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For Decision Makers in Healthcare
ManagedHealthcareExecutive.com
VOL. 23 | NO. 6
JUNE 2013

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# GREAT STATES

## Models experiment with health reform

Massachusetts

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# Bare-bones plans reduce employer commitment

## A few employers find loopholes but most will offer health plans to keep workers happy

BY JULIE MILLER

Julie Miller is editor-in-chief of MANAGED HEALTHCARE EXECUTIVE. She can be reached at julie.miller@advanstar.com

Employers are considering alternatives—okay, let's call them "loopholes"—to the Patient Protection and Affordable Care Act provisions. The latest one I've come across is the bare-bones coverage strategy.

Here's how it works.

A large employer (remember that's 50 full-time workers or more) offers its employees a weak coverage plan that might cover preventive services and generic drugs, for example, but does not cover surgery. The employer knows full well that the package is below the minimum standard of 60% actuarial value.

Assume a lot of workers need better coverage, so they go to the exchanges to buy their own health plans and probably end up with subsidies as well. As a result, the employer with the substandard plan must pay a penalty of $3,000 for each of those subsidized employees. To the employer, this is a better deal financially than paying for superior benefit packages for everyone.

Had the employer opted out of coverage entirely, it would be paying a guaranteed $2,000 penalty for nearly every worker, regardless of how or if the workers ultimately get coverage. So a firm with low-wage employees might consider gambling on the potential $3,000 per subsidized worker in the exchanges over the guaranteed $2,000 per worker for not offering coverage at all.

Not to mention that employees who are eligible for Medicaid will not receive subsidies, which means employers will not face any penalties there.

Add it all up and bare-bones plans are certainly a way for large employers to minimize their financial obligations. Some might call it a brilliant business strategy while others see it as an insult to hard-working Americans.

But what about the health reform law's essential-benefits requirement? Recall that the mandate only affects full-risk plans for small business and individuals—not large employers. By the way, the employees would actually be welcomed into the exchanges based on the fact that their employer wasn't offering minimum value coverage.

### NOT MANY TAKERS

I discussed this loophole with Timothy S. Jost, the Robert L. Willett Family Professor of Law at Washington and Lee University, and he tells me that policymakers likely considered this scenario and decided that most employers would go ahead with a decent benefit package.

"And people in low-wage situations where the employer does not offer insurance, they'd be better off in an exchange anyway," Jost says. "So when you get down to it, the obligation that's placed on the employer is not that great."

He says the bare-bones plans will be quite few and far between for several reasons:

- A nondiscrimination requirement expects employers to offer the same coverage for all employees. Therefore, a bare-bones plan offered to the janitor would be the same one offered to the CEO. "And the CEOs will not be too happy about that," Jost says.
- The tax subsidy for employer coverage adds up to a lot of money. "For employers to walk away from that and expect employees to be happy is a stretch," he says.
- Most employers need to maintain good benefits to recruit and retain workers.

Of course, the bare-bones plans seem a lot like the mini-med plans that will be driven out of town next year under health reform. Even though federal officials say the plans appear to qualify, it's possible they will face future regulatory scrutiny. **MHE**

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Printed in U.S.A.


**MANAGED HEALTHCARE EXECUTIVE** (ISSN 1533-9300, Digital ISSN 2150-7120) is published monthly by Advanstar Communications Inc., 131 W First St., Duluth MN 55802-2065. Subscription rates: 1 year $99.00, 2 years $145.00 in the United States & Possessions; 1 year $122.00, 2 years $173.25 in Canada and Mexico; 1 year $192.00, 2 years $295.00 in all other countries. For air-expedited service, include an additional $87.00 per order annually. Single copies (prepaid only): $9.00 in the United States, $22.00 all other countries. Back issues, if available: $15.00 in the U.S.; $17.00 all other countries. Include $6.85 per order plus $2 per additional copy for U.S. postage and handling. If shipping outside the U.S., include an additional $10 per order plus $3 per additional copy. **Periodicals postage paid** at Duluth MN 55806 and additional mailing offices. **POSTMASTER:** Please send address changes to Managed Healthcare Executive, P.O. Box 6178, Duluth, MN 55806-6178. Canadian GST number: R-124213133RT001, PUBLICATIONS MAIL AGREEMENT NO. 40612608, Return Undeliverable Canadian Addresses to: IMEX Global Solutions, P. O. Box 25542, London, ON N6C 6B2, CANADA. Printed in the U.S.A.

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# State model hints at national change

## Massachusetts adds cost containment goals, which is something PPACA lacks

**JULIA BROWN** | CONTENT SPECIALIST

**NATIONAL REPORTS —** Cost containment was not initially addressed when Massachusetts' health reform was enacted in 2006. Early reforms basically served to increase coverage, and a separate cost-containment law, Chapter 224, passed in August 2012.

The law became effective January 1 and is projected to save nearly $200 billion over the next 15 years, according to state officials. Industry observers believe the Patient Protection and Affordable Care Act (PPACA) was modeled in part after Massachusetts' reform, but PPACA cost-containment provisions remain questionable.

### LIMIT SPENDING GROWTH

Chapter 224 calls for overall growth of healthcare expenditures within the state of Massachusetts to be limited to the potential gross state product (PGSP), or a lesser percentage of it. Each year, the health policy commission—a new state agency created to implement and monitor Chapter 224—will estimate a PGSP figure in advance of the year in which it will be applied.

"You can't have healthcare dominating everything and have it take away from the state's ability to provide other benefits and services," says Matt Fisher, attorney and chair of the Health Law Group at Mirick, O'Connell, DeMallie & Lougee, LLP. "The law is trying to make sure that we're all still able to access good-quality healthcare that's sustainable and not going to undermine everybody financially."

Plans and providers will have to report their costs and reimbursement amounts to the state on an annual basis. Fisher says it's somewhat unclear whether or not individual healthcare entities must operate within the cost benchmark, or if the measurement will aggregate the state expenditures overall.

**$200 billion**

**Savings over 15 years from Chapter 224**

He says the details of Chapter 224 suggest more of a case-by-case basis where the health policy commission might approach an individual organization to ask for a demonstration of compliance with the cost benchmark. If the commission were to decide that an entity is beyond the designated growth benchmark, it would most likely suggest or impose a performance improvement plan prior to issuing a penalty.

### TRANSPARENCY AND DISCLOSURE

Making payment information available to patients will hopefully drive actions and enable advocacy for change, Fisher says. However, transparency might be problematic for plans.

"Part of the challenge for insurers will be struggling with how much information needs to be provided, how to present it and how to make sure that inaccuracies aren't released because once the information is out in the public sphere, it's impossible to pull it back," says Fisher.

Currently, PPACA does not have a similar spending growth target, and Fisher does not foresee any movement towards national cost control—for now.

"That's not to say it couldn't happen," he says. "Medicare is certainly experimenting with alternative payment methodologies and encouraging coordination of care and more efficient, high-quality care. But that's only for those participating in Medicare and engaging in particular projects created by PPACA."

Similar to Massachusetts reform, a key provision of PPACA is expanding coverage. While there are cost offsets in the national law, it's possible that more aggressive national cost containment could be pursued down the road.

Additionally, Fisher says health reform is a lot more manageable within one level of government and one state, especially one as small as Massachusetts.

### COSTS CONTAINED

One of the state's primary changes so far has been a shift in payment methodologies, Fisher says. Insurers are moving away from fee-for-service toward global risk and bundled payments for providers. But if the law needs additional tweaking, more legislation will be proposed by state legislators.

"It's not going to be walked away from," he says. "There's a desire to see this succeed and figure out how we can tackle unsustainable growth."

Fisher says Chapter 224 aims to encourage new methods of delivering care, containing costs and working together to solve the growth of health costs. **MHE**

# Oregon Medicaid study fails to provide complete answers

## Study reveals mixed results in expanded Medicaid plan

JULIE MILLER
EDITOR-IN-CHIEF

**NATIONAL REPORTS —** Medicaid isn't the ideal model for healthcare delivery, but it's not a train wreck either. Industry observers continue to volley the pros and cons of a recent study that reviewed Oregon's expanded Medicaid program over a two-year period.

The *New England Journal of Medicine* reported in May that low-income Oregonians who won a 2008 lottery to be included in expanded Medicaid benefits had mixed results on health measures compared to their counterparts who did not win a place on the rolls. Authors say the effects of expanding coverage are unclear.

Those who did gain coverage improved on certain measures, such as self-reported good health, increased use of preventive measures and lessened out-of-pocket costs. The most significant gain was a 30% reduction in depression. However, other areas showed no improvement, such as control of blood pressure, cholesterol and HbA1c levels.

"The study used a small number of measures, looking at a two-year period," says Margaret Murray, CEO of the Association for Community Affiliated Plans (ACAP) and an **MHE** editorial advisor. "It is possible—and makes intuitive sense—that health status among those with Medicaid coverage would further improve over time, particularly for those with chronic illnesses."

She says the improvement in depression is statistically significant and underscores Medicaid's role in increased access to and use of healthcare services. Further, she says, continuous coverage for Medicaid populations moving forward would help improve not only their care but the industry's ability to measure quality.

"If Congress were to enact legislation providing for standardized quality measurement and reporting across the entire Medicaid program, think of the comparisons we could make that we can't today, owing to a lack of measurement or small sample sizes," Murray says.

Currently Congress is debating the Stabilize Medicaid and CHIP Coverage Act, which would bring continuous enrollment to targeted populations.

### RETURN ON INVESTMENT

As parts of the country ramp up Medicaid expansion, policymakers will be looking for evidence of a return on their investment of taxpayers' dollars. While the Oregon study can't ultimately prove benefits of Medicaid coverage, it can't disprove benefits either.

"It's a phenomenon that will be played out over the next couple years as Medicaid expansion takes hold," says Don Hall, principal, DeltaSigma, LLC, based in Littleton, Colo., and an **MHE** editorial advisor.

Hall, who is a former Medicaid managed care CEO, says Oregon has a robust safety-net system with federally qualified health centers and rural clinics that can serve patients who don't have health coverage. Residents moving from the ranks of the uninsured to the Medicaid system basically gained a different funding system rather than dramatically improved access, he says.

"It's a tribute to the federally qualified health centers and the rural centers that create that safety net," he says.

However, as more Americans gain Medicaid coverage, they will have additional access to the Medicaid network of providers. Community clinics that assist the needy might see a drop in patients as they migrate to other facilities. Reduced numbers of patients can disrupt funding or in some cases cause the clinics to shut down, Hall says.

The Congressional Budget Office estimates that health reform expansion of Medicaid will cost about $6,000 per patient per year. The question of whether Medicaid is a good investment continues to play out among state governments still undecided on expansion. **MHE**

### OREGON MEDICAID STUDY FINDINGS

**What increased:**

- State costs
- Outpatient care
- Prescription drugs
- Hospital admissions
- Diagnosis of diabetes
- Having a regular physician
- Use of preventive care
- Self-reported good, very good or excellent health

**No effect found on:**

- Emergency room use
- Prevalence of hypertension and high cholesterol
- Control of HbA1c

**What decreased:**

- Patients borrowing money to pay medical bills
- Medical bills going into collections
- Screening positive for depression

**Source:** *New England Journal of Medicine*

# Drug trend curves down 3.5% while members pay more

## Members are paying three times more in overall healthcare costs

CHRISTINE BLANK
MHE CONTRIBUTOR

**NATIONAL REPORTS —** Growing use of generic medications and brand patent expiries are major reasons why U.S. spending on medicines declined in 2012, according to a new report. The trends contributed to the overall decline in healthcare service utilization.

