said Ness.

Patients, said Ness, haven't always been at the center of the reform conversation. "We can't get to that triple aim unless we begin to see patients and families as co-creators of healthcare. We can't get there if they're not at the table helping to shape that care."

In the past, said Ness, "we've had the mindset of, if we build it, they'll come. This time I hope what we do is…build it with them so that they're already there…engaging with us. Then we get to a care system that leads to giving people…the kind of care they need."

IN THIS ISSUE

Humana has created Transcend and Transcend Insights, a population health management platform to help providers and health systems manage value-based models of care.

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The Medicaid Expansion divide

Non-expansion states face shortfalls while counterparts deal with population influx

by **JUDY PACKER-TURSMAN**

After the first year of Medicaid expansion under the Affordable Care Act (ACA), some healthcare providers and plans on the front lines are confronting operational—as well as political—challenges.

In Washington, an expansion state, a safety net plan's Medicaid enrollment skyrocketed by 50% and newcomers' pent-up demand created initial customer-service issues.

In Texas, a non-expansion state, a safety net plan's parent hospital district that cares for a significant number of uninsured patients is facing a $14 million-dollar shortfall despite staff layoffs and other cost-cutting measures.

When enacted in 2010, the ACA required all states to expand Medicaid coverage to adults with incomes up to 138% of the federal poverty level. However, the U.S. Supreme Court ruled in 2012 that states could refuse to participate in Medicaid expansion under the reform statute without being penalized. While 28 states and the District of Columbia have opted to expand their Medicaid programs since this component of the ACA first took effect in January 2014, fully 22 states have not.

The ACA's drafters assumed Medicaid expansion in all states, but it is anyone's guess as to what happens next. Hundreds of pro-expansion community activists recently marched on the Missouri Capitol. If the state raises Medicaid eligibility to the ACA's standard, which its Democratic governor wants and GOP-controlled legislature opposes, then proponents say 300,000 more Missourians would gain health coverage and the state would reap about $2 billion in additional federal dollars.

In Kansas, a standing-room-only crowd listened to pro-Medicaid expansion testimony at a legislative hearing March 18. H.B. 2319 calls on Gov. Sam Brownback (R) and state regulators to devise an expansion plan and negotiate with U.S. Centers for Medicare and Medicaid Services (CMS) for its approval.

Kansas' failure to expand Medicaid lost the state $334 million in 2014 and an estimated $380 million-plus this year in federal dollars, with 6,400 fewer jobs being created over the two years, says a George Washington University study sponsored by the Kansas Hospital Association.

Currently, KanCare, the state's Medicaid managed care program, covers about 466,000 people; expansion would add between 140,000 and 170,000 adults. State officials testified against expansion March 19,

arguing it could cost at least $100 million annually and push healthy adults ahead of disabled people awaiting Medicaid services.

Across the U.S., advocates insist Medicaid expansion not only will help more people get access to affordable care, thus improving their health, but it also will contribute to states' economic health. They anticipate that some expansion states' positive preliminary 2014 data, starting to appear in March, could sway elected officials in the increasing number of states that are considering alternative models through federal waivers as a politically viable way to expand Medicaid. Specifically:

- **A March 11 briefing paper by Kaiser Family Foundation cites state budget savings and revenue gains, alongside limited costs, from Medicaid expansion in Connecticut, New Mexico and Washington state.**
- **Analysis by Manatt Health Solutions for the Robert Wood Johnson Foundation estimates net savings of $820 million for Kentucky and $370 million for Arkansas from 2014 through 2021, as a result of the states' use of new federal funds and enhanced federal matching under Medicaid expansion. In 2014 alone, Kentucky saved $9 million when Medicaid paid for behavioral health and mental health services previously paid by the state, according to the report, and Arkansas saved $17.5 million by using a 100% federal match for high-need enrollees.**

"We have found that without exception the economic benefit [of Medicaid expansion] outweighs the cost... and there is no negative fiscal state impact well past 2020," says Deborah Bachrach, a partner at Manatt Health Solutions and lead author of the firm's March 4 Arkansas/Kentucky issue brief. She says analysis of more states' expansion results is expected soon.


BACHRACH

The bottom line? "There's a big difference between projecting and realizing savings, and states are now realizing savings," Bachrach says.

The ACA called for the federal government to foot a state's entire bill for Medicaid expansion for three years starting in 2014, paying 90% thereafter. While 10 states with Republican governors have expanded Medicaid, Missouri and others with GOP-controlled legislatures either worry they ultimately may have to pick up a greater share of the tab—or they take broad exception to what they call Obamacare.

Proponents counter that still-reluctant states ought to embrace Medicaid expansion as soon as possible to cover millions of people who would be left uninsured if the Supreme Court decides to eliminate federal subsidies for low-income people buying private coverage on the ACA-created health insurance exchanges. The high court's ruling is expected by June.

In March, the U.S. Department of Health and Human Services (HHS) reported that 16.4 million Americans had gained coverage in the five years since the ACA's enactment. Coverage gains were especially strong in Medicaid expansion states. While 55% of people in expansion states with incomes below 138% of federal poverty lacked coverage prior to expansion, they experienced the largest coverage gain of 13%. That compares to a 7% hike for people at the same income level in non-expansion states.

Providers in all states, including states not expanding Medicaid, are seeing drops in uncompensated care, says Manatt's Bachrach, a former New York Medicaid director. But hospitals in expansion states are reporting "considerable reductions" in their uncompensated care levels, she says, describing the program's expansion as critical for safety net and rural hospitals.

Moreover, Bachrach notes there is continuous coverage in Medicaid expansion states, instead of the traditional gaps when low-income people lose Medicaid eligibility but can't afford private plans. This stability "gives health insurers the ability to truly manage the care and reduce costs," she says.

UNITED, ANTHEM TOUTING GAINS

Publicly traded commercial plans, including UnitedHealthcare and Anthem, Inc., are touting financial gains from Medicaid enrollment boosts. In January, United cited a 29% increase in its Medicaid revenue in 2014 as compared to 2013, driven by expansion, and anticipates further growth of 15% to 17% in the business line this year. Anthem said it gained 815,000 new Medicaid enrollees in 2014.

13%

Percent of people below federal poverty level who gained coverage in expansion states between 2010-2015.

7%

Percent of people below federal poverty level who gained coverage in non-expansion states between 2010-2015.

Medicaid expansion has added about 300,000 enrollees to CareSource's 1.3 million members in Ohio and Kentucky, says Steve Ringel, CareSource's Ohio market president. "These members have struggled financially and have not been able to make health care a priority and now they have access," he says.


RINGEL

Given CareSource's size, there were no corporate operational changes from Medicaid expansion, Ringel says. But some small local safety net plans, while also strong advocates of extending Medicaid to improve their communities' access to care, are confronting a different reality.

HANDLING THE INFLUX

Community Health Plan of Washington (CHPW) has added about 95,000 adults from Medicaid expansion to its membership base of 180,000 in the Temporary Assistance for Needy Families (TANF) program, says Stacy Kessel, chief financial officer. The largest enrollment was in January, but membership is continuing to grow, with about 4,500 members added in the first half of March.


KESSEL

"Our [statewide Medicaid] enrollment also increased tremendously because our [state] exchange was very successful," she says. CPHW added about 1,300 members in its subsidized exchange product for people churning on and off Medicaid, she notes.

Kessel stresses that CHPW is "thrilled" that Washington state opted for Medicaid expansion, thus improving preventive care for many people. But she adds CHPW, a nonprofit plan, founded and governed by community health centers, initially struggled with new members' pent-up demand for care, completion of their health-risk assessments, and getting new members into disease management, behavioral health and other needed services and orienting them to the care delivery system. "Because of the pent-up demand, there was definitely this bolus of effort that was needed up front," says Kessel.

According to Kessel, CHPW's network includes 21 federally qualified community health centers (FQHCs) which operate 127 clinic sites in Washington; including its non-FQHC network, CHPW has more than 2,700 contracted primary care providers, 15,000 specialist providers and 100-plus hospitals.

While about 70% of the health plan's TANF members have FQHC primary care physicians, almost nine in 10 new members in the expansion population have a primary care physician (PCP), she adds.

"Health centers have certainly had to ramp up" to handle the heavy influx of Medicaid expansion members, Kessel says. "But they've been doing it for awhile—increasing their ability to care for more patients," including bricks-and-mortar construction.

Kessel also notes that CHPW has stretched its reserves to be able to handle premiums. "Our risk-based capital percentage was just over 350% at the end of 2014, still well within NAIC's [i.e., the National Association of Insurance Commissioners'] healthy range," she says. "But we were sitting close to 500%" previously. Washington state insurance regulators "like $1 of reserves for every $8 of premium," she explains, "so basically 12.5% of premium coming in, they want to see in reserves." While reserves are adequate, she says, "Obviously, we're not making money with this population."

FROM TELEMEDICINE TO CLINICS

Margaret A. Murray, chief executive officer of the Association for Community Affiliated Plans (ACAP) and *Managed Healthcare Executive* editorial advisor, says her group is examining what safety net plans are doing to address expansion demand.

First, Murray cites plans' active use of telemedicine and e-consults that allow PCPs to leverage limited specialist networks. L.A. Care Health Plan in southern California is using e-consults, particularly with dermatologists, she says, while telemedicine is being used by Driscoll Health Plan in Corpus Christi, Texas, to connect members with child psychiatrists, and by Partnership HealthPlan of California, particularly for hepatitis C consults.


MURRAY

In addition, safety net plans are starting to build their own clinics, Murray says. Texas Children's Health Plan in Houston built its

own clinic and, because of its success, is considering a second site, she says. Moreover, she adds, plans are working to integrate care delivery models to meet significant demand for behavioral health and substance abuse services. "For us, it's 100% our mission to cover these populations, and we'll do whatever is necessary."

PUSHING FOR CHANGE IN TEXAS

In Texas, which has about 4 million Medicaid recipients, hospitals, county officials and plans have spent the past few years urging the state's politicians to act on statewide expansion – including an initial failed effort to phase in expansion through county-led efforts.

"It's totally a political issue. If you just do the math, it's a 'no brainer' [to expand Medicaid under the ACA], but that's not how our state legislators see it," says Ken Janda, president and chief executive officer of Houston-based Community Health Choice, Inc. The nonprofit managed care plan covers about 265,000 Medicaid STAR program and Children's Health Insurance Program (CHIP) members, and another 35,000 enrollees through its HMO products from Texas's federally-facilitated exchange.


JANDA

None of the introduced pro-Medicaid expansion bills are moving, Janda says. "The reality is it will take some near-miracle for the Texas state legislature to pass expansion in this session which ends May 31," he told MHE March 16.

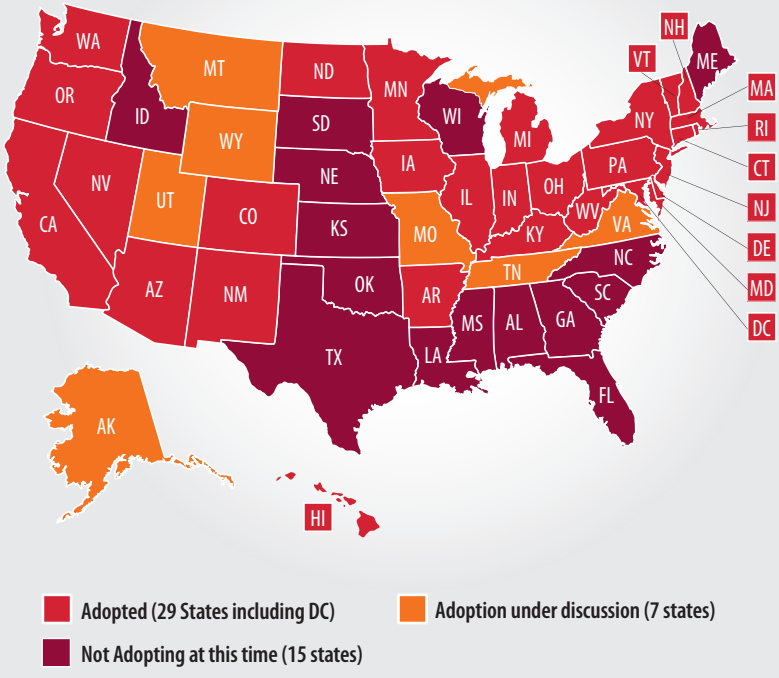
In Texas, "what the legislature sees is Medicaid costs continuing to rise, but it's the number of enrollees [rising], not the cost per enrollee," Janda explains. He says the slight decline in Texas's statewide uninsured rate to 23% in 2014—still the highest rate in the U.S.—"is 100% attributable to subsidized products on the exchange." For 2015, about 1.2 million people in Texas got coverage through exchange plans, of which about 700,000 previously had individual policies and 500,000 previously were uninsured, he says. "If the Supreme Court says no subsidies, there could be more trouble," he adds.