Total spending on medicines declined by 3.5%, according to the IMS Institute for Healthcare Informatics. In addition, nominal pharmaceutical spending reached $325 billion in 2012, or per capita spending of $898, a decline of 1%.

"IMS has been tracking overall sales in the U.S. for nearly 60 years, and we have never seen a medicine spend decline," says Michael Kleinrock, director of research development at IMS, who spoke during a media conference call.

### OUT OF POCKET RISES

Although the drug trend is curving down, members are bearing greater financial responsibility for healthcare costs in general. Patients were likely cutting back on physician visits in 2012 because those with insurance had higher deductibles, copays and co-insurance, according to the report. The average out-of-pocket costs for commercially insured patients under 65 years old reached $1,146 in 2012, a 30% jump from 2011.

The spike is "entirely the result of higher deductibles," according to IMS. In 2008, average deductibles were $131, climbing to $818 in 2012.

"Consumer-driven health plans, including health savings accounts, are clearly having an impact on patients' decision-making. Some small to mid-size employers are only offering these types of plans," Kleinrock says.

In fact, out-of-pocket costs have risen three times higher than they were five years ago. In consumer-driven plan arrangements, member financial responsibility has risen seven times higher in five years.

As is typical of an insured population, 5% of members accounted for 51% of healthcare costs overall, at $15,684 per member. And the highest 1% of care utilizers accounted for 26% of total spending, at $48,735 per member. Members with lower costs tend to have more spending concentrated in pharmacy benefits, however. The lowest 50% of utilizers accounted for 3.3% of expenditures, spending less than $937 per member.

While patients paid higher overall out-of-pocket costs, average prescription drug copays declined by $2 to $121 in 2012. Patients filled 72% of all prescriptions with a copay of $10 or less.

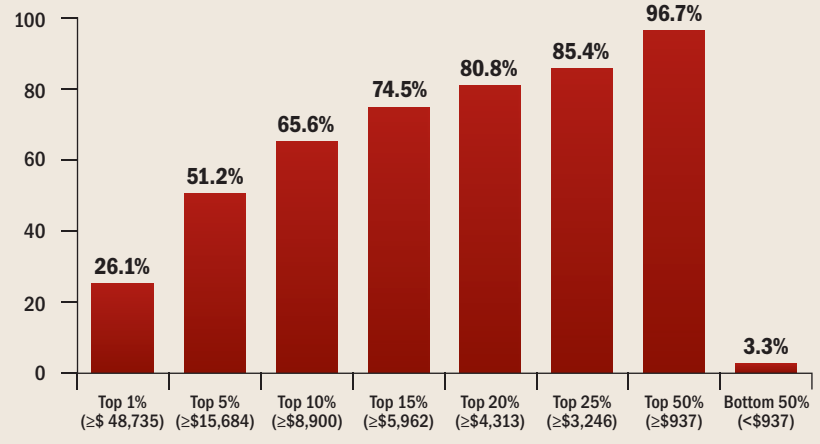
"Lower co-pays tend to have a dramatic impact on the ability and willingness to afford that medication," Kleinrock says.

### GENERIC MARKET

Medicine spending dropped for a few different reasons, including effects of major brand drugs' patent expirations, including Lipitor and Plavix, in 2011. Because of patent expirations, 2012 saw $744 million less in brand spending. At the same time, spending on generic medications increased by $8 billion and generics now account for 84% of all prescriptions.

"Generics capture most of the volume of usage of a molecule following patent expiry and, as a result, they reduce drug costs substantially," Kleinrock says.

**Percent of health plan members ranked by healthcare spending**




**Source:** IMS PharMetrics, Jun 2012

Other factors impacting the overall medicine spend decline include: a decrease of 0.9% in patient visits to physicians' offices; a slight decline in outpatient treatments; a drop of 0.5% in elective surgeries at hospitals; and a less severe flu season in the early part of 2012, according to IMS.

At the same time, emergency room visits and admissions increased a significant 5.8% in 2012.

"The visits are driven by the insured, not the uninsured. They could have visited an urgent care clinic or a doctor's office," Kleinrock says.

The top five therapy areas for spending on medications in 2012 were:

- Oncologics ($25.9 billion)
- Mental health ($23.5 billion);
- Respiratory agents ($22.1 billion)
- Antidiabetics ($22.0 billion); and
- Pain ($18.2 billion).

The oncologic class took the lead from mental health medications, which was the top spending category in 2011. Absolute spending growth gains were highest for antivirals (excluding HIV), multiple sclerosis, ADHD, HIV antivirals and autoimmune diseases.

Antivirals—the therapy area that includes flu vaccines and newer treatments for hepatitis C virus—grew by more than 20%, driven by the breakthrough therapy teleprevir, according to the IMS report. However, a rise in novel disease treatments last year might lower future healthcare costs.

"The new medicines in 2012 represent an amazing group of breakthroughs, including nine new cancer drugs. That is the most new cancer drugs in over a decade," Kleinrock says.

In total, 28 new molecular entities launched in 2012. Seven orphan drugs, including novel treatments for cystic fibrosis, chronic myeloid leukemia and multiple myeloma also became available. **MHE**

# Ohio groups push legislature to back Medicaid expansion

## Decision would come from stand-alone bill rather than budget plan

JULIE MILLER
EDITOR-IN-CHIEF

**NATIONAL REPORTS —** Like many Republican-led states, Ohio is struggling to achieve agreement between the governor and the legislature on Medicaid expansion.

Ohio Governor John Kasich, a Republican, introduced his budget proposal for fiscal years 2014 and 2015, which includes a plan to expand Medicaid coverage. However, a house committee later removed the expansion provisions, and the legislature placed the issue outside of the budget process. State Senate President Keith Farber recently commented that a deal could be reached by the end of the year but not in time for finalizing the budget.

### FEDERAL FUNDING

Advocates are coming out of the woodwork to help drive the state to adopt the federal health reform provision to expand Medicaid eligibility to all low-income populations under 138% of federal poverty level (FPL). Ohio could add some 366,000 residents to its rolls, including single adults without children.

"What keeps getting lost in this conversation is that most of these poor, single women work," says Mike Gonidakis, executive director of Ohio Right to Life.

Gonidakis also says the new populations added to expanded Medicaid would benefit from the "basic right to healthcare."

According to the Health Policy Institute of Ohio, by expanding Medicaid, Ohio would net $709 million in savings through 2022 because of higher federal match payments associated with Medicaid enrollment. It would also gain $1.8 billion in revenue in that time frame from taxes associated with managed care enrollment.

David L. Bronson, MD, president of Cleveland Clinic Regional Hospitals and past president of the American College of Physicians, says providers are concerned about losing disproportionate share hospital (DSH) payments from the federal government, which would not be offset by reduced uncompensated care if Medicaid is not expanded. The Cleveland Clinic alone would lose 75% of its DHS payments, he says.

"It's more than just the Cleveland Clinic," Dr. Bronson says. "Small safety net hospitals are dependent on these payments to survive."

He also says the Ohio Medicaid system had a negative reputation, but it's become more effective and efficient.

"A lot of good people are struggling to figure out how to do the right thing here," he says. "There are a lot of fixed opinions, and it's time to update people on Ohio Medicaid."

Carol Caruso, senior vice president of the Greater Cleveland Partnership, says not expanding Medicaid in Ohio will result in cost shifting to the insured and as much as $90 million a year in penalties for small businesses that do not offer insurance. The bipartisan partnership's members voted unanimously to advocate for expansion, so the business community is clearly onboard, she says.

Gonidakis says there are enough votes in the state house and senate to pass a stand-alone bill. **MHE**

# Highmark buy continues national insurer trend

## Payer and provider affiliation deals vary in structure and bring up new questions for regulators

BY LISA G. HAN, ESQ., AND DAVID KOPANS, ESQ.

Lisa G. Han, Esq., is a partner with Squire Sanders LLP.

David Kopans, Esq., is an associate with Squire Sanders LLP.

The Pennsylvania Insurance Department (PID) approved the affiliation of Highmark Inc. and West Penn Allegheny Health System (WPAHS), a five-hospital health system. This affiliation represents a growing trend of insurer and provider integration where the line between them has become blurred.

Unlike more straightforward acquisitions where an insurer acquires ownership of a provider, the Highmark-WPAHS affiliation sought to: preserve Highmark's control over its insurance operations; and protect WPAHS's tax-exempt status. A new nonprofit parent company, UPE, was established as the sole corporate member. UPE holds a new class of corporate membership in Highmark in addition to the existing class of members of Highmark. While the Highmark directors-members will retain significant control over Highmark's operations, UPE was given certain reserved powers.

A nonprofit subsidiary of UPE was formed to become the sole member of WPAHS.

### NIMBLE NEGOTIATIONS

Nothing demonstrates the continuously changing deal terms more than the price of the affiliation. While the initial cost to Highmark was set at $475 million, it appears that the cost will actually exceed $1 billion.

Payer-provider affiliations have varied greatly in form, ranging from acquisitions, joint ventures, private label products, reinsurance/coinsurance arrangements, performance-based compensation and accountable care organization (ACO) affiliations.

Despite the variety of methods, each deal has resulted in unique features and raised new questions:

**Antitrust Scrutiny—**A typical inquiry from the regulators is the impact that an affiliation may have on competition. The Department of Justice generally views vertical integration as increasing competition and lowering prices for consumers. However, in the Highmark transaction, PID imposed a number of conditions for the approval of the deal, including that the parties must not enter into an exclusive contract; no contract between the parties may include a most favored nation provision; and the parties must implement a firewall policy that prevents Highmark and WPAHS from sharing competitors' pricing or product information.

**Network and Operational Transparency—**Insurers may have to be more transparent about their network strategy and comply with unique requirements to secure the approval of a transaction. For example, in Highmark's case, PID required that tiered network products be based upon transparent, objective criteria that include quality and cost. It will continue monitoring the impact.

**Provider Oversight from Insurance Regulators—**In addition to having direct jurisdiction over insurers, insurance regulators are increasingly interested in assessing the "enterprise risk" of insurers' non-insurance affiliates and their business to determine how the affiliates' operations may impact the insurer's operations. The National Association of Insurance Commissioners has adopted revisions to one of its model acts to require holding company systems to report annually on the enterprise risk created by its non-regulated affiliates.