Medicaid expansion would add roughly 1.7 million—out of about 6 million—uninsured Texans to the program's rolls, according to initial estimates, of which about 400,000 would be in the Houston area, Janda says.

Prior to the Supreme Court's 2012 decision allowing states to opt out, Texas had a preliminary plan to expand its Medicaid managed care model by using five HMOs in the Houston area. Janda says that proposal would have resulted in about 80,000 new enrollees per plan; and Community Health Choice, which has a strong network for adults, was looking at bringing in childless adults and parents of children in Medicaid and CHIP. "We still think that's what we should do," he says.

Houston, similar to Dallas, San Antonio and Fort Worth, has a public hospital system supported by local tax dollars that serves

OVER HALF OF STATES HAVE ADOPTED MEDICAID EXPANSION WHILE DISCUSSION CONTINUES IN OTHERS



Source: "Status of State Action on the Medicaid Expansion Decision," KFF State Health Facts, updated January 27, 2015

> "The reality is it will take some near-miracle for the Texas state legislature to pass expansion in this session..."
>
> KEN JANDA, PRESIDENT AND CEO, COMMUNITY HEALTH CHOICE, INC.

significant numbers of uninsured patients, Janda explains. Community Health Choice's parent organization is Harris County Hospital District, now known as Harris Health System, he says, "and, frankly, they are really struggling, because as part of the ACA they have had reductions in DSH [Medicaid's Disproportionate Share Hospital] and uncompensated care payments," totaling about $40 million over the past year.

For the last fiscal year, Harris Health had about a $25 million deficit that was projected to climb to $70 million for this fiscal year, Janda says. The projected deficit was seen as untenable, so the hospital district had to lay off staff, reduce hours and outsource certain services, which resulted in an approved budget projecting a $14 million loss, he says.

"Next year it will be really bad for Harris Health if we don't get Medicaid expansion or more DSH and uncompensated care funding," Janda asserts. He says the hospital district got about $525 million of its $1 billion-plus annual budget from local property taxes last year; local funds could help with the state's 10% of the Medicaid expansion tab after 2016—"but county taxes can't cover growth in uninsured and DSH payments," he says.

As for how the situation is playing out for Community Health Choice, Janda says: "We haven't really been negatively impacted because [enrollments for] pregnant women and kids continue to grow...and we hope we're helping the hospital district by covering some previously uninsured."

Meanwhile, he says Community Health Choice is "advocating very strongly" for a federal Medicaid waiver that includes "principles of individual responsibility and a marketplace solution."

MARYLAND EXPECTS SAVINGS

By contrast, heavily-regulated Maryland is a Medicaid expansion state where hospitals operate on global budgets. Since the 1970s, state regulators have used a waiver to set prices that hospitals charge patients, regardless of whether they have private or government-sponsored insurance.

Shannon McMahon, Maryland's Medicaid director, says that when she testified before state lawmakers in early March on the forthcoming Medicaid budget, she cited a Manatt study's finding that hospitals in expansion states have seen a 46% decrease, on average, in uncompensated care. This would translate into a $500 million reduction in uncompensated care across Maryland's hospitals, she notes.

Moreover, McMahon tells *Managed Healthcare Executive* that her Medicaid-expansion state likely will save $17 million in state general funds over the next year from the enhanced federal matching rate.

"We know that we have just over 300,000 new Medicaid enrollees as a result of expansion," says McMahon, deputy secretary for healthcare financing in the Maryland Dept. of Health and Mental Hygiene. Nearly 201,000 enrollees are from ACA-driven Medicaid expansion; the rest are childless adults enrolled in a limited-benefit Primary Adult Care program who automatically converted to Medicaid last year.

Overall, Maryland's Medicaid program is budgeting for 1.4 million enrollees in the coming fiscal year, which represents nearly a doubling of enrollment over the past seven years, McMahon says. "It's a big number," she says, explaining the drive to get the expansion population into managed care plans and connect them to PCPs—and, for those with severe and persistent mental illness, to health homes.

In addition, McMahon says the Medicaid program will set managed care payment rates for 2016 over the next several months. "For us, this is the big year where we'll see the impact of Medicaid expansion because we have a full year of data from [Medicaid] MCOs," she says.

"The ACA's Medicaid expansion has allowed the state to leverage federal funding to cover a broader group of individuals... and bring down hospital and uncompensated care costs," McMahon concludes, "and there's some consistency and predictability in the rate setting."

Yet McMahon concedes that the real test will come soon. Maryland's Medicaid program projects the state will need to spend $80 million in state general funds starting in January 2017, after the federal government stops paying states' full expansion costs. "We'll need to show expansion is a good thing for Maryland...and the taxpayers," she says. "You want to be able to say, 'We're big picture saving money.'" ◘

Judy Packer-Tursman *is a freelance writer in Washington D.C.*

SLOW THE PATH OF IPF PROGRESSION FOR YOUR MEMBERS

OFEV (nintedanib) has demonstrated reproducible reductions in the annual rate of FVC decline in 3 clinical trials[1]

OFEV significantly reduced the risk of first acute IPF exacerbation over 52 weeks compared with placebo in 2 out of 3 clinical trials[1]

Up to 132,000 people in the United States have idiopathic pulmonary fibrosis (IPF).[2,3]

Help your members with IPF find appropriate treatment. Learn more on the following pages.

Indication and Usage

OFEV is indicated for the treatment of idiopathic pulmonary fibrosis (IPF).

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Elevated Liver Enzymes

- The safety and efficacy of OFEV has not been studied in patients with moderate (Child Pugh B) or severe (Child Pugh C) hepatic impairment. Treatment with OFEV is not recommended in patients with moderate or severe hepatic impairment.
- In clinical trials, administration of OFEV was associated with elevations of liver enzymes (ALT, AST, ALKP, and GGT) and bilirubin. Liver enzyme increases were reversible with dose modification or interruption and not associated with clinical signs or symptoms of liver injury. The majority (94%) of patients with ALT and/or AST elevations had elevations <5 times ULN. The majority (95%) of patients with bilirubin elevations had elevations <2 times ULN.
- Conduct liver function tests (ALT, AST, and bilirubin) prior to treatment with OFEV, monthly for 3 months, and every 3 months thereafter, and as clinically indicated. Dosage modifications, interruption, or discontinuation may be necessary for liver enzyme elevations.

Please see additional Important Safety Information and accompanying Brief Summary on the following pages.

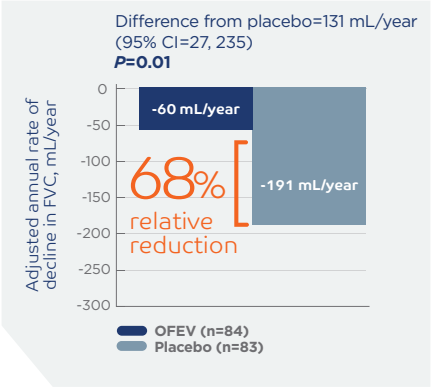
To learn more about OFEV, please visit OFEV.com/formularykit

OFEV®
(nintedanib)
capsules 150mg

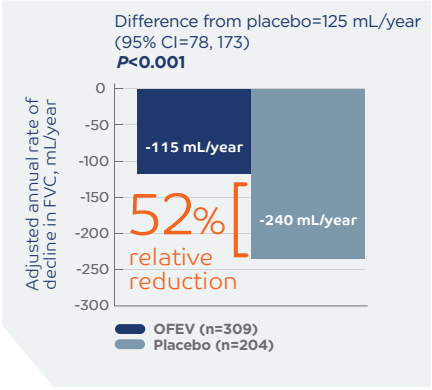
OFEV demonstrated a statistically significant reduction in the annual rate of FVC decline[1]*

Treatment effect on FVC was consistent across all 3 clinical trials

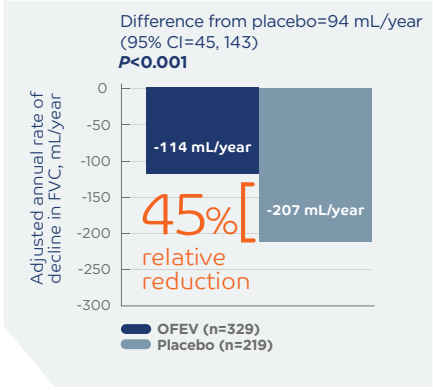
TOMORROW (Study 1)[1,4]



INPULSIS®-1 (Study 2)[1,5]



INPULSIS®-2 (Study 3)[1,5]



*The annual rate of decline in FVC (mL/year) was analyzed using a random coefficient regression model.[1] In the INPULSIS® trials, the statistical model used allowed for missing data. All available FVC values from baseline to week 52 were used, including FVC measurements from the follow-up visit for patients who prematurely discontinued trial medication and did not complete study visits through week 52.[1,4,5]

CI, confidence interval; FVC, forced vital capacity.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Gastrointestinal Disorders

Diarrhea

- Diarrhea was the most frequent gastrointestinal event reported in 62% versus 18% of patients treated with OFEV and placebo, respectively. In most patients, the event was of mild to moderate intensity and occurred within the first 3 months of treatment. Diarrhea led to permanent dose reduction in 11% of patients treated with OFEV compared to 0 placebo-treated patients. Diarrhea led to discontinuation of OFEV in 5% of the patients compared to <1% of placebo-treated patients.
- Dosage modifications or treatment interruptions may be necessary in patients with adverse reactions of diarrhea. Treat diarrhea at first signs with adequate hydration and antidiarrheal medication (e.g., loperamide), and consider treatment interruption if diarrhea continues. OFEV treatment may be resumed at the full dosage (150 mg twice daily), or at the reduced dosage (100 mg twice daily), which subsequently may be increased to the full dosage. If severe diarrhea persists despite symptomatic treatment, discontinue treatment with OFEV.

Nausea and Vomiting

- Nausea was reported in 24% versus 7% and vomiting was reported in 12% versus 3% of patients treated with OFEV and placebo, respectively. In most patients, these events were of mild to moderate intensity. Nausea led to discontinuation of OFEV in 2% of patients. Vomiting led to discontinuation of OFEV in 1% of the patients.
- For nausea or vomiting that persists despite appropriate supportive care including anti-emetic therapy, dose reduction or treatment interruption may be required. OFEV treatment may be resumed at the full dosage (150 mg twice daily), or at the reduced dosage (100 mg twice daily), which subsequently may be increased to the full dosage. If severe nausea or vomiting does not resolve, discontinue treatment with OFEV.

Embryofetal Toxicity

- OFEV is Pregnancy category D. It can cause fetal harm when administered to a pregnant woman. If OFEV is used during pregnancy, or if the patient becomes pregnant while taking OFEV, the patient should be advised of the potential hazard to a fetus. Women of childbearing potential should be advised to avoid becoming pregnant while receiving treatment with OFEV and to use adequate contraception during treatment and at least 3 months after the last dose of OFEV.

Arterial Thromboembolic Events

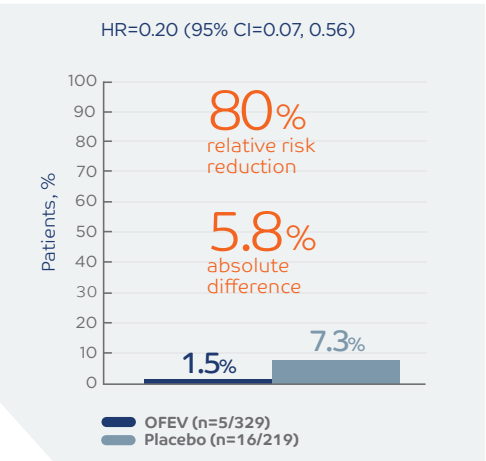
- Arterial thromboembolic events have been reported in patients taking OFEV. In clinical trials, arterial thromboembolic events were reported in 2.5% of patients treated with OFEV and 0.8% of placebo-treated patients. Myocardial infarction was the most common adverse reaction under arterial thromboembolic events, occurring in 1.5% of OFEV-treated patients compared to 0.4% of placebo-treated patients. Use caution when treating patients at higher cardiovascular risk including known coronary artery disease. Consider treatment interruption in patients who develop signs or symptoms of acute myocardial ischemia.

Risk of Bleeding

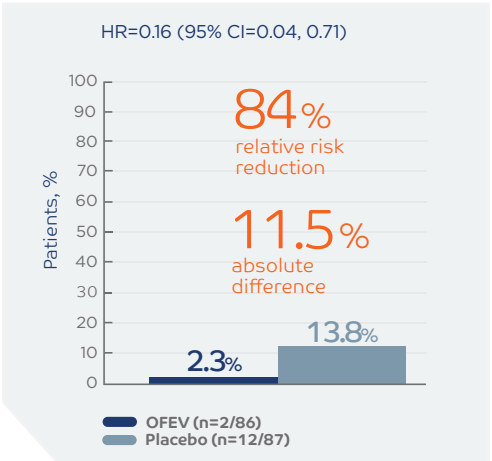
- Based on the mechanism of action (VEGFR inhibition), OFEV may increase the risk of bleeding. In clinical trials, bleeding events were reported in 10% of patients treated with OFEV and in 7% of patients treated with placebo. Use OFEV in patients with known risk of bleeding only if the anticipated benefit outweighs the potential risk.

OFEV significantly reduced the risk of time to first acute IPF exacerbation in 2 out of 3 clinical trials[1]

INPULSIS®-2 (adjudicated)[1,6]



TOMORROW (investigator-reported)[1,6]



- In INPULSIS®-1 (adjudicated), there was no difference in treatment groups (HR=0.55, 95% CI=0.20, 1.54)[1]

Diagnostic criteria for acute IPF exacerbations were prespecified in the trial protocol as events meeting all of the following criteria: unexplained worsening or development of dyspnea within 30 days, new diffuse pulmonary infiltrates on chest X-radiography and/or HRCT, or new parenchymal abnormalities with no pneumothorax or pleural effusion (new ground-glass opacities) since last visit, exclusion of infection (as per routine clinical practice and microbiological studies), and exclusion of alternative causes (as per routine clinical practice and including the following: left heart failure, pulmonary embolism, and identifiable cause of acute lung injury).[1,5]

HR, hazard ratio; HRCT, high-resolution computed tomography.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Gastrointestinal Perforation

- Based on the mechanism of action, OFEV may increase the risk of gastrointestinal perforation. In clinical trials, gastrointestinal perforation was reported in 0.3% of patients treated with OFEV, compared to 0 cases in the placebo-treated patients. Use caution when treating patients who have had recent abdominal surgery. Discontinue therapy with OFEV in patients who develop gastrointestinal perforation. Only use OFEV in patients with known risk of gastrointestinal perforation if the anticipated benefit outweighs the potential risk.

ADVERSE REACTIONS

- Adverse reactions reported in ≥5% of patients treated with OFEV and more commonly than in patients treated with placebo included diarrhea (62% vs. 18%), nausea (24% vs. 7%), abdominal pain (15% vs. 6%), liver enzyme elevation (14% vs. 3%), vomiting (12% vs. 3%), decreased appetite (11% vs. 5%), weight decreased (10% vs. 3%), headache (8% vs. 5%), and hypertension (5% vs. 4%).
- The most frequent serious adverse reactions reported in patients treated with OFEV, more than placebo, were bronchitis (1.2% vs. 0.8%) and myocardial infarction (1.5% vs. 0.4%). The most common adverse events leading to death in patients treated with OFEV, more than placebo, were pneumonia (0.7% vs. 0.6%), lung neoplasm malignant (0.3% vs. 0%), and myocardial infarction (0.3% vs. 0.2%). In the predefined category of major adverse cardiovascular events (MACE) including MI, fatal events were reported in 0.6% of OFEV-treated patients and 1.8% of placebo-treated patients.

DRUG INTERACTIONS

P-glycoprotein (P-gp) and CYP3A4 Inhibitors and Inducers

- Coadministration with oral doses of a P-gp and CYP3A4 inhibitor, ketoconazole, increased exposure to nintedanib by 60%. Concomitant use of potent P-gp and CYP3A4 inhibitors (e.g., erythromycin) with OFEV may increase exposure to nintedanib. In such cases, patients should be monitored closely for tolerability of OFEV. Management of adverse reactions may require interruption, dose reduction, or discontinuation of therapy with OFEV. Coadministration with oral doses of a P-gp and CYP3A4 inducer, rifampicin, decreased exposure to nintedanib by 50%. Concomitant use of P-gp and CYP3A4 inducers (e.g., carbamazepine, phenytoin, and St. John's wort) with OFEV should be avoided as these drugs may decrease exposure to nintedanib.

Anticoagulants

- Nintedanib is a VEGFR inhibitor, and may increase the risk of bleeding. Monitor patients on full anticoagulation therapy closely for bleeding and adjust anticoagulation treatment as necessary.

Please see additional Important Safety Information and Brief Summary for OFEV on the following pages.

OFEV®
(nintedanib)
capsules 150mg

Help your members find appropriate treatment for IPF

The totality of the evidence demonstrates that OFEV (nintedanib) slows disease progression[1,7-10]

- OFEV:
  - Reduced the decline of lung function, measured by annual rate of FVC decline, by approximately 50% in patients with IPF in all 3 clinical trials[1,4,5]
  - Significantly reduced the risk of time to first acute IPF exacerbation over 52 weeks compared with placebo in 2 out of 3 clinical trials[1]
- OFEV has demonstrated reproducible and statistically significant reductions in the annual rate of FVC decline in 3 clinical trials[1]
- OFEV offers twice-daily oral dosing[1]
  - Conduct liver function tests prior to treatment with OFEV, monthly for 3 months, and every 3 months thereafter, and as clinically indicated
  - OFEV capsules should be taken 12 hours apart, with food, and should be swallowed with a glass of water. OFEV capsules should not be chewed or crushed because of a bitter taste. If a dose is missed, treatment should resume at the next scheduled time and at the recommended dose. Do not exceed the recommended maximum daily dosage of 300 mg
  - In addition to symptomatic treatment, temporary dose reduction (100 mg twice daily) or treatment interruption should be considered for management of adverse reactions until the reaction resolves to levels that allow continuation of therapy. If a patient does not tolerate 100 mg twice daily, discontinue treatment with OFEV
  - For AST or ALT elevations >3 times to <5 times the ULN without signs of severe liver damage, interrupt treatment or reduce dose to 100 mg. Once levels return to baseline values, OFEV may be reintroduced at a reduced dosage (100 mg twice daily), which may be increased to the full dosage. Discontinue OFEV for AST or ALT elevations >5 times ULN or >3 times ULN with signs or symptoms of severe liver damage

ALT, alanine aminotransferase; AST, aspartate aminotransferase; ULN, upper limit of normal.

OFEV offers your members a robust patient support program

To learn more about OFEV patient support services for your members with IPF, please visit www.OFEV.com or call our patient support program at 1-866-OPENDOOR (673-6366) and ask to speak with an OPEN DOORS™ representative.

ONE CAPSULE, TWICE DAILY WITH FOOD[1]

Not shown at actual size.

IMPORTANT SAFETY INFORMATION

USE IN SPECIFIC POPULATIONS

Nursing Mothers

- Excretion of nintedanib and/or its metabolites into human milk is probable. Because of the potential for serious adverse reactions in nursing infants from OFEV, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Hepatic Impairment

- Monitor for adverse reactions and consider dose modification or discontinuation of OFEV as needed for patients with mild hepatic impairment (Child Pugh A). Treatment of patients with moderate (Child Pugh B) and severe (Child Pugh C) hepatic impairment with OFEV is not recommended.

Smokers

- Smoking was associated with decreased exposure to OFEV, which may alter the efficacy profile of OFEV. Encourage patients to stop smoking prior to treatment with OFEV and to avoid smoking when using OFEV.

OFHCPISIJAN15

Please see accompanying Brief Summary for OFEV on the following pages.

References: 1. OFEV® (nintedanib) Prescribing Information. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc; 2014. **2.** Raghu G et al. *Am J Respir Crit Care Med.* 2006;174(7):810-816. **3.** US Census Bureau, Population Division. Annual Estimates of the Population for the United States, Regions, States, and Puerto Rico: April 1, 2010 to July 1, 2011. December 2011. Washington, DC: US Department of Commerce; 2011. **4.** Richeldi L et al. *N Engl J Med.* 2011;365(12):1079-1087. **5.** Richeldi L et al; for the INPULSIS Trial Investigators. *N Engl J Med.* 2014;360(22):2071-2082. **6.** Data on file. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc. **7.** Zappala CJ et al. *Eur Respir J.* 2010;35(4):830-836. **8.** Schmidt SL et al. *Chest.* 2014;145(3):579-585. **9.** du Bois RM et al. *Am J Respir Crit Care Med.* 2011;184(12):1382-1389. **10.** Song JW et al. *Eur Respir J.* 2011;37(2):356-363.

OFEV® (nintedanib) capsules 150mg

Boehringer Ingelheim

OFEV® (nintedanib) capsules, for oral use

BRIEF SUMMARY OF PRESCRIBING INFORMATION
Please see package insert for full Prescribing Information, including Patient Information

INDICATIONS AND USAGE: OFEV is indicated for the treatment of idiopathic pulmonary fibrosis (IPF).

DOSAGE AND ADMINISTRATION: Testing Prior to OFEV Administration: Conduct liver function tests prior to initiating treatment with OFEV *[see Warnings and Precautions]*. **Recommended Dosage:** The recommended dosage of OFEV is 150 mg twice daily administered approximately 12 hours apart. OFEV capsules should be taken with food and swallowed whole with liquid. OFEV capsules should not be chewed or crushed because of a bitter taste. The effect of chewing or crushing of the capsule on the pharmacokinetics of nintedanib is not known. If a dose of OFEV is missed, the next dose should be taken at the next scheduled time. Advise the patient to not make up for a missed dose. Do not exceed the recommended maximum daily dosage of 300 mg. **Dosage Modification due to Adverse Reactions:** In addition to symptomatic treatment, if applicable, the management of adverse reactions of OFEV may require dose reduction or temporary interruption until the specific adverse reaction resolves to levels that allow continuation of therapy. OFEV treatment may be resumed at the full dosage (150 mg twice daily), or at the reduced dosage (100 mg twice daily), which subsequently may be increased to the full dosage. If a patient does not tolerate 100 mg twice daily, discontinue treatment with OFEV *[see Warnings and Precautions and Adverse Reactions]*. Dose modifications or interruptions may be necessary for liver enzyme elevations. For aspartate aminotransferase (AST) or alanine aminotransferase (ALT) >3 times to <5 times the upper limit of normal (ULN) without signs of severe liver damage, interrupt treatment or reduce OFEV to 100 mg twice daily. Once liver enzymes have returned to baseline values, treatment with OFEV may be reintroduced at a reduced dosage (100 mg twice daily), which subsequently may be increased to the full dosage (150 mg twice daily) *[see Warnings and Precautions and Adverse Reactions]*. Discontinue OFEV for AST or ALT elevations >5 times ULN or >3 times ULN with signs or symptoms of severe liver damage.