How affiliations, such as the Highmark-WPAHS transaction, will impact insurers' future business ventures going forward remains to be seen. **MHE**

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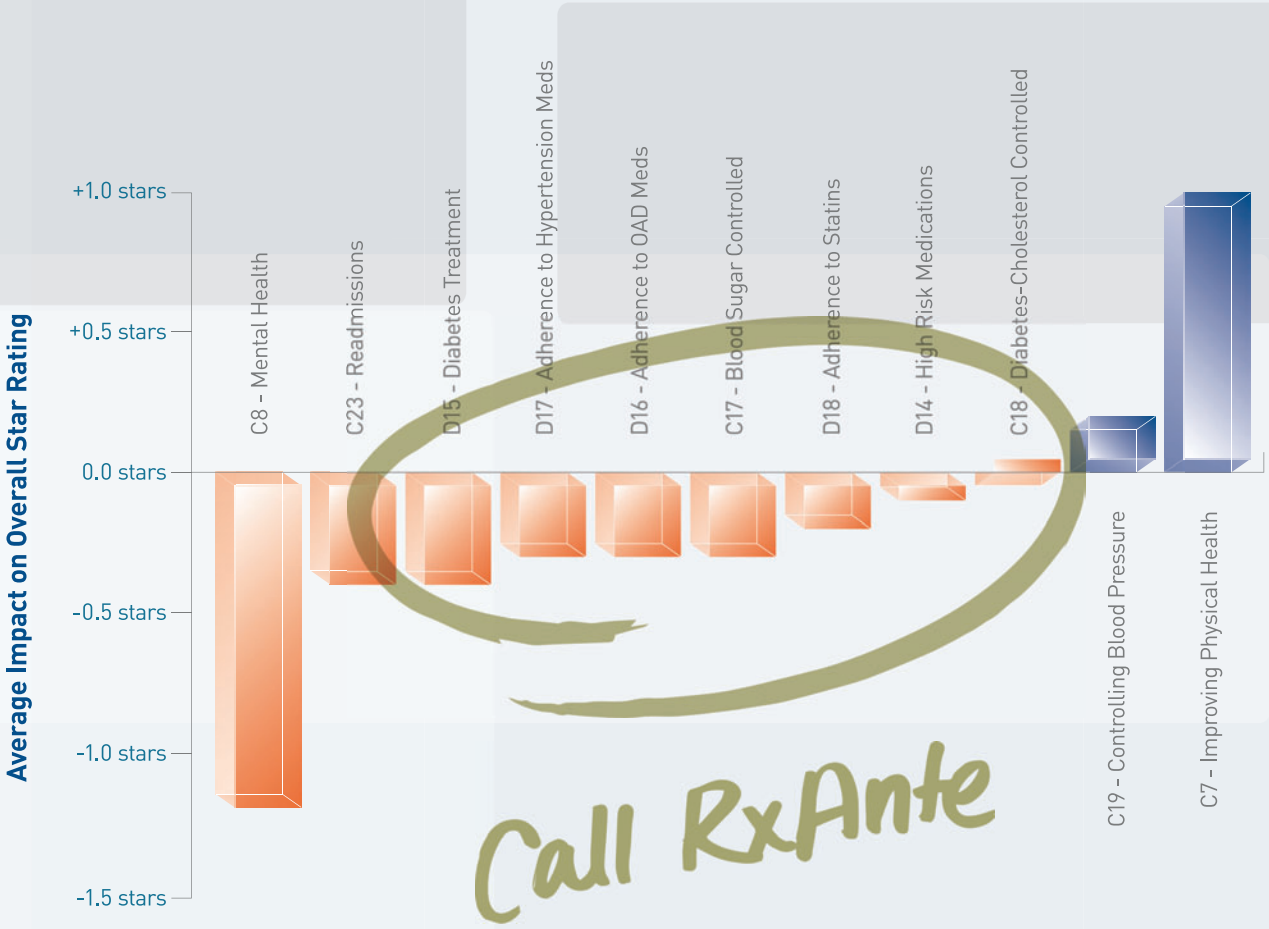
*This column is written for informational purposes only and should not be construed as legal advice.*

# Are Triple-Weighted Star Measures Dragging You Down? You're Not Alone.

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# States and insurers grapple with exchanges

## State experiences vary, and officials could assume a larger role by 2016

BY JILL WECHSLER

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

The looming deadline for launching state-based and federally facilitated exchanges (FFEs) is making a lot of people nervous. Insurers are especially worried that premium subsidies will fail to attract enough healthy people to form viable risk pools.

Partisan politics continue to plague the process. Republicans are blocking funds needed for smooth implementation and ratcheting up criticism. A report from the House Energy & Commerce Committee predicts "premium rate shock" in at least 45 states due to requirements to cover more services and benefits.

HHS officials say the system will provide immediate eligibility determinations for consumers who enroll online for coverage, but there will be a lot of geographic variation in the process. Only 17 states and the District of Columbia are operating their own exchanges; seven states are partnering with HHS and 26 states are defaulting to the FFE.

Utah will run an exchange for small businesses but leave the individual market to the feds. In Montana, an FFE state, officials are examining plan quality and rates as part of its oversight responsibilities, says general counsel Christina Goe at last month's Health Insurance Exchange Summit.

Insurers had to file plan applications with states in May, which have to submit recommendations to HHS by July 31, so the federal goverment can determine the qualified health plans by the end of August. That will give carriers and exchange operators a month to prepare. HHS is deferring to states on many oversight issues, and some may assume a larger role in exchange operations by 2016.

### EXCHANGE COMPETITION

Balancing plan choice is tricky. Too many exchange options can be confusing, but too few plans might lead to higher premiums.

The FFE is initially operating as a clearinghouse that accepts all insurers meeting minimum standards, according to Joel Ario of Manett Health Solutions. Oregon received applications from 16 insurers, plus two not-for-profit consumer operated CO-OP plans. Illinois officials announced that six insurers filed applications for 165 plans—much less than earlier predictions of 260 plans from 16 insurers, but "encouraging" to the governor.

Plans are working around the clock to comply with exchange filing requirements and formats, many different from company legacy systems, according to Kim Holland, director of state affairs at the Blue Cross Blue Shield Assn. Bonnie Washington of Avalere Health says that most insurers consider exchanges "a worthwhile endeavor" but are nervous about risks from uncertain utilization, costs and adverse selection.

Regional carriers and Blues feel it's important to maintain positions in long-served communities, including those where they're dominant. This is a logical step for Rocky Mountain Health Plans, says president Steve ErkenBrack, who expects to be an active player in Colorado's state-based exchange.

But large national carriers are not rushing into all markets, according to Washington. Instead they are limiting participation to states in which they already have a strong presence. Added options might come from some Medicaid-only plans, which are looking at exchanges as opportunities to expand coverage of low-income populations.

"2014 will be messy," says MIT professor Jonathan Gruber, "but ultimately exchanges will work well to provide consumers more choices." **MHE**

# Follow clinical evidence to manage cancer care

## Aetna examines technology solutions to advance evidence-based care and sustainable payment models

BY MICHAEL KOLODZIEJ, MD

Michael Kolodziej, MD, is the head of oncology strategy for Aetna.

The current rise in healthcare spending in the United States is unsustainable. Any solution that aims to address this trend must address the cost and quality of cancer care.

Cancer is a devastating diagnosis. What's more, cancer treatment is among the top three most costly conditions, and costs are rising faster than general medical costs.

Much of the rise in cancer care cost is attributed to better screening technologies, new medicines, improved surgery and advanced radiation therapy. Additionally, as baby boomers age, the rate of cancer increases since most cancers are diseases of aging. Almost 1% of a typical working-age population and 5% of a Medicare-age population are diagnosed with cancer each year.

### HIGH SURVIVAL RATES

At Aetna, we are focused on creating sustainable new models of healthcare delivery that address costs while improving the member experience and health outcomes. While cancer survival in the United States is superior to that in most of the world, considering that the United States spends two-and-a-half times more than most developed nations in the world, shouldn't our models be better?

Better models for cancer care are possible to give patients convenient access to more effective care with fewer side effects, less time in treatment and lower costs. The following elements are critical:

- Expertise and technology that delivers evidence-based decision support and a payer-agnostic system that is scalable and easily accessible to providers;
- An enhanced patient experience that provides proactive support throughout treatment and helps keep the patient in charge of his or her care and, if necessary, end-of-life planning; and
- A sustainable payment model that supports and preserves the benefits of community oncology care such as convenient, personalized care.

Aetna has been working with the clinical community on varying approaches to identify and share the best treatment models. We have shown that following clinical evidence can result in equal or better outcomes at lower costs. But to use evidence on a broad scale, connectivity has to be a significant part of the solution.

### PLATFORM FOR CONNECTION

Aetna has invested in Medicity, providers of health information exchange (HIE) technology solutions. Through Medicity, we can offer a platform for communication between hospitals, primary care physicians, specialists, payers and, most importantly, patients. We can also make evidence-based, decision support and reporting tools available through the HIE.

The information transfer facilitates real-time communication and is payer-agnostic, which addresses one of the most glaring problems in today's healthcare system: fragmentation. Multi-directional dialogue will be critical to the success of new delivery models that preserve community care, including patient-centered medical homes (PCMHs) and accountable care organizations (ACOs).

As a society, we must find better ways to make cancer care more effective, accessible and affordable. We must connect clinical evidence, dialogue, payment and patient support to improve outcomes and the patient experience. **MHE**

# GREAT STATES

## Innovative state experiments move health reform forward

Jill Sederstrom

As U.S. Supreme Court Justice Louis Brandeis once wrote, states can often "serve as a laboratory" for social and economic experiments. The sentiment still rings true today in the era of health reform.

With the implementation of the Patient Protection and Affordable Care Act (PPACA), states are creating their own models for how reform should be approached. State laboratories can test and put into practice reform concepts, ideas and policies that ideally could translate to a larger, national scope. Among states, policies can be vastly different—and sometimes contradictory—but they all aim to improve coverage, effectiveness, efficiency or cost.

"The Affordable Care Act and the whole body of national health reform are national initiatives, but local implementation is central to the process. And states are doing a whole variety of different approaches," says Allan Baumgarten, an independent analyst and consultant who also authors state health market reviews. "In some cases, you can say that states themselves have multiple approaches."

In fact, the Center for Consumer Information and Insurance Oversight (CCIIO), which is responsible for executing many of the health reform provisions that affect commercial plans, works with states and insurers in providing guidance on reform provisions. In 2012, for example, CCIIO defaulted to the states for the Essential Health Benefit packages, allowing them to choose a local benchmark plan rather than identifying a national standard. States have also had a choice on their insurance exchange models as well.

While all states are taking steps to move toward reform, healthcare experts say some states are adopting potentially innovative models that could carry national implications to further healthcare reform.

### MASSACHUSETTS

A discussion of state reform efforts would be remiss without the mention of Massachusetts, a state whose reform efforts have in large part served as a model for PPACA.

The state enacted a healthcare reform law in 2006 in an effort to move toward universal healthcare coverage. One primary tenet of the law was an individual mandate that required residents to carry health insurance coverage or pay a fine. Massachusetts also established a healthcare exchange to improve the nongroup insurance market.

While many states are just now trying to execute these same elements as part of PPACA compliance, Massachusetts has an established system with several years of experience under its belt. Healthcare experts say the state is already seeing some measureable outcomes from its efforts.

For instance, research by J. Kolstad and Amanda Ellen Kowalski found that reform in the state of Massachusetts has reduced hospital admissions that originate in the emergency room by about 5%.

"In Massachusetts before the reform, there was a lot of overuse of emergency rooms because low income, uninsured people were able to get totally free care at ERs through the Uncompensated Care Pool," says Sarah Miller, PhD, assistant professor at the University of Notre Dame. "There was this incentive in place for people to use

the ER as their personal doctor."