CONTRAINDICATIONS: None

WARNINGS AND PRECAUTIONS: Elevated Liver Enzymes: The safety and efficacy of OFEV has not been studied in patients with moderate (Child Pugh B) or severe (Child Pugh C) hepatic impairment. Treatment with OFEV is not recommended in patients with moderate or severe hepatic impairment *[see Use in Specific Populations]*. In clinical trials, administration of OFEV was associated with elevations of liver enzymes (ALT, AST, ALKP, GGT). Liver enzyme increases were reversible with dose modification or interruption and not associated with clinical signs or symptoms of liver injury. The majority (94%) of patients with ALT and/or AST elevations had elevations <5 times ULN. Administration of OFEV was also associated with elevations of bilirubin. The majority (95%) of patients with bilirubin elevations had elevations <2 times ULN *[see Use in Specific Populations]*. Conduct liver function tests (ALT, AST, and bilirubin) prior to treatment with OFEV, monthly for 3 months, and every 3 months thereafter, and as clinically indicated. Dosage modifications or interruption may be necessary for liver enzyme elevations. **Gastrointestinal Disorders:** Diarrhea: Diarrhea was the most frequent gastrointestinal event reported in 62% versus 18% of patients treated with OFEV and placebo, respectively *[see Adverse Reactions)]*. In most patients, the event was of mild to moderate intensity and occurred within the first 3 months of treatment. Diarrhea led to permanent dose reduction in 11% of patients treated with OFEV compared to 0 placebo-treated patients. Diarrhea led to discontinuation of OFEV in 5% of the patients compared to <1% of placebo-treated patients. Dosage modifications or treatment interruptions may be necessary in patients with adverse reactions of diarrhea. Treat diarrhea at first signs with adequate hydration and antidiarrheal medication (e.g., loperamide), and consider treatment interruption if diarrhea continues. OFEV treatment may be resumed at the full dosage (150 mg twice daily), or at the reduced dosage (100 mg twice daily), which subsequently may be increased to the full dosage. If severe diarrhea persists despite symptomatic treatment, discontinue treatment with OFEV (nintedanib). Nausea and Vomiting: Nausea was reported in 24% versus 7% and vomiting was reported in 12% versus 3% of patients treated with OFEV and placebo, respectively *[see Adverse Reactions]*. In most patients, these events were of mild to moderate intensity. Nausea led to discontinuation of OFEV in 2% of patients. Vomiting led to discontinuation of OFEV in 1% of the patients. For nausea or vomiting that persists despite appropriate supportive care including anti-emetic therapy, dose reduction or treatment interruption may be required. OFEV treatment may be resumed at the full dosage (150 mg twice daily), or at the reduced dosage (100 mg twice daily), which subsequently may be increased to the full dosage. If severe nausea or vomiting does not resolve, discontinue treatment with OFEV. **Embryofetal Toxicity:** OFEV can cause fetal harm when administered to a pregnant woman. Nintedanib was teratogenic and embryofetocidal in rats and rabbits at less than and approximately 5 times the maximum recommended human dose (MRHD) in adults (on an AUC basis at oral doses of 2.5 and 15 mg/kg/day in rats and rabbits, respectively). If OFEV is used during pregnancy, or if the patient becomes pregnant while taking OFEV, the patient should be advised of the potential hazard to a fetus. Women of childbearing potential should be advised to avoid becoming pregnant while receiving treatment with OFEV and to use adequate contraception during treatment and at least 3 months after the last dose of OFEV *[see Use in Specific Populations]*. **Arterial Thromboembolic Events:** Arterial thromboembolic events have been reported in patients taking OFEV. In clinical trials, arterial thromboembolic events were reported in 2.5% of patients treated with OFEV and 0.8% of placebo-treated patients. Myocardial infarction was the most common adverse reaction under arterial thromboembolic events, occurring in 1.5% of OFEV-treated patients compared to 0.4% of placebo-treated patients. Use caution when treating patients at higher cardiovascular risk including known coronary artery disease. Consider treatment interruption in patients who develop signs or symptoms of acute myocardial ischemia. **Risk of Bleeding:** Based on the mechanism of action (VEGFR inhibition), OFEV may increase the risk of bleeding. In clinical trials, bleeding events were reported in 10% of patients treated with OFEV and in 7% of patients treated with placebo. Use OFEV in patients with known risk of bleeding only if the anticipated benefit outweighs the potential risk. **Gastrointestinal Perforation:** Based on the mechanism of action, OFEV may increase the risk of gastrointestinal perforation. In clinical trials, gastrointestinal perforation was reported in 0.3% of patients treated with OFEV, compared to 0 cases in the placebo-treated patients. Use caution when treating patients who have had recent abdominal surgery. Discontinue therapy with OFEV in patients who develop gastrointestinal perforation. Only use OFEV in patients with known risk of gastrointestinal perforation if the anticipated benefit outweighs the potential risk.

ADVERSE REACTIONS: The following adverse reactions are discussed in greater detail in other sections of the labeling: Liver Enzyme and Bilirubin Elevations *[see Warnings and Precautions];* Gastrointestinal Disorders *[see Warnings and Precautions];* Embryofetal Toxicity *[see Warnings and Precautions];* Arterial Thromboembolic Events *[see Warnings and Precautions];* Risk of Bleeding *[see Warnings and Precautions];* Gastrointestinal Perforation *[see Warnings and Precautions]*. **Clinical Trials 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 rates in the clinical trials of another drug and may not reflect the rates observed in practice. The safety of OFEV was evaluated in over 1000 IPF patients with over 200 patients exposed to OFEV for more than 2 years in clinical trials. OFEV was studied in three randomized, double-blind, placebo-controlled, 52-week trials. In the phase 2 (Study 1) and phase 3 (Studies 2 and 3) trials, 723 patients with IPF received OFEV 150 mg twice daily and 508 patients received placebo. The median duration of exposure was 10 months for patients treated with OFEV and 11 months for patients treated with placebo. Subjects ranged in age from 42 to 89 years (median age of 67 years). Most patients were male (79%) and Caucasian (60%). The most frequent serious adverse reactions reported in patients treated with OFEV (nintedanib), more than placebo, were bronchitis (1.2% vs. 0.8%) and myocardial infarction (1.5% vs. 0.4%). The most common adverse events leading to death in patients treated with OFEV, more than placebo, were pneumonia (0.7% vs. 0.6%), lung neoplasm malignant (0.3% vs. 0%), and myocardial infarction (0.3% vs. 0.2%). In the predefined category of major adverse cardiovascular events (MACE) including MI, fatal events were reported in 0.6% of OFEV-treated patients and 1.8% of placebo-treated patients. Adverse reactions leading to permanent dose reductions were reported in 16% of OFEV-treated patients and 1% of placebo-treated patients. The most frequent adverse reaction that led to permanent dose reduction in the patients treated with OFEV was diarrhea (11%). Adverse reactions leading to discontinuation were reported in 21% of OFEV-treated patients and 15% of placebo-treated patients. The most frequent adverse reactions that led to discontinuation in OFEV-treated patients were diarrhea (5%), nausea (2%), and decreased appetite (2%). The most common adverse reactions with an incidence of ≥5% and more frequent in the OFEV than placebo treatment group are listed in Table 1.

Table 1 Adverse Reactions Occurring in ≥5% of OFEV-treated Patients and More Commonly Than Placebo in Studies 1, 2, and 3

Adverse Reaction	OFEV, 150 mg n=723	Placebo n=508
Gastrointestinal disorders		
Diarrhea	62%	18%
Nausea	24%	7%
Abdominal pain[a]	15%	6%
Vomiting	12%	3%
Hepatobiliary disorders		
Liver enzyme elevation[b]	14%	3%
Metabolism and nutrition disorders		
Decreased appetite	11%	5%
Nervous systemic disorders		
Headache	8%	5%
Investigations		
Weight decreased	10%	3%
Vascular disorders		
Hypertension[c]	5%	4%

[a] Includes abdominal pain, abdominal pain upper, abdominal pain lower, gastrointestinal pain and abdominal tenderness.

[b] Includes gamma-glutamyltransferase increased, hepatic enzyme increased, alanine aminotransferase increased, aspartate aminotransferase increased, hepatic function abnormal, liver function test abnormal, transaminase increased, blood alkaline phosphatase-increased, alanine aminotransferase abnormal, aspartate aminotransferase abnormal, and gamma-glutamyltransferase abnormal.

[c] Includes hypertension, blood pressure increased, hypertensive crisis, and hypertensive cardiomyopathy.

In addition, hypothyroidism was reported in patients treated with OFEV, more than placebo (1.1% vs. 0.6%).

DRUG INTERACTIONS: P-glycoprotein (P-gp) and CYP3A4 Inhibitors and Inducers: Nintedanib is a substrate of P-gp and, to a minor extent, CYP3A4. Coadministration with oral doses of a P-gp and CYP3A4 inhibitor, ketoconazole, increased exposure to nintedanib by 60%. Concomitant use of P-gp and CYP3A4 inhibitors (e.g., erythromycin) with OFEV may increase exposure to nintedanib. In such cases, patients should be monitored closely for tolerability of OFEV. Management of adverse reactions may require interruption, dose reduction, or discontinuation of therapy with OFEV. Coadministration with oral doses of a P-gp and CYP3A4 inducer, rifampicin, decreased exp sure to nintedanib by 50%. Concomitant use of P-gp and CYP3A4 inducers (e.g., carbamazepine, phenytoin, and St. John's wort) with OFEV should be avoided as these drugs may decrease exposure to nintedanib. **Anticoagulants:** Nintedanib is a VEGFR inhibitor, and may increase the risk of bleeding. Monitor patients on full anticoagulation therapy closely for bleeding and adjust

anticoagulation treatment as necessary *[see Warnings and Precautions]*.

USE IN SPECIFIC POPULATIONS: Pregnancy: *Pregnancy Category D. [See Warnings and Precautions]:* OFEV (nintedanib) can cause fetal harm when administered to a pregnant woman. If OFEV is used during pregnancy, or if the patient becomes pregnant while taking OFEV, the patient should be apprised of the potential hazard to a fetus. Women of childbearing potential should be advised to avoid becoming pregnant while receiving treatment with OFEV. In animal reproduction toxicity studies, nintedanib caused embryofetal deaths and teratogenic effects in rats and rabbits at less than and approximately 5 times the maximum recommended human dose (MRHD) in adults (on a plasma AUC basis at maternal oral doses of 2.5 and 15 mg/kg/day in rats and rabbits, respectively). Malformations included abnormalities in the vasculature, urogenital, and skeletal systems. Vasculature anomalies included missing or additional major blood vessels. Skeletal anomalies included abnormalities in the thoracic, lumbar, and caudal vertebrae (e.g., hemivertebra, missing, or asymmetrically ossified), ribs (bifid or fused), and sternebrae (fused, split, or unilaterally ossified). In some fetuses, organs in the urogenital system were missing. In rabbits, a significant change in sex ratio was observed in fetuses (female:male ratio of approximately 71%:29%) at approximately 15 times the MRHD in adults (on an AUC basis at a maternal oral dose of 60 mg/kg/day). Nintedanib decreased post-natal viability of rat pups during the first 4 post-natal days when dams were exposed to less than the MRHD (on an AUC basis at a maternal oral dose of 10 mg/kg/day). **Nursing Mothers:** Nintedanib and/or its metabolites are excreted into the milk of lactating rats. Milk and plasma of lactating rats have similar concentrations of nintedanib and its metabolites. Excretion of nintedanib and/or its metabolites into human milk is probable. There are no human studies that have investigated the effects of OFEV on breast-fed infants. Because of the potential for serious adverse reactions in nursing infants from OFEV, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. **Pediatric Use:** Safety and effectiveness in pediatric patients have not been established. **Geriatric Use:** Of the total number of subjects in phase 2 and 3 clinical studies of OFEV, 60.8% were 65 and over, while 16.3% were 75 and over. In phase 3 studies, no overall differences in effectiveness were observed between subjects who were 65 and over and younger subjects; no overall differences in safety were observed between subjects who were 65 and over or 75 and over and younger subjects, but greater sensitivity of some older individuals cannot be ruled out. **Hepatic Impairment:** Nintedanib is predominantly eliminated via biliary/fecal excretion (>90%). No dedicated pharmacokinetic (PK) study was performed in patients with hepatic impairment. Monitor for adverse reactions and consider dose modification or discontinuation of OFEV (nintedanib) as needed for patients with mild hepatic impairment (Child Pugh A). The safety and efficacy of nintedanib has not been investigated in patients with hepatic impairment classified as Child Pugh B or C. Therefore, treatment of patients with moderate (Child Pugh B) and severe (Child Pugh C) hepatic impairment with OFEV is not recommended *[see Warnings and Precautions]*. **Renal Impairment:** Based on a single-dose study, less than 1% of the total dose of nintedanib is excreted via the kidney. Adjustment of the starting dose in patients with mild to moderate renal impairment is not required. The safety, efficacy, and pharmacokinetics of nintedanib have not been studied in patients with severe renal impairment (<30 mL/min CrCl) and end-stage renal disease. **Smokers:** Smoking was associated with decreased exposure to OFEV, which may alter the efficacy profile of OFEV. Encourage patients to stop smoking prior to treatment with OFEV and to avoid smoking when using OFEV.

OVERDOSAGE: In the trials, one patient was inadvertently exposed to a dose of 600 mg daily for a total of 21 days. A non-serious adverse event (nasopharyngitis) occurred and resolved during the period of incorrect dosing, with no onset of other reported events. Overdose was also reported in two patients in oncology studies who were exposed to a maximum of 600 mg twice daily for up to 8 days. Adverse events reported were consistent with the existing safety profile of OFEV. Both patients recovered. In case of overdose, interrupt treatment and initiate general supportive measures as appropriate.