Miller's own research has found that before state reform, more than 40% of ER visits could be categorized as non-urgent and primary-care treatable. Once reform took place, the majority of the reduction in ER usage—more than 80%—was attributable to visits that could be classified as non-urgent or primary-care treatable.

While emergency room usage decreased, research has found that post-reform, routine office-based care, primary care and preventive services saw increases in utilization.

Miller says the reform efforts have been a step in the right direction in terms of cost control, but healthcare experts agree that the cost of expanding coverage is substantial nonetheless.

"It's expensive to provide 400,000 with health insurance, which is essentially what happened in Massachusetts. And those costs are bigger than the cost savings," she says.

Cost containment is the state's next challenge. In August 2012, the legislature passed a payment reform law that attempts to keep healthcare costs—and by extension insurance premiums—on par with the rate of growth of the Gross State Product (GSP) for the first five years. After 2017, the permitted annual increase will drop even lower to half a percentage point below the GSP before returning to the rate of growth of the GSP.

Wendy K. Mariner, JD, MPH, an Edward R. Utley professor of Health Law and a professor of socio-medical sciences at Boston University, says that would mean healthcare spending growth should be below 3.6% currently. According to information released by Governor Deval Patrick's office, the payment reform law could result in nearly $200 billion in healthcare cost savings over the next 15 years.

Mariner says one of the challenges of the new law is that there is little direct enforcement. For instance, providers who fail to meet the target will have to produce a written plan to meet that target in the future.

"It's not a cure-all," Mariner says. "It's a target."

She also says that while the healthcare reform law in 2006 went off essentially "without a hitch" in the state of Massachusetts, the model could be more challenging for other states because Massachusetts was much closer to universal healthcare coverage to begin with. Some states have a much larger coverage gap.

"The Massachusetts model is both a great model and an imperfect model," she says.

Many industry observers wonder if the state's policies to increase coverage first, then address the costs separately, is a better approach than attempting to address coverage and cost simultaneously. While PPACA attempts to balance out new spending with savings on existing costs—reducing hospital disproportionate share payments to reflect the reduction in the uninsured, for example—few believe the national law will reduce healthcare spending significantly.

## VERMONT

In Vermont, legislators are hoping the answer to healthcare reform is a single-payer system. The state plans to implement a tax-based, single-payer system in January 2017 in an effort to provide universal coverage to its 620,000 residents.

"The vision is that we move to a system where every Vermonter has insurance because they are a Vermonter, not because they happen to work for a generous employer or a large business," says Robin Lunge, Vermont's director of healthcare reform. "When we move to that universal system, it would be publicly funded, so everybody is in and everybody pays."

Another important component of Vermont reform efforts is cost containment. The state legislature has established the Green Mountain Care Board, an independent, five-member board, to recommend cost containment and determine areas of potential savings.

"The governor believes strongly that healthcare costs need to be brought under control," Lunge says. "If we can't figure out a way to control healthcare costs than there is no way that the state could actually afford to be a single payer."

She says in addition to one-time administrative savings, moving to a single-payer system will also allow the state to create more population health programs and reduce the fragmentation that exists in the system currently.

"When you are taking a holistic view of healthcare, you can really focus on healthcare instead of healthcare coverage," she says.

As a single payer, the state also plans to move from a largely fee-for-service structure to a value-based payment structure.

"If we move toward value-based payment so that we are paying providers to focus on the health of their patients instead of paying them piecemeal for the number of services they provide, that too will change the way that providers deliver healthcare and lead to decreased cost," Lunge says.

Although Green Mountain Care—an entity established by the legislature—will serve as the state's coverage provider, Lunge says there still may be a role for other insurers.

"Green Mountain Care will be a good solid plan for Vermonters, but some employers may want to continue to offer additional benefits on top of the single payer," she says.

The state may also choose to contract out parts of the single payer system. Lunge says insurance carriers have had mixed reactions to the state's plan.

"We have one national carrier who is not interested in participating in a single-payer system in any way, and we have a local carrier who thinks that it could bid to be a significant contributor to a single-payer system," she says.

While the idea of a single payer has been discussed for years in Vermont, healthcare experts say other states might not have the same political environ-





| | MASSACHUSETTS | VERMONT | MARYLAND | COLORADO | ARKANSAS |
|---|---|---|---|---|---|
| POPULATION | 6.5 million | 620,000 | 5.7 million | 4.9 million | 2.8 million |
| POLITICS | Democrat | Democrat | Democrat | Democrat | Democratic Governor/ Republican Legislature |
| UNINSURED | 290,000 | 55,000 | 771,000 | 716,000 | 520,500 |
| HEALTH SPENDING PER CAPITA | $9,276 | $7,635 | $7,492 | $5,994 | $6,167 |
| MEDICAID EXPANSION | Supports | Supports | Supports | Supports | Supports |

**Sources:** www.pewstates.org/research/data-visualizations/republican-rule-deeper-divides-85899444189; kff.org/statedata/

ment necessary to make such a shift. To operate the system in 2017, officials are planning to apply for a PPACA waiver, which Lunge says will probably be filed at the end of 2015 or early 2016.

"This effort by Vermont is likely to be something of an anomaly, and I'd be surprised if there were other states where there was significant interest in moving in that direction and trying to replicate whatever model Vermont develops," Baumgarten says.

## MARYLAND

In Maryland, its unique Health Services Cost Review Commission (HSCRC) sets hospital rates for all payers—Medicare, Medicaid and private insurers. The HSCRC has been operating since 1971 and setting hospital rates since 1977. When Medicare introduced its diagnostic-related group (DRG) reimbursement system, the state received a waiver from the federal government that allowed the HSCRC to continue setting rates for Medicare reimbursement.

But a new proposal submitted this spring to the Obama administration could mean a significant change for the state as it attempts to curb rising medical costs.

The proposal, which a spokesperson for the Maryland Hospital Assn. called a "huge change," would tie hospital rates to the state's economy and would make hospitals responsible for population health management instead of simply treating illness and injury.

To use its own model of setting hospital prices, the state must pass a waiver test with the Centers for Medicare and Medicaid Services (CMS). The waiver test would demonstrate that Medicare spending under Maryland's payment system is less than what spending would be under the prospective payment system Medicare uses in other states.

"Basically what was established was a waiver test that looked at the rate of growth in hospital spending per admission in Maryland relative to other states," says Bradley Herring, PhD, an associate professor at Johns Hopkins Bloomberg School of Public Health.

Under the new proposal, the state would switch from a waiver test that focuses on cost per admission to cost per person.

Herring says that over time, the waiver cushion has shrunk and the cost per case in Maryland has probably grown faster than other states.

"Maryland is in danger of no longer beating this so-called waiver test, so that in turn has led our state's rate setting commission...along with the state's department of health and mental hygiene to then come up with a proposal to CMS to now do something different," he says.

Jim Reiter, senior vice president of communications for the Maryland Hospital Assn., says the association supports the overall direction the proposal suggests, but does not support the initial proposal submitted because it lacks certainty. Provisions could cause hospitals to take on all the financial risk without clarity on how the policy would be implemented.

Unlike other states that have tried hospital rate setting in the past, the concept has been relatively successful in Maryland and has earned the support of many of the state's healthcare stakeholders. Reiter says hospitals have been supportive of hospital rate setting overall, which fixes hospital prices for all healthcare purchasers, because it ensures stability, equity and innovation.

To be successful, however, experts say it requires a certain buy-in from stakeholders.

"It requires collaboration and cooperation, an 'all-in' from payers, hospitals and the state," Reiter says.

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## COLORADO

The state of Colorado is centering its reform efforts on medical homes in an effort to improve care coordination and health outcomes. The Colorado Medical Home Initiative (CMHI) was established in 2001 as part of a frontrunner effort to promote the use of patient-centered medical homes (PCMHs). In addition, the state passed a law in 2007 that requires increased access to a medical home approach for children who are eligible for Medicaid and Child Health Plans (CHP).

"Colorado is one of the states where they tried Medicaid HMOs, Medicaid managed care, and were very unhappy with the results," Baumgarten says. "That's why they turned to patient-centered care management and similar kinds of programs where it's all about the primary care physician and the primary care clinic, playing a bigger role in care coordination."

One example of a managed care organization that has embraced the medical home concept is Rocky Mountain Health Plan, a not-for-profit health plan that serves approximately 214,000 enrollees across the state. Rocky Mountain Health Plan has served as both a lead agency in the Beacon Community Cooperative Agreement Program (a national health IT project) and a payment agent for the Comprehensive Primary Care Initiative (CPCI) program (a public/private Medicare effort). It is now looking at ways to incorporate behavioral health into coordinated care models.

"We have been working with the state Medicaid department to pursue a state innovation program grant to actually be on the ground, integrated with behavioral health," says Steve ErkenBrack, the chief executive officer for Rocky Mountain Health Plan.

The plan's approach to healthcare is centered on the primary care physician and focuses on collaboration to improve quality and efficiency. In fact, its hometown of Grand Junction, Colo., is often cited by policymakers as a benchmark location for advanced care coordination.

ErkenBrack says plan leaders have been able to see measurable decreases in healthcare costs through coordinated care efforts in hospital bed days, but he says the advantages of medical home models go beyond dollars.

For instance, the health plan has a program in which a nurse calls the patient directly 24 to 48 hours after a discharge from the hospital to make sure the patient fully understands the discharge instructions.

"Just having a telephone conversation actually lowered their unnecessary hospital readmissions, and it's better care for the patient obviously, and it's a less expensive system," he says. "You are avoiding an unnecessary hospital readmission."

The state model and Rocky Mountain Health Plan's own efforts to increase coordinated care could translate to other communities as well, ErkenBrack says.

"Western Colorado is an independent practice system," he says. "We are not a fully integrated health system or anything close to a fully integrated system. So we have to find a way to make this work for providers. That creates a community conversation, and that's what is sadly missing in a lot of communities."

## ARKANSAS

Arkansas is gaining attention for its efforts to provide an alternative to PPACA Medicaid expansion. In April, the state's governor signed a plan into law that would use federal Medicaid funds to buy private insurance for about 250,000 state residents who earn up to 133% of the federal poverty level. Under the plan, Baumgarten says individuals would receive subsidies to purchase insurance from private carriers through the state exchange, just like those who are not enrolled in Medicaid.

In this case, the network of physicians and hospitals could be wider than the existing Medicaid network, but the payment to providers would likely be higher too. Officials believe market competition would moderate prices.

Federal officials have not approved the Arkansas waiver request but are considering it. The model could be appealing for states where political posturing or opinions make expanding Medicaid eligibility a difficult proposal. Other states like Florida have also considered similar plans.

"The idea that you could do something else that sounds more like a private market solution is appealing in certain circles," Baumgarten says.

While the plan has yet to gain federal approval, Baumgarten says some of the early comments suggest that the Arkansas Medicaid model could have costs similar to Medicare Advantage and could cost the federal government more than its standard contribution to other state expansions by comparison.

"It's an interesting mix of political considerations layered over the specific interest of expanding coverage and trying to do it in a way that is acceptable to the leaders of the state," he says.

Whether it's a single payer system, state support of the medical home concept or hospital rate setting, it's clear that each state is establishing its own unique definition for healthcare reform. Over time, some concepts will prove more viable than others, but in many ways it's too early to tell which models will rise to the top or be translatable to other states looking for answers.

While the large diversity in reform efforts presents some challenges for national insurers who have to adapt to each individual state's policies and regulations, overall the variety in approaches could yield to innovation and more investment in approaches with in-practice results.

"As a whole I see diversity as a good thing," Baumgarten says. **MHE**

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*Jill Sederstrom is a freelance writer based in Kansas City.*

# PLANS DEVELOP COST Tools

## Transparency still has a long way to go

by Jennifer Webb

When Barack Obama hit the campaign trail to lobby for healthcare reform, along the way he developed a minor skin rash. The cream he was prescribed cost him $5, so even though it wasn't working very well, he had the prescription refilled. The third time he filled the prescription—this time at a different pharmacy—the cream cost $450.

"The president said, 'Wait a minute. This rash is not that bad,'" retells Rep. Michael C. Burgess (R-Texas), noting that Obama chose not to fill a prescription with a significant out-of-pocket cost.

The president related the story to legislators as an example of why prescription drug costs are in need of reform. But Burgess believes Obama "became an informed consumer."

Such forthcoming price information is vital for consumers to make knowledgeable decisions about their health and budget, he says, and to rein in healthcare spending that has seemingly little correlation with quality.

The large national health payers—and increasingly, smaller, regional payers—seem to agree. In recent years, they have begun to develop tools aimed at helping consumers understand the costs they may incur with various health procedures, prescriptions and durable medical equipment. Such price transparency signals a paradigm shift that elicits cataclysmic descriptions like "tidal wave" in its ability to revolutionize healthcare.

"This is a gun loaded not just at hospitals and doctors but at every sector of healthcare, and what they simply must do is quickly arrive at some uniformity of measures that are valid and reliable that can feed the appetite of this transparency engine and accept that it's the new normal," says Paul H. Keckley, PhD, executive director for the Deloitte Center for Health Solutions. "It's the way it's going to have to be."

### CHANGING MARKET EXPECTATIONS

As consumers are expected to pay increasingly greater shares of their healthcare costs, they are demanding more information that could transform healthcare decisions into something akin to buying a television. The key, health industry leaders and analysts say, is that this information must be delivered in readily available, accessible and understandable price transparency tools designed for average consumers.

Suzanne F. Delbanco, PhD, executive director of Catalyst for Payment Reform (CPR), a group of employers promoting price transparency, says health plans are finally responding to a call she has made since 2000.

"For the most part, health plans are working fast and furiously to create transparency tools for consumers that help them make more informed decisions," Delbanco says.

However, she says, there is a wide range of sophistication in the tools and how much consumers are using them. In March, CPR released a scorecard showing that 98% of plans offer some cost-calculator tool, but only 2% of members were using them.

"A lot of health plans can check a box and say 'we've got a tool,' but they're not necessarily making them relevant to their patients yet," Delbanco says. "For the most part, the health plans we communicate with are fully aware that we're in an era where these tools are needed and expected, but some health plans are fairly restrictive as to how their members gain access to data."

In a CPR study earlier this year, only New Hampshire and Massachusetts earned "A" grades for having state laws requiring healthcare price transparency and good public access to that information. Five states earned "B"s; 29 states earned "F"s.

### ONLINE TOOL

Michigan-based Priority Health will roll out its transparency tool in late summer to allow its more than 600,000 members to compare prices and quality for 300 most-used health services. By partnering with Healthcare Blue Book, the payer says it will enable members to compare costs by procedure, facility and physician.

"Our motivation to do this is that it will help patients save dollars and, in turn, save dollars for their employers," says John Fox, MD, associate vice president of medical affairs at Priority Health. "Patients have more out-of-pocket costs, and I think certainly patients have a right to know what they're buying and how much it's going to cost. And, if there's no difference between one service and another, then they have a right to shop."

Priority Health's online tool will list a current "fair price" for each procedure in each market, then list facilities by their cost and identify them as "green" (at or below the fair price), "yellow" (slightly above the fair price), or "red" (above the fair price).

"One of the values of transparency is healthcare costs act more like they would in another market," says Fox. "There are some systems that may be able to justify [a higher cost], and it will be left to the patients and their physicians to decide what is best."

Consumers and employers are becoming more aware of the vast price variations within a given market, especially after the U.S. Department of Health and Human Services released data last month showing price differences for common procedures. For example, services to treat heart failure range from $21,000 to $46,000 in Denver, and from $9,000 to $51,000 in Jackson, Miss.

Hospitals that charge especially high rates will face higher scrutiny, according to officials at the Centers for Medicare and Medicaid Services (CMS). However, industry observers were outspoken about the fact that the release of the hospital charge data is only a small step. The huge volume of information hardly translates into any type of action on the part of healthcare consumers.

But the fact that CMS and federal officials are openly sharing and discussing price variation is encouraging to many. Often such scrutiny leads to industry self-regulation to discourage new federal or state regulation.

"There's no question in my mind that the future of this healthcare system will entail much more transparency," Delbanco says. "It's really up to the healthcare industry how we get there. There's going to be such demand for transparency that it's going to happen, one way or the other."

## FEDERAL LEGISLATION

Scrutiny is exactly what Burgess wants. In legislation he has introduced every year since 2006, Burgess—a physician—seeks a federal law that would direct states to establish and maintain provisions requiring disclosure of information on hospital charges. The bill also would require hospitals and health plans to provide that pricing information to the public, along with their estimated out-of-pocket costs. The bill, called the Health Care Price Transparency Promotion Act, has bipartisan support and is endorsed by the American Hospital Assn.

Although the Patient Protection and Affordable Care Act does include a provision aimed at transparency, Burgess says it became so watered down that additional legislation is necessary.

As more Americans turn to high-deductible, consumer-driven plans today, they expect more information about cost, he says. Burgess himself is enrolled in a consumer-driven plan.

The U.S. Department of Labor, citing a study published by National Business Group on Health and Towers Watson, says 2% of companies with 1,000 or more employees offered consumer-driven health plans in 2002, whereas 54% offered such a choice in 2010. CPR's Delbanco says that number is closer to 66% now.

Such plans are proving more popular with employers and enable consumers to decide how to spend—or save—their healthcare dollars, Burgess says. He wants consumers to have three sets of data: the actual cost of the procedure; the price the consumer will be charged; and some quality measure.

"If they have the information, they're going to make good decisions," he says. "We can trust them to do that."

Making quality information available along with prices could help consumers rethink the assumption that higher price means higher quality, Delbanco says.

"Because we know there's almost no correlation between price and quality, it can be very misleading if only price is out there," she says.

It's a significant culture shift, too.

"That's the biggest myth in the delivery system—that higher charges mean higher quality," Deloitte's Keckley says. "The younger folks get it, they know that's not the case, but if you challenge that with seniors and people in their 50s, they still hold to that."

## WAYS TO IMPLEMENT

Health plans should have easily searchable websites with relevant and easily accessible data. Keckley says studies show data should be simplified and presented in symbols that are easy to comprehend.

"Consumers gloss over when they see nominal data," he says.

In fact, a recent study by PwC notes that consumers are overwhelmed by the information they can access and don't always know where the trusted sources might be. Fewer than half of the 1,000 consumers surveyed had read a healthcare review online and only 21% had used a review to choose a doctor.

"The irony will be if we overwhelm people with data, and they don't have any information," Keckley adds.

Online and mobile apps that consider costs in each market based on each plan will be critical. Stakeholders are still in an early stage of developing the tools, however.

Price information in particular must be personalized and specific. Priority Health's tool will calculate an individual's deductible level to more accurately predict the out-of-pocket cost of medical procedures and equipment.

"At the end of the day, that's what patients want to know," Fox says. "It's just an imperative that we do our due diligence to get that correct."

Although the healthcare market is still quite fragmented—with some 397 health plans, 5,800 hospitals, 6,000

medical device companies, and so on—payers and providers must move quickly to keep up with a singular demand for transparency, Keckley says.

"I think transparency is going to be a reality in the bigger health plans and bigger employers in the next two to three years," Delbanco says. "It's imminent."

But information is not necessarily knowledge, says Christine Evans, senior marketing manager at Castlight Health, a San Francisco-based transparency software developer.

She believes the healthcare market is "onboard with transparency" to deliver better and more affordable care. Self-insured companies using price transparency programs have seen a 13% reduction in healthcare spending versus their projected trend, she says.

"The movement has started," Evans says. "People have gotten a taste of some of the information that is out there. In an ideal world, we'd love to get to the point where price and quality of care is open to everybody and we create a truly efficient market."

However, not everyone wants the information "open to everybody" because of competitive pressures and privately negotiated contracts.

Megan Cundari, the American Hospital Assn's senior associate director for federal relations, says hospitals are in favor of transparency—within a given plan and its members.

"If you're putting it on a public website, that's where we start to get nervous," Cundari says. "We consider those negotiated rates proprietary information. We feel that's information that should be kept between negotiated parties."

Plans also need to be careful that they don't direct consumers to one provider over another, she notes.

"An insurance company can try to give its policyholders as much information as possible, but I don't think it can tell them where to go," Cundari says. "They can suggest, but it's ultimately a policyholder's decision."

Still, the AHA supports Burgess' proposal for a state-based reporting system.

"We want to build on what they're already doing instead of there being some national reporting requirement," Cundari says.

## PAYER TRANSPARENCY

As the call for price transparency gains acceptance, Deloitte's Keckley says health plans must be prepared to reveal more about themselves.

Millennials and Generation Y-ers are demanding greater access to such information throughout society, he says, and health plans must disclose information in four areas to build credibility:

- Coverage and denials;
- Executive compensation;
- Risk-based contracts with providers; and
- Granular-level price transparency.

Younger consumers adopt an "occupy healthcare movement" that's skeptical of a health system they don't understand, he says. They assume there is unnecessary profit and waste among not only hospitals and doctors, but insurance plans.

He advocates administrative simplification in which plans share transparency mechanisms and develop consistent methods to evaluate hospitals, doctors and themselves.

"That's where the health plan industry loses credibility," Keckley says. "It's the chief proponent of health transparency and cost, but about its own operation there's reluctance. It's obvious in the data that health plans still don't enjoy the complete trust of consumers, and employers view health plans as not having delivered as much value as health plans say they do."

Many consumers think health plans enjoy 30% to 50% margins or more, when the reality is probably closer to 7%, he says. Health plans could counteract such misinformation by being more transparent themselves.