PATIENT COUNSELING INFORMATION: *Advise the patient to read the FDA-approved patient labeling (Patient Information).* Liver Enzyme and Bilirubin Elevations: Advise patients that they will need to undergo liver function testing periodically. Advise patients to immediately report any symptoms of a liver problem (e.g., skin or the whites of eyes turn yellow, urine turns dark or brown (tea colored), pain on the right side of stomach, bleed or bruise more easily than normal, lethargy) *[see Warnings and Precautions]*. Gastrointestinal Disorders: Inform patients that gastrointestinal disorders such as diarrhea, nausea, and vomiting were the most commonly reported gastrointestinal events occurring in patients who received OFEV (nintedanib). Advise patients that their healthcare provider may recommend hydration, antidiarrheal medications (e.g., loperamide), or anti-emetic medications to treat these side effects. Temporary dosage reductions or discontinuations may be required. Instruct patients to contact their healthcare provider at the first signs of diarrhea or for any severe or persistent diarrhea, nausea, or vomiting *[see Warnings and Precautions and Adverse Reactions]*. Pregnancy: Counsel patients on pregnancy planning and prevention. Advise females of childbearing potential of the potential hazard to a fetus and to avoid becoming pregnant while receiving treatment with OFEV. Advise females of childbearing potential to use adequate contraception during treatment, and for at least 3 months after taking the last dose of OFEV. Advise female patients to notify their doctor if they become pregnant during therapy with OFEV *[see Warnings and Precautions and Use in Specific Populations]*. Arterial Thromboembolic Events: Advise patients about the signs and symptoms of acute myocardial ischemia and other arterial thromboembolic events and the urgency to seek immediate medical care for these conditions *[see Warnings and Precautions]*. Risk of Bleeding: Bleeding events have been reported. Advise patients to report unusual bleeding *[see Warnings and Precautions]*. Gastrointestinal Perforation: Serious gastrointestinal perforation events have been reported. Advise patients to report signs and symptoms of gastrointestinal perforation *[see Warnings and Precautions]*. Nursing Mothers: Advise patients to discontinue nursing while taking OFEV or discontinue OFEV while nursing *[see Use in Specific Populations]*. Smokers: Encourage patients to stop smoking prior to treatment with OFEV and to avoid smoking when using with OFEV. Administration: Instruct patients to swallow OFEV capsules whole with liquid and not to chew or crush the capsules due to the bitter taste. Advise patients to not make up for a missed dose *[see Dosage and Administration]*.

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HOSPITAL RATINGS: ADVANCING OR OBSCURING CHOICES?

Consumers need to "look under the hood"

by **BARBARA L. HESSELGRAVE**

From televisions to toasters and pizza to plumbers, ratings have been the collective pulse of consumer satisfaction for product or service-buying decisions. Only recently, however, has healthcare joined the fray.

Now, multi-media promotion on billboards, bus posters, direct mail and more feature splashy headlines of local hospitals as "Ranked Highest," "Rated #1," or "Best Rated in Specialty." Sounds like good marketing, but does it help the consumer?

In the recent article, "National Hospital Ratings Systems Share Few Common Scores and May Generate Confusion Instead of Clarity," *Health Affairs*, March, 2015, authors took ratings to task and examined four national hospital ratings systems:

- **"Best Hospitals" from U.S. News and World Report,**
- **"America's Top 100 Hospitals" from Healthgrades,**
- **"Annual Hospital Survey" from Leapfrog Group, and**
- **Hospital ratings provided by Consumer Reports.**

With the exception of *Consumer Reports,* ratings research and publication is self-financed by the respective groups, and hospitals are permitted to use the results in their marketing and advertising.


AUSTIN

Lead study author J. Matt Austin, M.S., Ph.D., assistant professor at the Armstrong Institute for Patient Safety and Quality at Johns Hopkins Medicine, explains the study incentive. "There were a growing number of consumer-directed hospital ratings and we were curious to understand how much agreement there was across these systems—is there a consistency in rating? We were interested in what was the disagreement or agreement."

Austin says the study found differences in the top performers' definition. "Leapfrog Group uses an A,B,C,D hospital score; Healthgrades has 'America's Top 50 and 100 Hospitals', *U.S. News & World Report* has an honor roll," says Austin. "*Consumer Reports* doesn't necessarily have high or low performers, but uses a hospital safety rating system which includes proprietary and outside public rating data.

"One of the more interesting findings," says Austin, "is in the case of 27 hospitals that were found high on one rating system, [but] were low on another. So what does that say? It seems that every hospital has bright spots and opportunities for improvement."

With the exception of *Consumer Reports*, which only makes its information available to paid subscribers, the others are publicly available online.

Comparing apples to pineapples

While the Affordable Care Act (ACA) has brought millions under the umbrella of coverage, Austin says the current and growing number of patients in high-deductible health plans "puts the onus on consumers to become savvy purchasers. They are purchasing expensive services out-of-pocket and they really do need information on quality and safety."

Austin is heartened by recent emphasis on paying for the value of care, rather than simply volume. "We're now moving toward value and volume, and away from volume alone."

But can consumers discern value when ratings appear conflicted? Evan Marks, chief strategy officer of Healthgrades, agrees that the differences between survey instruments can be confusing to consumers, but he asks, "Why would they all point to the same thing?


MARKS

"Let's take car ratings as an example. The Safety and Transportation Board are going to review cars on test crash statistics; *Car & Driver* tests cars on road

feel and handling; and *Motorweek* tests on costs and reliability. But if we line up each best-rated car, we're going to have three different sets of cars, not one. The same thing is happening here, so yes, the report is correct in that people are confused."

Marks explain that Healthgrades develops "America's Best 50 and 100 Hospitals" by evaluating data from multiple sources for all 4,500 licensed hospitals in the U.S. That includes data from 17 all-payer states, the U.S. Centers for Medicare and Medicaid Services (CMS), other third party public data, consumers, and facilities themselves. Facilities that decline to participate are noted as a non-responder facility.

Using the Agency for Health Quality and Research (AHRQ) software technology, Marks says they integrate this data and adjust for risk to create statistically-valid reports. The "Top 100" reflects patient safety, patient-year experience in specific domains like surgery or a disease, clinic mortality, complications, and statistically significant better or worse outcomes. Marks says all of their methodologies are available online at Healthgrades.com, which he boasts logs more than a million visits a day, and thirty million visits a month—"Twenty times more than CMS."

Marks says the current driver of transparency and ratings popularity "is our current system of health delivery with high deductibles and [the] effects of the Affordable Care Act.

"Other factors driving this 'need to know' is that today, people are very mobile. The docs are going to different systems as a result of the ACA, allegiances are changing, everyone is moving, looking and comparing."

The result, says Marks, is "an explosion in need for consumers to have access to help them differentiate hospitals; in what they do, and what they specialize and excel in." And the Internet is the galvanizing link to make it all accessible, he summarizes.

Disparity Is No Surprise

Like Marks, study author Robert M. Wachter, M.D., professor and associate chair in the Department of Medicine at the University of California, San Francisco, is similarly not surprised that the study found disparity among the four systems' ratings for the same facility.

"In some ways, it's the old story: you perceive the totality on the part of the animal you're looking at. Four different systems are looking at hospitals four different ways, with four different core questions."

Wachter says that the web is "democratizing" the information, but adds that searching for health service is very different from searching for a reliable washing machine.

"People have an urgency and an anxiety in this pursuit—you don't search for healthcare unless you need it. So, there is a level of complexity here that ratings can help. You may partly trust an online consumer survey format, like Yelp, but you may want some validation from a reasonable set of criteria so that the rating is not just what people felt like when they walked in the door."

Ratings, says Wachter, must provide information that is truly useful for patient decision-making. "We all want to know specifics—is the surgeon technically good? How good are they [physicians, hospitals] in treating Lupus? This goes beyond the view of any individual patient. Any kind of rating needs to blend things that are similar domains."

Wachter notes that "adjusting for how sick people are when they are admitted" and whether "a hospital adjusts for preexisting factors," for example, can lead to different outcomes which can affect overall ratings.

But the ratings process, he asserts, is still very much in a learning curve. "People might have expected a 'good place' gets it all right…[but] in healthcare, no place is that good—yet; and quality and patient experience also says something about the measures. We're at an early stage using public data."

Bar charts for easy comparison

Leah Binder, chief executive officer of Washington, D.C.-based Leapfrog Group, says their system focuses primarily on patient safety.

"Hospitals are extremely complex; as a patient you need to know a lot of different information before you walk in the door. Patients should look at hospital safety, errors and accidents."

BINDER

However, Binder adds, "Our market research finds that consumers don't know what safety is."

Binder explains Leapfrog is highly transparent; they report not only a letter grade for their hospital review but also publish the methodology and the origin of the data for all 28 measures the survey team analyzes annually. Site users can access a see-at-a-glance bar chart for comparisons of hospitals in several domains. The charts denote the facility's level in meeting Leapfrog safety standards, with links to details on what the individual standards are and how they are derived. If a facility fails

to respond, the non-response is noted.

"We pilot-test our survey with hospitals, we make every effort to be aligned with the AHRQ's principles of the National Quality Strategy (NQS), the Joint Commission and CMS—we have a very intensive scientific review," says Binder.

The Internet is one piece "turning patients into consumers," seeking ratings, but Binder echoes Marks in that, "the biggest influence is high deductible health plans.

"This is a fast-growing phenomena. Sixty percent of insured now have some form of high deductible, so basically [the cost of] more and more direct care is being shouldered by the consumer."

> In some ways, it's the same old story: you perceive the totality on the part of the animal you're looking at.
>
> —ROBERT M. WACHTER, M.D.

She cautions that ratings are not a one-size-fits-all assessment. "Some hospitals have excellent cardiac care, but have challenged OB units. You need a certain kind of rating, and more than just one rating. Consumers need to look at what they do want—quality nursing care, specialty expertise—and what they don't want, such as accident or infections.

"It is a positive thing that there are so many rating systems," she adds, "but much room for proficiency. We are nowhere close to where we need to be—our markets say they want more and they deserve more."

CMS' compare website

Consumers also have another tool at their disposal: the CMS Hospital Compare website (www.hospitalcompare.hhs.gov). Created in partnership with the Hospital Quality Alliance (HQA), the site began publishing core measures of care in 2005, adding data from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS)

"There is definitely value in multiple perspectives on quality and safety."

—J. MATT AUSTIN, M.S., PH.D.

survey in 2008. Hospital outpatient data including imaging efficiency data, emergency department and surgical care processes, was incorporated in 2009; 30-day readmissions statistics for heart attack, heart failure and pneumonia patients were added in 2010; and data from the CMS readmission reduction program along with hospital-submitted data from the American College of Surgeons National Surgical Quality Improvement Program was added in 2012. Recent additions are HCAHPS care transition data, outcomes data for chronic obstructive pulmonary disease and strokes, and Prospective Payment System-exempt cancer hospital measures data.

The classic case of Caveat Emptor

As the ratings process evolves to encompass more data and increase transparency, stakeholders agree that consumers wield the buying power. But, says Austin, consumers also have to do their homework.

"One of the recommendations we would offer is for consumers to really look under the hood a bit more. It falls upon the consumer to understand what is being measured—is it aligned with your values? You have to look at safety issues, best medical centers, and the facilities need to be tailored to the patient needs.

"I think the readers have to look at each rating system, and what is being measured to be informed, what the rating represents. There is definitely value in multiple perspectives on quality and safety."

Barbara L. Hesselgrave is a freelance writer in Baltimore, Maryland.

Publisher	Hospital Survey product	Audience	Data Source(s)	Eligibility/Current Sample size	Distribution channels
U.S. News and World Report	Best Hospitals	Subscribers, online consumers	U.S. News reputational survey; government agencies.	Eligibility limited to 1,928 hospitals	U.S. News and World Report website; health.usnews.com/best-hospitals/rankings
Healthgrades	America's Top 50 and 100 Hospitals	Online consumers	Government agencies, third party public data, consumers, and facilities.	Nearly 4,500 hospitals	Healthgrades website: healthgrades.com
Leapfrog Group	Annual Hospital Survey and Hospital Safety Score	Online consumers	Leapfrog Hospital Survey; government agencies, third party public data.	Eligibility limited to 1,500 hospitals	Leapfrog website: hospitalsafetyscore.org
Consumer Reports	Health Safety Score	Subscribers	Government agencies; independent sources.	Eligibility limited to 1,159 hospitals	Consumer Reports print publication, and website: consumerreports.org/health/doctors-hospitals/hospital-ratings.htm
Centers for Medicare and Medicaid Services (CMS)	Hospital Compare website	Online consumers	CART tool; CASPER system; HCAHPS survey; CDC; National Healthcare Safety Network; Medicare enrollment and claims data; American College of Surgeons National Surgical Quality Improvement program.	4,000+ hospitals	Hospital Compare website: hospitalcompare.hhs.gov

THE FUTURE OF PUBLIC AND PRIVATE EXCHANGES

E-commerce is driving change

by **KAREN APPOLD**

Change has proliferated how health insurance is offered in recent years, and experts predict that private exchanges will now seek to emulate the e-commerce format that public exchanges have embraced.

Public exchanges—such as HealthCare.gov and state exchanges—are the sanctioned websites where residents can get guaranteed issue and community-rated health plans with assistance from the federal government if they qualify for subsidies, explains Devon M. Herrick, PhD, senior fellow and health economist, National Center for Policy Analysis, Dallas, Texas.


HERRICK

Private exchanges, on the other hand, are owned and operated by private sector companies—such as health insurance companies, brokers, or consulting firms. Individuals, small and large groups, and retirees can purchase health insurance through a private exchange, notes Jonathan Rickert, chief executive officer and co-founder, Array Health, Seattle, Washington.