"The notion of standardizing a definition of administrative costs and publishing that does expose one to competitive pressure, but that's exactly the kind of thing that dispels myths," Keckley says. **MHE**

### Report Card on State Transparency Laws

Based on varying levels of price information and public access to information

| | |
|---|---|
| Alabama | F |
| Alaska | F |
| Arizona | F |
| Arkansas | D |
| California | D |
| Colorado | B |
| Connecticut | F |
| Delaware | F |
| Florida | D |
| Georgia | F |
| Hawaii | F |
| Idaho | F |
| Illinois | C |
| Indiana | F |
| Iowa | C |
| Kansas | F |
| Kentucky | C |
| Louisiana | D |
| Maine | B |
| Maryland | F |
| Massachusetts | A |
| Michigan | F |
| Minnesota | B |
| Mississippi | F |
| Missouri | F |
| Montana | F |
| Nebraska | F |
| Nevada | C |
| New Hampshire | A |
| New Jersey | F |
| New Mexico | F |
| New York | F |
| North Carolina | F |
| North Dakota | F |
| Ohio | D |
| Oklahoma | F |
| Oregon | F |
| Pennsylvania | F |
| Rhode Island | F |
| South Carolina | F |
| South Dakota | C |
| Tennessee | F |
| Texas | D |
| Utah | C |
| Vermont | C |
| Virginia | B |
| Washington | F |
| West Virginia | D |
| Wisconsin | B |
| Wyoming | F |

**Source:** Catalyst For Payment Reform, "Report Card on State Price Transparency Laws," March 18, 2013

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# Risk adjustment audits can actually be helpful to plans

## Long-term gains outweigh the short-term pains

BY KIM BROWNING

FOR PLANS offering Medicare Advantage (MA) products, or soon to be offering products in the health insurance exchanges, Risk Adjustment Data Validation Audits (RADV) have become a four letter word. In fact, just hearing the term can raise a leader's blood pressure and get them thinking about the plan's risks. For MA, the plan must be informed if it has been selected. For exchanges, plan leaders wonder what resources they will need for the annual audit, which members will be selected and how much might be at stake financially.

These are all legitimate questions—if a plan is actually selected for a RADV. But the purpose of this article is to suggest both an alternative attitude and concrete preparations your plan can take to prepare. Specific behaviors and changing the perception of what it means to have, and prepare for, a RADV can go a long way.

In general, the current risk adjustment methodology relies on enrollee diagnoses to prospectively adjust capitation payments for a given enrollee based on the health status.

### PERCEPTION IS REALITY

For executives responsible for risk adjustment, very few ask: "How can a RADV audit actually help our plan?"

RADV audits can help by confirming that a plan has actually captured the most accurate and complete diagnostic information about its members to deliver the right care to those members based on their needs. Put another way, the original intent of what risk adjustment has set out to accomplish is capturing the right information to deliver the right care.

If preparing for the RADV accomplishes this goal, it is obviously a positive step.

This is not to minimize the legitimate downside risks of an unsuccessful audit: financial impacts, operational conflicts, reputation decline, strained network relationships, etc. But when considering the big picture, the long-term gains outweigh the short-term pain.

For example, a plan is unlikely to want to be paid incorrectly for inaccurate information. With the right information about a plan's members, the ability to care for them will pay benefits down the road.

### AN OUNCE OF PREVENTION

First off, plans must dissuade themselves from the notion of preventing a RADV. Put simply, that is not possible. Second, there are ways to mitigate—but not completely eliminate—some of the risk by implementing some or all of the five action steps described below.

## 1 Promote an internal attitude change

If perception is reality, perhaps leaders can change the perception of a RADV by becoming internal champions. Communicating an attitude within your plan that RADV is not a threat but rather an opportunity could go a long way toward reducing the perceived burden a RADV has placed on your plan.

## 2 Reduce or eliminate taking risk adjustments solely from claims

Not surprisingly, a fair number of plans continue to take risk adjustments solely from claims. Instituting a robust coding effort makes good economic sense. In fact, according to the Government Accountability Office, risk scores for

Kim Browning is executive vice president of Cognisight, LLC. She can be reached at *kbrowning@cognisight.com*.

Medicare Advantage beneficiaries were on average 5% to 8% higher than those of fee-for-service after coding strategies were deployed. Moreover, plans can expect a 2% annual increase in scores for MA plans from better clinical coding. For example, each 1% of clinical documentation improvement can yield payments from 1% to 5% of individual and small group premiums. Plans should expect a similar impact with the health insurance exchanges.

## 3

## Don't neglect to retrospectively review the charts of members who have had in-home prospective assessments

Just because a member of a plan has been prospectively reviewed does not guarantee that no additional risk adjustments will be captured in their other medical records. Done well, a prospective assessment will capture the right diagnostic information for the member. However, the assessment will not completely eliminate additional diagnostic information found in the charts. For example, one organization had carved out 5,000 members from retrospective reviews because they had been prospectively reviewed earlier in the same year. After completing a retrospective review for these members, the organization recovered almost $400,000 from those members.

## 4

## Conduct an internal audit

There is continued debate about the pros and cons of conducting an internal audit. Some risk adjustment professionals suggest it is simply a waste of time and money because there is no way to guarantee that the diagnoses substantiated in the internal audit will be the same ones that Medicare selects. While this is true, a plan must consider completing an internal audit to determine where the risks are as well as to prepare operationally for the actual RADV. A RADV audit is time and labor intensive.

Conducting a dry run in the form of an internal audit will help prepare all parties involved by giving them the chance to determine where the land mines are and also work out the operational kinks.

### MHE EXECUTIVE VIEW

- **Capture the right information to deliver the right care.**
- **Remember as much as 20% of claims' diagnostic information is incorrect.**
- **Don't wait; proactively get in front of the challenge of RADV.**

## 5

## Consider instituting a Risk Verification Program

Perhaps the most important option for plans, one that is neither inexpensive nor easy, is to proactively substantiate diagnoses that have been previously submitted before they even get selected for a RADV. To some executives, this may seem to be a radical idea. But if one goes back to the true intent of risk adjustment—the most accurate and complete capture of member's diagnostic information—implementing a risk verification program simply supports this intention. Most experts suggest that upwards of 20% of claim-based diagnostic information is wrong—one out of every five diagnoses. In other words, a plans' disease and case management professionals are working with inaccurate information.

It's not just about the money. But it does boil down to how much money a plan is willing to invest to not only reduce the risk of RADV financial payments but also paint the most accurate picture of its members.

So how can a risk verification program be implemented that doesn't break the bank and will legitimately reduce a plan's risk?

The RADV extrapolation methodology segments the targeted diagnoses into three equal payment stratums—high, medium and low. A plan could consider targeting the highest paid stratum, or about one-third of its population, and verify the diagnoses for those individuals.

Our organization modeled such an approach for a plan with 20,000 members using a 10% and 20% error rate. The results are significant. By verifying the top one-third diagnoses, or approximately 7,000 members, the plan reduced its payment recovery between $3.2 million and $12.7 million, or a 4% to 8% reduction in error rate. Deciding to move forward with risk verification will depend on the cost of that service and the plan's threshold for the projected return on its investment.

### THE BOTTOM LINE

Plans do not have easy decisions to make when it comes to RADV. Ultimately, the determination comes down to a simple decision. Does a plan take a wait-and-see approach and hope things work out well? Or does a plan proactively get in front of the challenge? Our guidance is to get in front of the challenge. Only then can a plan truly protect itself from the RADV downside risks and ultimately optimize the healthcare services being delivered to its members. **MHE**

# Few care models manage Alzheimer's members

## National program aims to accelerate treatment

BY SUSAN SANDLER

ALTHOUGH few models have emerged for managing care and costs of Alzheimer's disease, some coordinated care models in limited use show promise. The aim is cost control while providing care that avoids or delays nursing home residency. Additional models are in development under the National Plan to Address Alzheimer's Disease, released last year.

In 2012, the average annual per-person payment for health and long term care for Medicare beneficiaries over age 65 with Alzheimer's and other dementias was $45,657—more than triple the average $14,452 payment for beneficiaries without the condition, according to the Alzheimer's Assn. Medicare and Medicaid pay 70% of care costs; the balance is covered through private insurance, out of pocket or other payers.

The association estimates that aggregate costs for healthcare, long-term care and hospice for Alzheimer's and dementia patients will rise from $203 billion this year to $1.2 trillion by 2050.

Almost all Alzheimer's patients—about 96%—are on Medicare, says Matthew Baumgart, senior director of public policy for the Alzheimer's Assn. He estimates that 500,000 to 800,000 Alzheimer's patients are enrolled in Medicare Advantage plans. There is very little data about Alzheimer's-specific care models today, and he says that cost data can be hard to gather with Medicare Advantage's capitated structure.

Initiatives under development by the National Alzheimer's Plan—which was authorized by President Obama in 2011 and is managed by the Department of Health and Human Services—should help to provide more information as well as additional financial resources to fund the project. Coordinated care and treatment are just two of many goals; others include more research and services across multiple federal agencies, accelerating treatment development and improving early diagnosis.

The Center for Medicare and Medicaid Innovation (CMMI) is testing payment and service delivery models to cut Medicare and Medicaid costs while maintaining or enhancing the quality of care for beneficiaries.

Although not Alzheimer's/dementia-specific, some of the CMMI's work could apply to Alzheimer's and dementia care. For example, CMMI's medical home models use a team approach to provide care and improve healthcare quality and coordination, and the Independence at Home Demonstration tests a payment and services system with physicians and nurse practitioners coordinating home-based primary care with long-term services and support.

Annual health costs for Medicare beneficiaries with Alzheimer's and other dementias who live in their communities averaged $26,869 per person in 2012, while the costs for those in a residential facility averaged $71,917, according to the association's Facts & Figures report.

### COORDINATED CARE

Managed care plans may hold the key to the best patient management as well as cost controls, since managed care is "a little ahead of the curve" with its coordinated care philosophy, Baumgart says. The approach is especially helpful in addressing the population's needs, since more than 75% of Alzheimer's patients have other chronic conditions, he says. Common comorbid conditions include coronary heart disease, diabetes and congestive heart failure, according to the Alzheimer's Assn.

There are only two Medicare Advantage Special Needs Plans (SNP) for individuals with dementia. Universal Health Care offers an HMO in 21 counties in Florida, and Medica Com-

Susan Sandler is a freelance wrtier based in Rockville, Md.

plete Solution offers an HMO in 22 counties in Minnesota.

Medica's SNP was established in 2008 and now has 26 participants, says Julie Faulhaber, senior director, state public programs. Another plan in the state, the Minnesota Senior Health Options Plan, is a dual eligible plan with 9,600 participants. While there is no data on the total number of enrollees with dementia, Faulhaber believes it is a "significant number."

The care coordination model for the two programs is similar, and each program is set up for either home or facility residency. In the home environment, care coordination staff are usually registered nurses or licensed social workers. They assess the patient as well as create and adjust a care plan.

For facility enrollees, a nurse practitioner is the primary care person and a similar care plan is developed. In addition to healthcare, the programs provide services such as home-delivered meals for enrollees who live at home and family support services to ensure health and safety.

"We are maintaining the programs with the money from state and federal governments, and that says it is working," Faulhaber says.

Coordinated care is a logical approach to managing Alzheimer's and dementia patients, since those enrollees often suffer from other chronic health problems, says Andrew Davis, vice president for the Center for Healthy Aging at Medica. Proper diagnosis is important for Alzheimer's and dementia patients, and cognitive assessment can be part of patient management where warranted.

"Don't think of dementia as a standalone disorder," Davis says. "Think of it as part of the fabric of managing the beneficiary's health."

While these programs are small in scope, they represent possibilities that can help care for Alzheimer's and dementia patients beyond the limitations of Medicare fee-for-service. Davis says in fee-for-service plans, there is not a lot of support for the patient and the family unless a physician is willing and able to help. It is "a missed opportunity that will affect treatment and drive costs," he says.

One existing model that shows promise for managing both care and costs for Alzheimer's patients is the nonprofit Program of All-Inclusive Care for the Elderly (PACE). An estimated one-half of program participants have Alzheimer's or some other dementia, says Robert Greenwood, vice president of public affairs for the National PACE Assn.

PACE provides comprehensive long-term services to Medicare and Medicaid enrollees that include healthcare, hospitalization and emergency care, as well as social support such as door-to-door transportation to and from day centers. The day centers are the hub of a PACE program serving as medically intensive facilities that provide health services, care coordination, nutrition, family services and administrative support. Some centers are adding separate activity rooms for those with cognitive disabilities.

Most PACE enrollees live at home; just 8% are in nursing homes, Greenwood says. If nursing home care becomes necessary, the cost is covered by PACE. A team of healthcare professionals meets daily to assess and coordinate care for the 150 to 180 participants at each center. Some PACE programs have over 1,000 enrollees in multiple centers, including San Francisco, Denver and New York City. About half of the programs operate with more than one center.

There are 92 PACE programs in 29 states with 29,000 enrollees, Greenwood says.

PACE is a lower cost approach since providers are paid 85% of what the state would expect to pay for fee-for-service plan costs. Helping to sustain patients at home—the key goal of PACE—instead of in a facility also provides substantial savings.

Currently there are five FDA approved drugs to treat symptoms of Alzheimer's disease. According to the Alzheimer's Assn., new drugs in development aim to modify the disease process and halt its progression. There are no known preventive measures, so manage care's task is to help coordinate care and social supports. **MHE**

## FDA-approved medications to treat Alzheimer's symptoms

| Drug | Brand Name | Approved For | FDA Approval |
|---|---|---|---|
| Donepezil | Aricept | All stages | 1996 |
| Galantamine | Razadyne | Mild to moderate | 2001 |
| Memantine | Namenda | Moderate to severe | 2003 |
| Rivastigmine | Exelon | Mild to moderate | 2000 |
| Tacrine | Cognex | Mild to moderate | 1993 |

**Source:** Alzheimer's Association

# Acid reflux guidelines reduce overuse of testing services

## Start with lifestyle modifications prior to testing

BY LISA ZAMOSKY

THE OVERUSE of medical tests and procedures remains a major issue of concern in the United States. Gastrointestinal (GI) disorders, including gastroesophageal reflux disease (GERD), are an area of clinical practice in which the overuse of diagnostic procedures adds unnecessary cost. GERD is the most common GI-related diagnosis, representing 8.9 million patient visits.

According to data from the Centers for Disease Control and Prevention (CDC), outpatient GI endoscopy exams alone, which are commonly used to diagnose GERD and rule out related illness, cost the healthcare system $32.4 billion annually. The Institute of Medicine estimates $765 billion worth of waste in the U.S. healthcare system annually, $210 billion of which is comprised of unnecessary medical services.

### LACK OF EVIDENCE

GERD, a chronic digestive disease marked by acid reflux that irritates the lining of the esophagus, is fairly common. At least 40% of the U.S. population experiences at least one episode of heartburn monthly, according to an October 2012 paper "Managing chronic gastroesophageal reflux disease," published by the American Academy of Family Physicians (AAFP).

"I see people daily who are treated for GERD. It may not be why they are there in my clinic, but I am definitely seeing them every day," says Dean Seehusen, MD, MPH, an AAFP member and co-author of the AAFP paper.

Also relevant but often overlooked is the evidence demonstrating that, in many cases, upper GI endoscopy to diagnose GERD and/or rule out other related illnesses is performed unnecessarily.

According to Nicholas Shaheen, MD, MPH, director of the Center for Esophageal Diseases and Swallowing at the University of North Carolina School of Medicine, Chapel Hill, the literature shows that anywhere from 10% to 40% of upper endoscopies performed for GI concerns do not conform to clinical guidelines.

What's more, the rate at which upper endoscopy is used is increasing. Nationwide, a 40% increase has occurred in its use in the past decade among Medicare patients.

"We're spending a lot of money," Dr. Shaheen says.

Much of that money seems to be wasteful given scant evidence to support the use of endoscopy in diagnosing GERD, experts say.

According to Dr. Seehusen, if the clinical picture fits GERD with no other complications, such as a patient who is coughing up blood, has difficulty swallowing, or is losing weight, then it is easy and relatively inexpensive for providers to perform a trial of treatment, including lifestyle modification and medications.

"If you do a trial of treatment and it helps, then you pretty much have your diagnosis," Dr. Seehusen says.

Still, the pressure to test can be great, particularly in patients whose conditions don't improve over time.

"All of us want to do right by our patients but are often not sure of what's useful and what will be helpful. There is just so much to keep up with," says Molly Cooke, MD, president of the American College of Physicians (ACP).

When the condition is long-standing, many physicians understandably worry about the possibility of missing something more serious, such as esophageal cancer.

"Heartburn is extremely common, and all physicians appreciate that some patients with chronic heartburn end up with esophageal cancer," Dr. Cooke

Lisa Zamosky is a freelance writer based in Tustin, Calif.

says. "It's a little like the headache and brain tumor situation. The vast majority of people with a headache don't develop a brain tumor, but many patients with tumors have headaches. To decide is hard."

## GUIDELINES TOUGH TO FOLLOW

A lack of clarity in the professional guidelines is another major cause of endoscopy overuse.

"We, as a field, have done a good job of confusing generalists about when to do this test. Part of what we see in terms of inappropriate utilization is our own fault for not giving people unambiguous guidance," says Dr. Shaheen, lead author of the ACP's new guidelines.

The guidelines indicate that endoscopy should not be used to screen for GERD in the general population. They were developed for internal medicine and family physicians as well as other clinicians who diagnose and treat GERD.

The ACP clinical guidelines, published in the December 2012 edition of the *Annals of Internal Medicine*, outline the confusion caused by competing guidelines among three major U.S. gastroenterologic professional societies.

- The American Society of Gastrointestinal Endoscopy recommends that screening upper endoscopy be considered "in selected patients with chronic, longstanding GERD;"
- The American Gastroenterological Assn. recommends against screening the general population with GERD for Barrett's esophagus—a condition in which cells change after a history of GERD—and esophageal adenocarcinoma, but say that it should be considered in patients with GERD who have several risk factors associated with esophageal adenocarcinoma; and
- The American College of Gastroenterology guidelines note that "screening for Barrett's esophagus in the general population cannot be recommended at this time. The use of screening in selective populations at higher risk remains to be established, and therefore should be individualized."

Two particular ACP guidelines stand out: upper endoscopy should not be routinely performed in women of any age; and men under 50 years who have heartburn should not routinely be screened via upper endoscopy.

The incidence of cancer in both these populations is very low. In fact, a woman with heartburn has a lower risk of esophageal cancer than a man without heartburn.

"It doesn't make a lot of sense to be scoping the women with heartburn but not the men without heartburn if you want to stop the cancer," says Dr. Shaheen.

In the end, it seems that heartburn is not a very useful marker of cancer risk. In fact, esophageal cancer in heartburn sufferers affects only about one in 2,500 patients over age 50 each year, according to a 2012 report by Consumer Reports, ACP and the *Annals of Internal Medicine*. Even among people with Barrett's esophagus, the risk of cancer is quite low.

## OTHER PRESSURES

Another possible reason cited for the overuse of endoscopy ties in with physicians' concern over missing a diagnosis of cancer. Patients with unexplored symptoms could be viewed by their providers as having a higher medical-legal risk.

Then there's the culture of expectation among some groups of patients who want their symptoms fully explored. Americans have become accustomed to being repeatedly checked for a medical problem. In some cases, that approach is clinically advisable, but not so in the case of GERD.

Of course, the economics of testing and its benefit to endoscopists' business cannot be overlooked as another possible cause of overuse.

As new budget-based payment models associated with accountable care organizations (ACOs), medical homes and shared savings programs increase in prominence compared with traditional fee-for-service models, those incentives likewise will shift.

## ELIMINATING OVERUSE

Providers can take several steps to reduce the improper use of testing in patients with GERD that can help to lower healthcare costs overall. On average, upper endoscopy costs more than $800 per examination, according to the ACP.

Dr. Shaheen says many physicians will send patients with heartburn for recurrent exams as "checkups" for heartburn.

In fact, a patient with chronic heartburn for five years who has had a single endoscopy that was clear does not need to be tested again unless other troublesome symptoms, such as anemia, weight loss, or difficulty swallowing, arise. Most cancers show up early on in a patient experiencing symptoms. If it didn't show in the initial test, it's unlikely to be an issue, Dr. Shaheen says.

Dr. Cooke advises providers' use of an electronic health record (EHR) system to support effective testing.

"The holy grail would be the integration of guidelines into the medical record," she says. "You could imagine one set up so that, if I referred a patient to a gastroenterologist with the diagnosis of GERD, the record would just remind me that unless the patient has red-flag symptoms—if she is a woman or a man under 50—he or she probably does not need an endoscopy."

She points out that EHRs can also be used as a tool to educate patients who do not need further testing.

Finally, Dr. Seehusen of the AAFP

suggests a general orientation toward using step therapy, in which the least expensive treatment to manage GERD is used as a first step. Members can start with lifestyle modification that will cost less than treatments.

"Limiting your diagnostics to only those patients who you have a high index of suspicion for underlying Barrett's or underlying malignancy is the right answer," Dr. Sheehusen says. "You do not need to do endoscopy on everyone who walks through the door." **MHE**

*This article originally ran in Medical Economics.*

## Colonoscopy remains high-value preventive care

The United States Preventive Services Task Force and most gastroenterology organizations recommend that adults get screened for colorectal cancer (CRC) every 10 years beginning at age 50 via fecal occult blood testing (FOBT), sigmoidoscopy or colonoscopy. People at high risk are recommended to get screened earlier and sometimes more frequently.

"There's enough data to show that if you catch colorectal cancer early enough it's treatable," says Brian Hemstreet, PharmD, FCCP, BCPS, associate professor and director of Pharmaceutical Care Learning Center, University of Colorado Anschutz Medical Campus. "Colon cancer is one of the top cancers in the U.S. so the impact of the screening is a lot higher than it is for some of the rarer cancers."

Hemstreet says quandaries can occur because the right amount of surveillance for patients with a history of colon cancer is uncertain and colonoscopies can be very costly. In the long run, however, it's more effective than managing patients with CRC.

"Even if it only prevents two or three polyps from developing into full-blown cancer, from a monetary perspective it's pretty cost-effective and far easier to manage than the alternative," says Geoffrey Wall, PharmD, FCCP, BCPS, CGP, professor of clinical sciences, Drake University College of Pharmacy and Health Sciences and internal medicine clinical pharmacist, Iowa Methodist Medical Center.

Technology might cut back on the amount of colonoscopies conducted in the future. Hemstreet says CT scanning is rapidly approaching the level of accuracy that colonoscopies have.

"While CT scans are certainly going to be expensive, they're going to be less expensive than a full-blown colonoscopy," he says. "It will help screen out patients who don't need one, which of course makes them happy because not too many patients are jumping up and down to get a colonoscopy."

### MANAGEMENT AND PREVENTION

For the past eight years, Cigna has worked to combat CRC with an award-winning screening program. This past March, during National Colorectal Cancer Awareness Month, the program reached 2 million people that were due for a screening through online messages and direct mail. Highlights include:

About 300,000 newly eligible individuals, age 50 through 64, whose claims data showed they hadn't had a screening received information in the mail about CRC tests, including colonoscopy. Members also received information on dealing with CRC symptoms.