"Employers are quoted a price for various options, and their employees can choose among competing options within the private exchange," Herrick says. This type of private exchange is generally a defined contribution plan, with the exchange administrator underwriting a price for an employer plan.


RICKERT

While private exchanges have been around for some time, it was the advent of the Affordable Care Act (ACA) that spotlighted the concept of online marketplaces as a place to purchase health insurance.

Looking ahead, Rickert sees an enormous opportunity in the coming years to extend an e-commerce business model to health insurance through private exchanges. "Private exchanges will close the gap between consumers and insurers and allow insurers to embrace the consumer-centric world we live in," he says. "Just as other industries use multi-channel approaches, health insurers will also adopt multi-channel strategies and will offer their products on both single and multi-insurer platforms."

The early health insurance exchanges, introduced in the late 1990s, only addressed the individual market, which is a small sliver of the overall market. "Almost 90% of Americans have health coverage through either their employers, Medicaid, or Medicare," Rickert says. "While online shopping and enrolling for health insurance isn't a new concept, applying an e-commerce approach to employer-sponsored health insurance is."

Other types of private exchanges have also emerged as a way to allow large employers or groups of small employers to band together and allow workers to select the coverage of their choice. "It is part of the movement to define contribution in employee benefits," Herrick says.

The Status Quo

More than 2.5 million individuals enrolled in health insurance through a private exchange in 2014, according to the recent Kaiser Family Foundation's (KFF) report, "Examining Private Exchanges in the Employer-Sponsored Insurance Market. KFF's research found that 20% to 33% of employers will adopt a private exchange approach over the next three to five years.

Rickert notes that "the future looks bright" for private exchanges. Array Health conducted a survey of health insurers in 2014, and more than 75% of respondents said they believed that most health insurers will offer single-insurer exchanges by the end of 2016.

"There are many reasons for the

optimism," Rickert says. "Single-insurer private exchanges are now offering a breadth of choice through various contribution models—defined contribution, defined benefit, and combinations of the two—as well as a robust array of ancillary insurance options."

Herrick reports a trend in employers reducing part-time workers' hours and shifting some full-time workers to part-time. "While it's too early to tell, I expect more small firms to drop coverage entirely because they will not be fined for not providing health insurance," he says. "Over the next few years, I also expect more restructuring to occur."

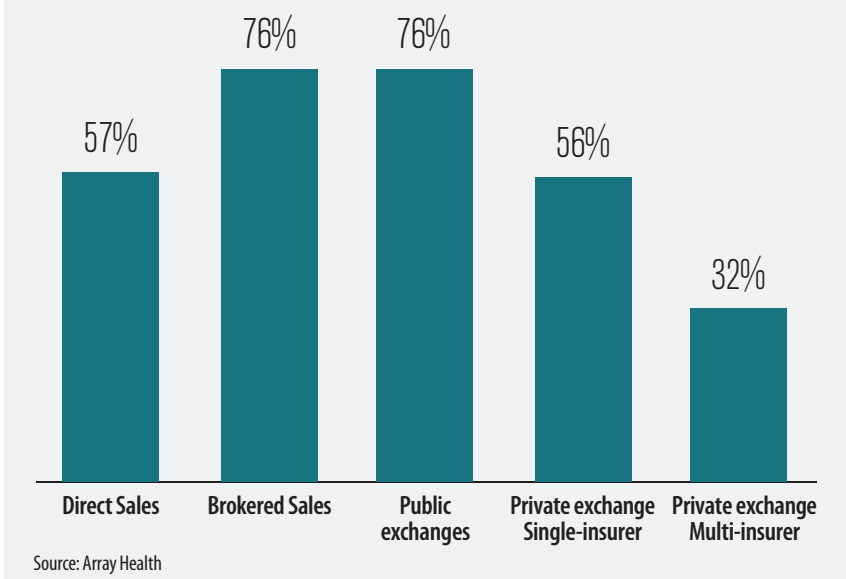
Large employers that employ low-wage workers (e.g., hotels with housekeeping staffs) will lease custodial workers rather than employ them. The firms they lease from would likely be small firms that are not required to offer coverage. The workers would be free to get subsidized coverage in the exchange.

According to James R. Smith, FACHE, senior vice president, The Camden Group, Rochester, New York, with private exchanges many employers are seeing an advantage in meeting their compliance requirements under the ACA while capping their cost at a certain dollar amount and giving their employees more options and the ability to purchase insurance through a private exchange. "Employees may be advantaged by either greater coverage options or multiple insurance company options," he says.


SMITH

"On the downside, employees will have to make more decisions regarding what services to seek and how to pay for their share of a larger deductible plan." To help, many employers are paying health plans or other companies to have health navigators assist their employees in helping them to find the best value for their health and healthcare needs. This is driving a greater need for transparency of price, quality, and service.

Smith predicts that private exchange use will grow for both small and large employers as many employers move to a defined contribution strategy to cap their healthcare expenses and comply with the law. "More people will have high-deductible plans and may struggle to maintain their health and their personal solvency," he says.



An Unstable Future

In July, the US Supreme Court will rule on whether providing subsidies for health insurance is constitutional. "If it rules that subsidies aren't allowed, then you will see an affordability issue and some people will discontinue their insurance with the exception of those people with chronic conditions," says Paul Fronstin, PhD, director, Health Research and Education Program, Employee Benefit Research Institute, Washington, DC. "So rates will increase, because the healthier people dropped out. There will be a cycle of instability."


FRONSTIN

Karen Appold is a freelance writer in Lehigh Valley, Pennsylvania.

HUMANA'S PROVIDER TOOLS AID VALUE-BASED CARE

Platforms offer population health strategies

by **TRACEY WALKER**

As the Medicare program and the healthcare industry at large begins the transition from fee-for-service to value-based reimbursement models, health plans are responding by ramping up collaboration with providers to improve health outcomes, especially for medically-complex Medicare members.

At the same time, healthcare systems are often challenged to integrate both interoperability and analytics components into their population health management strategies.

Enter: Humana's formation of Transcend and Transcend Insights to serve as partners for healthcare systems, physicians and care teams, regardless of where they are in their population health journeys.

Transcend is a population health management company that meets doctors where they are on the path to practicing value-based medicine, according to Humana. It collaborates with physicians, medical groups and integrated delivery systems to make the transition to value-based care by engaging, partnering and offering practical services and solutions. It builds on Humana's experience with specialty network care management, pharmacy management, clinical studies, and implementation and training.

"The launch of Transcend and Transcend Insights is reflective of Humana's goal to improve the health of the communities we serve by making it easy for people to achieve their best health," said Bruce Broussard, Humana's president and chief executive officer. "Transcend and Transcend Insights reflect the continued evolution of Humana's Integrated Care Delivery model. As physicians continue on their population health journeys, Transcend and Transcend Insights are strategically positioned to serve as their trusted partners while meeting their evolving population health needs."

"Moving more physicians towards value-based payment models is a proven strategy that increases clinical quality and patient satisfaction, and reduces medical costs," said Patrick Adams, president of Transcend. "Through our first-hand knowledge in implementing successful integrated care solutions and proactive patient engagement strategies that support positive outcomes, Transcend is strategically positioned to help physicians spend more time with their patients and less time on the behind-the-scenes elements of population health."

Transcend Insights is an integration of the insurer's subsidiaries Certify Data, Anvita Health and nliven systems. According to the company, it simplifies the complexities of

"Moving more physicians towards value-based payment models...increases clinical quality and patient satisfaction, and reduces medical costs."

—PATRICK ADAMS, PRESIDENT, TRANSCEND

"Transcend and Transcend Insights reflect the continued evolution of Humana's Integrated Care Delivery model."

—BRUCE BROUSSARD, PRESIDENT AND CEO, HUMANA

population health in three main ways:

- **Through advanced community-wide interoperability;**
- **Real-time healthcare analytics, and**
- **Intuitive care tools.**

Transcend Insight's HealthLogix platform provides healthcare systems, physicians and care teams with real-time clinical insights that help improve the health of the populations they serve. This leads to a higher level of patient care and lower costs.

"In order for healthcare organizations to tap into the transformative power of value-based payment models, we have to collaborate with physicians and care teams by engaging, partnering and offering practical services and solutions," says Marc Willard, president of Transcend Insights and founder and former chief executive officer of Certify.

"Last year we identified 36 million opportunities for care improvement and helped physicians close gaps in care."

—MARC WILLARD, PRESIDENT, TRANSCEND INSIGHTS

"We collect, normalize and analyze the data and give doctors and care teams the real-time clinical insights they need to care for their patients," Willard adds.

Willard says Transcend Insight's focus is helping close care gaps. "We present the information at the point of care in a way that is intuitive to doctors. Last year we identified 36 million opportunities for care improvement and helped physicians close gaps in care."

"Payers are working hard to find ways...to add value to their traditional role as insurers."

—MARTY HAUSER, PARTNER, CHANDLER GROUP AND FORMER CEO OF SUMMACARE

Value shift driving population health tools

Given the national focus on healthcare transformation through population health, Marty Hauser, partner, Chandler Group, and former chief executive officer of SummaCare, Akron, Ohio, believes that these types of programs will continue to evolve "and be developed by all carriers including the regional provider sponsored plans because of the need to support behavioral changes with 'actionable data' and support of the care delivery system.

"In addition, I would suspect that the payers are working hard to find ways through programs like this to add value to their traditional role as insurers," says Hauser.

"One of the challenges as we see the industry evolve to these types of models and expanded services will be the ability of the providers, especially physician practices, to understand and manage the often-differing programs and approaches of the payers," notes Hauser.

"As we learned in the past with pre-certification and pre-authorization lists and protocols, it is very difficult for physicians and their offices to implement and adapt a different process and data requirement for each payer.

"If you were to speak with physicians I would suspect that they would be supportive of these types of tools and support systems but express concern about the lack of 'industry standards' with every plan potentially developing their own programs. It ultimately goes back to the concept of creating actionable data and processes that are consistent, standard, and easy to follow and implement if providers are going to use them."

Humana's goal is to have 75% of its individual Medicare Advantage members covered under value-based relationships by 2017. ■

Tracey Walker is content channel manager for Managed Healthcare Executive.

MORE INSIDE

Read about Humana's plans to tie 75% of its Medicare Advantage payments to value-based models by the end of 2017, page 6.

340B DRUG PROGRAM CAUSING CONTROVERSY

Program for needy patients not always used as intended

by **MARI EDLIN**

The Affordable Care Act (ACA) has thrown the 340B Drug Discount Program into the limelight. Many industry leaders agree that the advent of the healthcare law, which has added more eligible hospitals to the program, plays a large part in the current controversy over 340B.

Overseen by the Health Resources and Services Administration (HRSA), the program enables safety net healthcare organizations serving uninsured, vulnerable and indigent populations to purchase outpatient prescription drugs at a discount. The program generates 25% to 50% savings for participating hospitals.

To put the size of the program into perspective, the U.S. Department of Health and Human Services (HHS) reported that in 2012, 340B sales totaled $6.9 billion. Apexus, a nonprofit selected by HRSA to consolidate contracting and manage the distribution process for covered entities, estimated that 340B purchases in 2013 were $7.5 billion, or a 2.3% share of the U.S. prescription drug market.

A brief history

Introduced in 1992, the federal program has only been tweaked a few times, but now it faces a major overhaul if many in the healthcare industry have their way.

In 1996, HRSA made it possible for participating organizations to contract with outside pharmacies if they did not have their own. But the floodgates opened in 2010, when covered entities (participating safety net hospitals) were allowed to contract with multiple pharmacies.

In 2013, HRSA published a legislative rule prohibiting newly-eligible covered entities from purchasing orphan drugs at a discounted rate unless the drugs are being used for different conditions than those for which the orphan drugs received their status.

In October 2014, the Pharmaceutical Research and Manufacturers of America (PhRMA) reacted by filing a lawsuit in Washington D.C.'s District Court challenging HRSA's interpretation and arguing that Congress never afforded HRSA the power to issue such a regulation.

Venson Wallin, managing director, BDO Center for Healthcare Excellence and Innovation, says the lawsuit puts PhRMA in a Catch 22 situation: On one hand, manufacturers want HRSA to provide specific guidance, yet it is suing the agency on the grounds that HRSA doesn't have the authority to make decisions concerning orphan drugs.

On November 13, 2014, HRSA withdrew its anticipated "mega-reg" that would have provided clarity on some of the issues raised by entities affected by the regulation—defining the patient population and hospital eligibility and outlining compliance for contract pharmacies. It intends to address these and other issues this summer.

WALLIN

What's the gripe?

A November 2014 health policy brief from *Health Affairs* outlines some of the issues:

- **Lack of sufficient oversight and management.**
- **Potential undue benefit for participating hospitals.**
- **Diversion, when a 340B drug is given to an ineligible patient or resold by a covered entity.**
- **Duplicate discounts when a covered entity receives a 340B discount and a Medicaid drug rebate from the same manufacturer for the same drug. Not enough oversight to prevent this unintentional practice.**
- **Clear definition of eligible enrollees (whether 340B enrollees need to be uninsured).**
- **Insufficient scrutiny of multiple contract pharmacies.**

- **Scope of program beyond its original intention.**

Covered entities are statutorily prohibited from both diversion and duplicate discounts. "Neither are a widespread practice and due to misinterpretation; they also are not fraud," Wallin says.

Although some 340B issues under scrutiny have drawn battle lines among covered entities, insurers, pharmaceutical companies and pharmacies, for the most part, these constituencies agree the current regulation is filled with ambiguity. However, some of these entities are pointing fingers at each other.

Who really benefits from 340B?

Wallin says that 340B provides a great benefit for hospitals serving safety net populations and enables them to use savings on services that otherwise might be unavailable because of a lack of funding.

On the other hand, he notes that pharmaceutical manufacturers and the government believe that larger health systems may be using funds for growing their businesses rather than for providing programs to low-income patients. While Wallin does not think the practice is intentional, it could happen because the regulation has opened itself up to interpretation.

Wallin also says that manufacturers do not trust covered entities' record keeping to distinguish between their Medicaid patients and those eligible for 340B.

As for insurers, he says they do not want to see 340B disappear because it enables hospitals to negotiate lower drug prices costing payers less money to provide care to their members.

Sally Pipes, president and chief executive officer of Pacific Research Institute, a think-tank based in San Francisco, is not quite as optimistic about 340B as Wallin. She would like to see the program discontinued because it costs taxpayers money. She admits, however, that if revised, 340B could offer some benefit to those the program was designed to help.


PIPES

She points a finger at hospitals, saying they are benefitting from the program by purchasing drugs at a discount but selling them at full cost to patients because they do not have to pass along discounts to vulnerable patients.

An investigation by the Raleigh, North Carolina-based *News & Observer* found that several large local hospitals sold chemotherapy drugs discounted by 20% to 50% at up to 10 times the cost, according to Pipes.

She also believes that contract pharmacies are making money at the expense of the program. Walgreens, she says, is expected to make a quarter of a billion dollars off the program over the next five years due to a lack of oversight.

"If anyone thinks these hospitals are taking advantage of the discounts, then where is the money?" asks Randy Barrett, vice president, communications for Safety Net Hospitals for Pharmaceutical Access, a trade association of 1,000 hospitals in the 340B program. "Many of the hospitals in the program are running on thin margins with even thinner ones for rural hospitals."

Barrett says HRSA developed the program with the intent of helping low-income patients have better access to necessary medications. "It would be disastrous for communities if they could not take advantage of the lower pricing and could cause clinics to close and a panoply of services to vanish," he says.


BARRETT

The gray areas in the regulation bother Barrett and the members of his organization. He looks forward to clarification from HRSA this summer.

PhRMA takes a stand

Although PhRMA cannot comment on the ongoing litigation in the orphan drug lawsuit, in a statement last October it confirmed its support of the 340B program while emphasizing that the ACA "expressly exempts manufacturers from having to provide these discounts on orphan drugs to newly eligible providers."

"Unfortunately, over time the 340B program has steadily slipped away from its core mission and while some providers rely on the program to improve access for needy patients, others do not," says Allyson Funk, director, communications, PhRMA.


FUNK

Continued on page 43

Continued from page 36

PhRMA believes that the following areas of the program require reform to bring it back in line with its original intent and ensure uninsured and vulnerable patients are the ones benefitting:

- **Covered entities not always passing 340B discounts onto needy, uninsured patients.**
- **Clearer definition of eligibility criteria for covered entities because program is not always targeting hospitals that serve large number of uninsured and vulnerable populations.**
- **Patient definition dictating whether 340B healthcare providers can receive significant discounts for covered outpatient drugs. HRSA guidance, however, does not currently require that patients receive discounts on these drugs.**
- **Too many multiple pharmacies to properly oversee issues of diversion and duplicate discounts. According to the Berkeley Research Group, there were nearly 30,000 contract pharmacy arrangements at the beginning of 2014.**
- **340B hospitals buying up physician-based oncology practices, driving up Medicare costs and narrowing patient access to community treatment centers.**

According to the Berkeley Research Group, acquisitions have bumped up the volume of chemotherapy claims billed to Medicare—excluding oral chemotherapy drugs—resulting in $196.55 million in additional payments by the Medicare program and Medicare beneficiaries to 86 340B hospitals that acquired private oncology practices.

Concerns grow

The Alliance for Integrity and Reform of 340B (AIR 340B), an ad hoc organization of patient advocacy groups, clinical care providers and biopharmaceutical innovators and distributors, has a desire to preserve 340B and return it to its original intent, says its spokesperson, Stephanie Silverman, "but it came off the rail."

The organization is particularly concerned about the growth in the number of qualifying hospitals in the 340B program and the increases in contract pharmacies.

SILVERMAN

According to HHS' Office of Inspector General, the contract pharmacy program grew by more than 1,000% in three years.

Silverman points to the disproportionate share hospital (DSH) criteria—especially for hospital eligibility—as one of the culprits in the rise in covered entities. It has allowed many hospitals to qualify for the program even though they may not serve a significant number of vulnerable and uninsured patients nor provide enough charity care.

DSH, which is related to the number of inpatient Medicaid and low-income Medicare patients treated at a hospital, can be used as a proxy for identifying hospitals that serve enough indigent patients. It targets large urban hospitals that can demonstrate that more than 30% of their total net inpatient care revenues come from state and local governments for indigent care (other than Medicare or Medicaid).

Although 340B hospitals should provide a certain amount of charity care to qualify, Silverman does not think that hospitals are aligned with Congress' expectations.

According to Avalere Health, charity care provided by about 25% of 340B hospitals represents 1% or less of patient costs, and more than two-thirds of 340B hospitals provide charity care at a rate below the national average of 3.3% for all hospitals.

With the explosion in the number of hospitals and expansion of contract pharmacies, Silverman says oversight has not kept pace.

There also is no indication that vulnerable patients are actually benefitting from the multiple pharmacy rule or receiving improved access to drugs, she says.

"Instead, allowing multiple pharmacies creates disproportionate benefits for the largest retail pharmacies and could lead to more diversion and duplicate Medicaid and 340B discounts for the same drug," Silverman says.

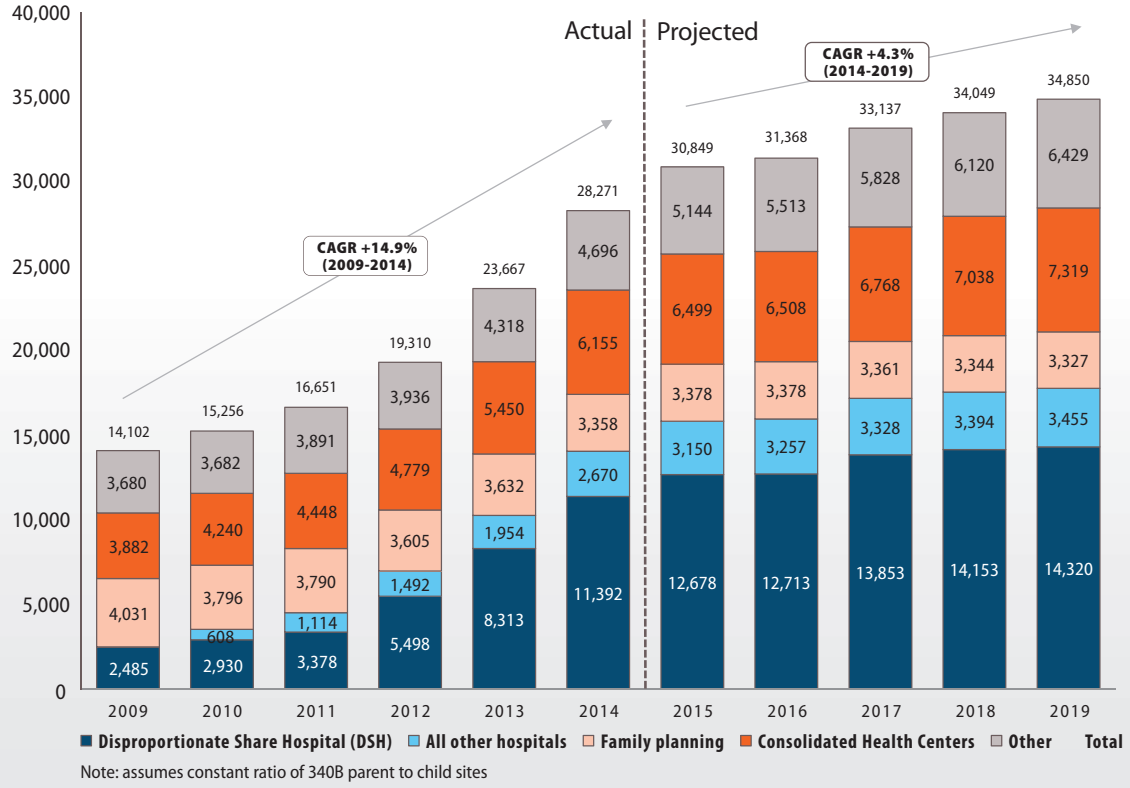
She notes that some of these pharmacies are in mid- and high-income neighborhoods so that they can charge higher prices, a price arbitrage between covered entities and pharmacies.

More to say

The House Energy and Commerce Committee was due to conduct a hearing on 340B on Thursday, March 5, but it was postponed due to a snowstorm.

According to *Congressional Quarterly*, the Medicare Payment Advisory Commission (MedPAC)

TOTAL 340B SITES



Note: assumes constant ratio of 340B parent to child sites

Source: Avalere analysis of HRSA 340B Database. Data extracted March 9, 2015.

plans to discuss the program in its June report to Congress.

HRSA also expressed its intention to address the growing concerns with 340B this summer. PhRMA is optimistic that the planned guidance from HRSA will address some of its concerns, but believes it will take congressional action to truly reform the program.

AIR 340B also has big hopes for changes in the program anticipated this summer: definition of patient eligibility to correspond with the original intent of the rule; more clarity around rules with contract pharmacies; and stricter rules about which covered entities can participate. ■

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

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.

MOBILE HEALTH GOES MAINSTREAM

Industry forges ahead with apps, plans

by **DONNA MARBURY**

While technology used to be an accessory to the healthcare experience, in today's world, it's a requirement. Health plans and providers are working with tech companies to make sure that the digital experience is as smooth and engaging as online shopping.

"We believe that the provider industry has the most to gain from a mobile-first, cloud-first world because, compared to every other industry, providers are more mobile, fragmented, collaborative, and regulated," says Dennis Schmuland, M.D., FAAFP, chief health strategy officer of U.S. Health & Life Sciences for Microsoft Corp., and *Managed Healthcare Executive* editorial advisor. Microsoft is collaborating with Kaiser Permanente and Cognizant to create mobile technology that links patient data with clinicians, with aims of reducing the cost of care.

"Mobile and cloud computing can support every one of those issues better than on-premise devices and software can," Schmuland says.

Consumers are becoming more aware of and open to mobile apps that can help them track their health information. As health plans team up with tech companies to maximize the mobile app experience for patients and providers, they are also harvesting usable data.

"Mobile technology is an important enabler toward the vision of members being able to manage their health when, where, and how they want," says Tom Olenzak, director of Innovation at Independence Blue Cross. Independence and Penn Medicine has partnered with DreamIt Health, a health tech startup, since 2013. The collaboration has developed 19 companies that are creating innovative digital health solutions.

"That being said, mobile is an important tool, but we need to recognize that it is a means to the end of developing more effective and efficient care, not an end in and of itself," Olenzak says.

Growth of mobile apps

There are more than 100,000 Android and iOS health apps, a number that has doubled in 2.5 years, according to the 2014 research2guidance mHealth App Developer survey. Thirty-one percent of those apps manage chronic illness, and 28% track health and fitness.

A recent survey suggests that health plan members who use apps are more satisfied with their providers. Patients who communicated with their health plans were happier with services compared with those who communicated over the phone, according to a survey of more than 30,000 health plan members by J.D. Power. Of all the health plans studied, Kaiser Permanente, which has more than 1 million downloads, topped satisfaction ratings.

"Health plans need to take a more customer-centric approach and keep their members engaged through regular communications about programs and services available through their plan. When members perceive their plan as a trusted health partner, there is a positive impact on

"Mobile technology is an important enabler toward the vision of members being able to manage their health when, where and how they want."

—TOM OLENZAK, INDEPENDENCE

loyalty and advocacy," said Rick Johnson, senior director of the healthcare practice at J.D. Power.

Though many health plans have mobile apps that serve as a patient portal, there is huge potential for health plan-run apps to play a bigger role in patients' lives. Mobile apps have been proven to increase patient adherence to prescription drugs, assist patients in establishing personal control over chronic disease management, and help reduce readmissions when patients are prescribed mobile monitoring apps, according to a 2014 whitepaper by MobileSmith. By 2017, it is estimated that 69% of health apps will provide and market healthcare services, including urgent, outpatient and wellness care, according to the research2guidance report.

"The breakthrough opportunities will come with the technology innovations that empower clinicians and consumers, rather than burdening them," Schmuland says. "Technology needs to empower clinicians to work together in patient-centered teams, wherever they are and while on the move, by connecting them not just to information but also to the people, insights and processes they need to do their jobs more efficiently and effectively."

Mainstream recognition

In March, for the first time, the Centers for Disease Control and Prevention acknowledged three digital health platforms that manage the onset of diabetes and lower healthcare costs: Omada Health, Noom Health and DPS Health. And Apple, Inc. recently released ResearchKit, an open-source platform that allows the use of iPhone's GPS system, microphone, accelerometer, and other features to develop secure healthcare and medical apps.

"As the strategy evolves, there are opportunities to start to incorporate elements unique to mobile, for example enabling location-based provider locators," Olenzak says. "Eventually, mobile becomes a part of a plan's member engagement strategy, fully integrated into other channels but also fully utilizing some of the unique features of the mobile platform."

Olenzak says that hundreds of Independence associates and several senior executives have worked on the DreamIt programs to ensure that regulations and patient security are a priority.

"One area we are extremely careful about is that of patient safety and privacy," Olenzak says. "We end up spending a lot of time with these startups helping them understand and comply with all the regulations and standards necessary to protect patient safety and data. It's a big investment, but a necessary one if we are going to experiment with these new ideas."

Third-party websites, excessive mobile app permissions and third-party code libraries used to shorten app development time are the top threats to patient data, according to a December 2014 survey of health insurers by RiskIQ, a digital risk-assessment company.

"New competitive pressures in healthcare are forcing insurance providers to expand their web and mobile self-service assets, which opens up new attack vectors for targeting customers that use them," said Elias Manousos, chief executive officer of RiskIQ.

Schmuland suggests that health plans looking to broaden their digital footprint start small and leverage the economic and speed advantage of the cloud to improve existing technology.

"As health systems move toward continuum-based payment, their workforce must be more mobile, or virtual. And they must find ways to share more and communicate more with external entities with less risk, less complexity and at a lower cost," Schmuland says. "Most healthcare organizations want to reserve the right to public, private, or hybrid cloud operations in addition to, rather than instead of, their on premise operations. They need the reassurance that if at any time they decide to move from the cloud back to on-premise, they can." ◘

"As health systems move toward continuum-based payment, their workforce must be more mobile, or virtual."

—DENNIS SCHMULAND, M.D., FAAFP, MICROSOFT CORP.

Donna Marbury *is a freelance writer in Columbus, Ohio.*

Hep C, compounded meds fuel 13.1% increase in U.S. drug spend

Brand-drug price inflation also remains significant driver

TRACEY WALKER
CONTENT CHANNEL MANAGER

NEW HEPATITIS C therapies with high price tags and the exploitation of loopholes for compounded medications drove a 13.1% increase in U.S. drug spending in 2014—a rate not seen in more than a decade, according to Express Scripts 2014 Drug Trend Report.

Hepatitis C and compounded medications are responsible for more than half of the increase in overall spending. Excluding those two therapy classes, 2014 drug trend (the year-over-year increase in per capita drug spending) was 6.4%.


STETTIN

Specialty medications—biologic and other high-cost treatments for complex conditions, such as multiple sclerosis and cancer—accounted for more than 31% of total drug spending in 2014. As Express Scripts forecasted last year, specialty drug trend more than doubled in 2014, to 30.9%.

Additional key findings:

- **Drug-maker consolidation and drug shortages also led to increases in traditional drug trend, which rose to 6.4% in 2014.**
- **Diabetes remains the leading traditional therapy class for a fourth straight year based on total costs; Express Scripts expects double-digit increases in spend in this class over the next 3 years due to once-weekly oral and injectable drugs in the pipeline.**
- **Cost for medications to treat pain increased 15.7% in 2014, due in part to new tamper-resistant formulations for opiates.**
- **Inflammatory conditions, which include treatments for rheumatoid arthritis and psoriasis, maintained their position as the costliest specialty drug class due to expanded indications and increased prevalence of treatment.**

"Based on these findings, we believe that now, more than ever, plans need to tightly manage the pharmacy benefit, implement smarter formularies, control compounded medication use and offer the right clinical support to ensure all patients are able to achieve the best possible health outcomes at a price our country can afford," says Glen Stettin, M.D,. senior vice president of research and new solutions at Express Scripts.

"Payers who tightly manage their plans are seeing the financial benefits," Stettin says. "More than 15% of Express Scripts' clients spent less, per capita, on prescription drugs in 2014 than in 2013. Closely managed pharmacy plans achieved nearly zero traditional drug trend and spent nearly 30% less per member on traditional medications compared to less managed plans.

"Employers with a tightly managed specialty pharmacy benefit reduced annual specialty drug spend increases by 32% and saw higher average medication adherence rates compared to unmanaged plans," he adds.

COMPOUNDED THERAPIES

Compounded medications emerged in the top 10 traditional therapy classes for the first time ever, according to the report.

"Despite having the lowest prescription volume among traditional therapy classes, compounded medications accounted for 35% of total traditional trend—the most of any traditional therapy class," Stettin says.

The reason for this sudden increase in compounded medication spending is not due to patient demand, according to Stettin.

"Some compounding pharmacies, drug manufacturers and physicians have driven up the cost of compounds significantly by taking advantage of a loophole to pad their pockets while offering little to no benefit to patients," he says. "By charging hundreds or thousands of dollars per gram of bulk powder or cream, certain compounding pharmacies have needlessly driven up the cost of care. As a result, some elements that are used to make compounded medications have been exorbitantly overpriced. Our clients and their members have been paying the price."

BRAND-NAME INFLATION

Brand-drug price inflation remains a significant driver of trend, according to Stettin. "We are pleased that biosimilars are moving forward in the United States, and we are hopeful that their adoption will not be limited by a confusing naming structure or unnecessary state substitution laws."

Although the manufacturer hasn't announced U.S. pricing yet, Express

Scripts anticipates that Zarxio, the first biosimilar approved in the United States will save the U.S. healthcare system $5.7 billion over the next decade. The approval also opens the door for a wave of other biosimilars that will save more than $250 billion for the nation over that same 10-year span, according to Stettin.

The Express Scripts Drug Trend Report examines annual changes in utilization, unit costs and overall prescription drug spending, based on the pharmacy claims data from Express Scripts.

Study finds PCMHs improve cancer screening rates

BCBS of Michigan program lowered costs and improved care

TRACEY WALKER
CONTENT CHANNEL MANAGER

BLUE CROSS Blue Shield of Michigan's (BCBSM) Patient-Centered Medical Home (PCMH) model improved overall cancer screening rates for colon, breast and cervical cancer, according to a study published last month in *JAMA Internal Medicine*.

The three-year longitudinal study reviewed breast, cervical and colon cancer screening rates of 2,218 practices across the state providing care for a wide variety of socioeconomic groups. Researchers set out to find whether improved cancer screening occurred within the PCMH model, and whether the improvement was dependent on the socioeconomic context in which the physician practiced.

"Smaller practices and practices operating in disadvantaged areas face additional challenges that larger, well-funded practices typically don't. So we wanted to see whether the effects of PCMH were uniform across practice environments, or whether the model has differing benefits based on where it is implemented," says David Share, M.D., M.P.H., BCBSM senior vice president for Value Partnerships.

Results showed improved cancer screening rates across all socioeconomic contexts, and the disparity in cancer screening rates among patients in high and low socioeconomic groups significantly narrowed in practices where the PCMH model was fully implemented.

"Executives should take into consideration their population when assessing the potential benefits from a PCMH program."

—DAVID SHARE, M.D., M.P.H., BCBSM
SENIOR VICE PRESIDENT FOR VALUE PARTNERSHIPS

"Because the effects of the PCMH model appear to vary by socioeconomic context, executives should take into consideration their population when assessing the potential benefits from a PCMH program," says Share. "Supporting providers in developing and implementing the Patient-Centered Medical Home model may improve your bottom line as well as improve patient outcomes."

BCBSM's Patient-Centered Medical Home program is the largest of its kind in the nation, and has shown to improve patient health and outcomes. The program achieved certified savings of $155 million in prevented ER and hospital claims from the first three years of the PCMH designation program.

Data from 2013 to 2014 show adult patients in Blue-designated PCMH practices had a 27.5% lower rate of hospital stays for certain conditions than non-designated practices, and a 9.9% lower rate of ER visits over non-PCMH doctors.

THE PCMH MODEL

In the PCMH model, physician-led care teams coordinate and track patients' healthcare including non-clinical factors such as emotional, behavioral and social needs that may influence a person's health. In July 2014, BCBSM announced it designated 1,422 practices, comprised of more than 4,020 physicians, as PCMHs. These practices had made the most progress toward implementing the various capabilities of a PCMH model.

"The impacts of the PCMH model are stronger in areas traditionally disadvantaged under the old system, most likely because of improved access to care with the PCMH model," notes Share. "If adequately resourced, the PCMH model may improve health equity."

Cancer screenings should ideally catch cancers in their earliest, most treatable stages, which improves outcomes, enables cancers to be treated early before major illness or complications set in, and costs less to treat, according to Share. "One of the goals of our PCMH model is to improve preventive care including cancer screenings."

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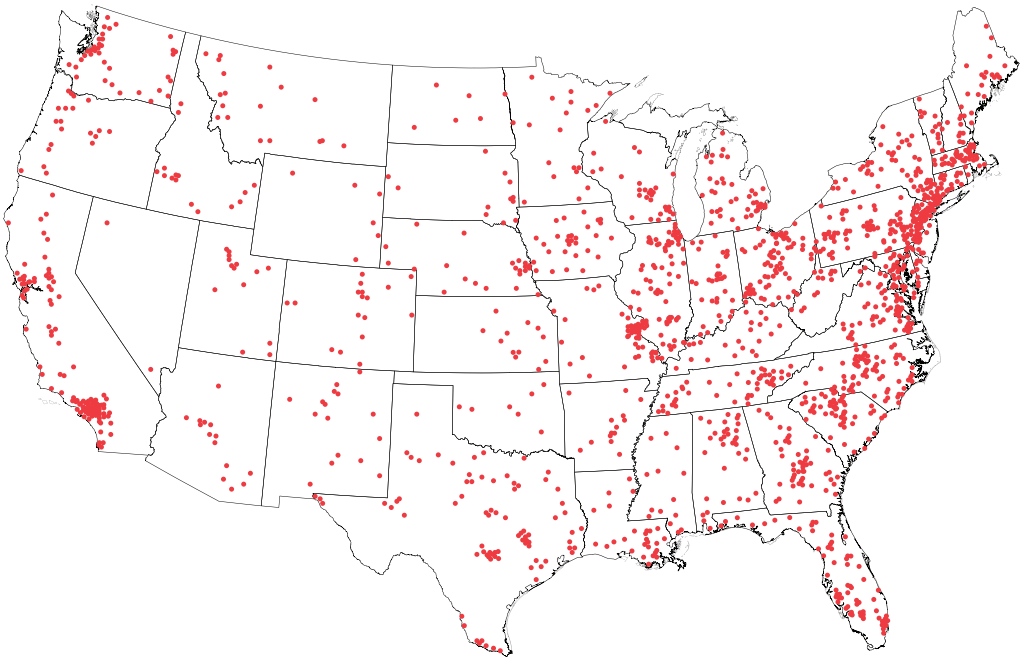

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Across the nation, we support about 7,500 local community pharmacies, and roughly 86 percent of hospitals use our products and services. This network positions us to serve hard-to-reach members and coordinate with care teams after the MTM consultation is complete.

Serve hard-to-reach members

We use predictive modeling based on risk stratification to identify members who could benefit the most from pharmacist intervention. We then complete MTM cases with those members to close gaps in care.

Improve your Star Ratings

Our end-to-end process enables us to complete MTM cases at four times the industry average, increasing the delivery rate of Comprehensive Medication Reviews and improving Star Ratings performance.

Learn more about how Cardinal Health supports health insurance plans at cardinalhealth.com/MTMbenefits