The same members were offered the chance to request the InSure FIT screening kit, an at-home test that detects abnormalities in the lower gastrointestinal tract through a sample of fecal matter. Through an agreement with the manufacturer, the kits are free of charge and lab fees are covered as a preventive benefit. Confidential results are mailed to members who are encouraged to share with their physician.

About 11,000 Cigna customers were selected to receive the InSure FIT kit because, based on Cigna claims data, they completed either the at-home kit or a FOBT in the last three years and did not get a follow-up colonoscopy or sigmoidoscopy this year.

Members age 50 to 64 saw a targeted message about CRC screening and the InSure FIT kit when they logged on to Cigna's web portal, myCigna.com.

### SEEING RESULTS

In March 2012, the program reached nearly 542,000 customers. Claims data showed that nearly 31,000 had a screening—a rate of 5.7% compared to 4.4% in 2010.

Among the members, colonoscopies had the highest screening rate at 57% of all screenings, while the InSure FIT and the FOBT accounted for 43% of screenings. Fifty percent had normal findings, 48.8% detected polyps that were removed, and 1.2% resulted in a diagnosis of CRC.

Cigna also worked with supermarket operator Harris Teeter in 2012 to develop a campaign including e-cards and a newsletter. As a result, employees and beneficiaries had a screening rate of 20.6%—nearly four times the Cigna national average.

*—Julia Brown*

# PBMs concerned oversight involves conflict of interest

## State boards of pharmacy would see PBM data

BY MARI EDLIN

PHARMACY BENEFITS MANAGERS (PBMs) are concerned about states that are considering turning over the regulation of PBMs to state boards of pharmacy. Typically, state insurance commissions oversee PBMs. To date, only Mississippi has passed such legislation.

"State pharmacy boards comprised of pharmacists will be out for their own best interests since they compete with PBMs and their mail-order businesses," says Ed Buthusiem, director, Berkeley Research Group's Healthcare Practice in Washington, D.C. "Pharmacies could buy directly from manufacturers and drive drug costs up."

Buthusiem says it's been a 10-year debate over the role of PBMs and believes that most states will not pass a law giving state pharmacy boards authority for overseeing them.

"The boards should only be responsible for monitoring the behavior of pharmacists and licensing professionals in the discipline," he says.

He is concerned that if boards assume oversight, PBMs will be required to disclose costs, and once that proprietary information is available, pharmacists will leverage it to their own competitive advantage. Ironically, a 2006 survey by the International Foundation of Employee Benefit Plans found that 69% of plan sponsors using a pharmacy benefit manager require their PBMs to pass through all manufacturer rebates, discounts, fees and other payments. The survey also indicated that 63% of plan sponsors require an unrestricted right to audit their PBMs.

"It is a conflict of interest to be regulated by those with whom PBMs contract, those who negotiate their payments. It would open up a hornet's nest," says Mark Merritt, president and CEO of the Pharmaceutical Care Management Assn. (PCMA).

PCMA threatened to sue Mississippi this year for attempting to push through additional regulations that would have imposed fiduciary mandates on PBMs. The state backed down. The initial regulation allowing the state board to oversee PBMs passed in April 2011.

"We understand the need to be regulated, but we already are by state insurance commissioners," Merritt says. "Transferring responsibility to a board of pharmacy would only bring value to retailers. It may seem like a Mom and apple pie scenario, but if you look more closely, retailers just want to increase their profits."

PCMA, the trade association representing PBMs, warns that the legislation is like "letting the fox guard the henhouse."

The Federal Trade Commission (FTC) stated that such provisions could make collusion easier and increase prescription drug prices if a pharmacy board obtains and discloses PBMs' competitively sensitive information.

The state of Mississippi defends its decision to move PBM oversight to its state board of pharmacy by contending that the new relationship enables the board to regulate licensing and ensure that appropriate statutes are passed—rather than meddle in PBM business.

"We have been aware of the argument against board oversight since it began, but it doesn't hold water," says Steve Parker, PBM administrator for the Mississippi Board of Pharmacy. "We have not overstepped our bounds, we have not said anything against PBMs, and we have not fined them for any of their actions."

The board charges a $500 licensure fee, which some PBMs say will cause an increases in prices.

"We are not out for blood," Parker says.

However, he is concerned that

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

transparency regarding PBMs does not exist and that payers have little idea of a PBMs' pricing spread.

"Our primary goal is to find out who the PBMs are that operate in our state and how to contact them," Parker says. "Prior to moving oversight to our board, if an issue arose with a PBM in relationship to a pharmacy, the only avenue of recourse was through a call center, a toll-free number. Now we are able to resolve 85% to 90% of problems."

He says that protecting the consumer is one of the board's key initiatives.

### SIMILAR REGULATION

Other states, including Oregon, Oklahoma and Hawaii, are considering legislation similar to that adopted by Mississippi, allowing pharmacy board oversight.

"Departments of insurance don't have the expertise or ability to oversee PBMs. They don't know what a PBM is," says Oklahoma State Representative David Derby (R-Owasso), who is also a pharmacist, and introduced HB 2100 to bring PBMs under the guidance of the state's board of pharmacy. "The pharmacy board could ensure that PBMs follow regulations. The job of the board should be to protect the public from pharmacists."

Oklahoma's legislation explicitly allows the board of pharmacy to demand confidential information about the business practices of PBMs. The bill has passed in the Oklahoma House but not yet in the state Senate. It will not come up for reconsideration until the legislature meets in 2014.

Derby says that the board of pharmacy would assume the same responsibilities as the insurance department does, monitoring the use of mislabeled drugs, inaccurate dispensing and expired medications, and would serve as the point of contact for any consumer issues related to PBM activities. A general toll-free number is currently the only vehicle.

He notes that a PBM's concern over sharing its client information if the board oversees its action is overblown.

"Sensitive materials like contracts are not open to the public," he says.

Although he admits that as a pharmacist himself, he would like to know about the financial arrangements PBMs have with drug manufacturers and how much they reimburse pharmacies for dispensing.

Matt Diloreto, director, state government affairs for the National Community Pharmacists Association (NCPA), agrees with Rep. Derby that the switch of oversight to a state board of pharmacy has been blown out of proportion.

**MHE EXECUTIVE VIEW**

- **Mississippi is the only state to allow the board of pharmacy to oversee PBMs.**
- **PBMs are concerned about turf wars and competition.**
- **Some believe patient out of pocket costs will rise.**

NCPA says it is imperative that state boards of pharmacy provide oversight to ensure that decisions are made based on the best interests of the patient—a recurring theme among state board proponents.

He says that state boards of pharmacy are the logical place for regulating PBMs, which control more lives than pharmacies, have access to electronic health records and operate as plans.

"If there is any accusation of higher costs, it has to do with the PBM, not with legislation," Diloreto says.

While PBMs question the role of the boards in their regulation—citing higher healthcare costs, disclosure of competitive information and a conflict of interest for pharmacists—NCPA notes that most state legislative proposals that would require PBM licensure by boards of pharmacy also contain provisions that would require both the board of pharmacy and health plan sponsors to treat any information disclosed to it by PBMs as strictly confidential, as it does with pharmacies and pharmaceutical wholesalers.

"Whether it be a PBM or any other entity or individual regulated by a state board of pharmacy, any conflict of interest must be identified and addressed," says Carmen Catizone, executive director, National Association of Boards of Pharmacy.

"PBMs, in terms of their regulation by state boards of pharmacy, should be responsible for the same objective and patient protection processes and goals as any other entity or individual regulated by a state board of pharmacy," he says.

### COMPETITIVE TURF WARS

Dismissing any conflict of interest, Catizone says boards must not engage in any actions that involve economic or turf protection objectives. He notes that there would be no more of a conflict of interest than if there were a health-systems pharmacist on a board regulating chain or other retail entities that may be competitors—something that he says must be monitored.

In short, Catizone says that state boards should be responsible for the self-regulation of the competency and behavior of pharmacists, as well as ensuring that they are legally accountable and responsible for their practices.

"Similarly, if a PBM is engaged in the practice of pharmacy, it should be regulated by the board of pharmacy fairly, objectively and competently," he says. **MHE**

# MHE Resource

## Contract terms more nuanced

MARKET DYNAMICS will drive future contracting trends. But certain strategic capabilities are lacking for payers and providers, according to industry experts.

"If you're in a market that hasn't done any risk sharing or if you're in a market where your competitors aren't doing certain things, there's more of a wait-and-see attitude," says Mike Meyer, president of Meyer Consulting.

More than half of respondents to the company's recent survey of contracting executives said they are actively participating in accountable care organizations (ACOs). The average number of members in their ACOs is 46,900, and the average number of years of participation is 2.1.

Meyer also says the managers working on new contract arrangements need different skills than in the past. Negotiations between payers and providers today might include consideration for risk management or technology support, for example, rather than just bickering over payment rates.

In fact, payers are looking for provider leaders to recruit for their contracting teams and vice versa.

If a large percentage of ACOs fail to meet expectations, the reason will center more on execution rather than the ACO concept itself, Meyer says. The practice of medicine is changing quickly, and ACOs and other up-and-coming contract arrangements must be able to keep up with new trends in care delivery such as personalized medicine, for example.

"It's not just market specific; it's entity specific," says Aran Ron, MD, physician partner for Meyer Consulting.

### PROVIDER SOLUTIONS

"Providers are waking up and being part of the solution rather than just being on the complaining side of the debate," says Cynthia Ambres, principal in the advisory practice of KPMG as a partner in its Global Healthcare Center of Excellence. "For many years, you heard from physicians who just didn't like the reimbursement."

Ambres says bundled payment will drive more providers into taking responsibility for patient outcomes and the cost of care. At the same time, providers need to manage care and communicate back to the payers what is appropriate for patients, including treatment and actual costs.

"These are big changes in the culture of care in the United States and that's why we are struggling so much," she says. "These are changes in physician behavior, how insurers pay, how providers accept payment and how they distribute it."

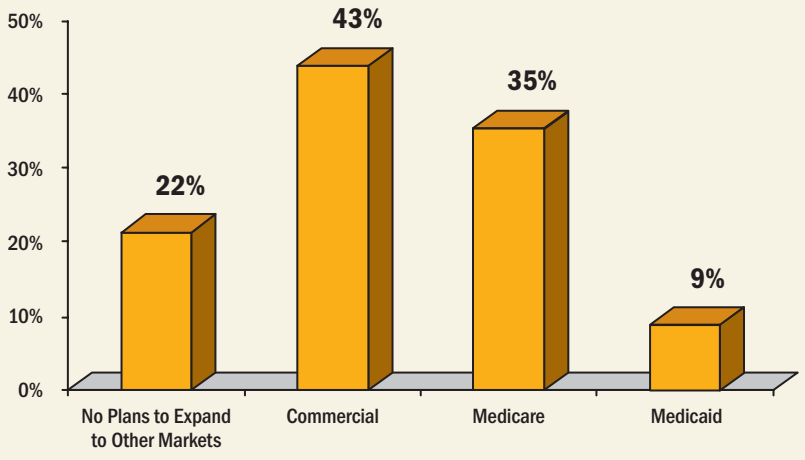
Contract terms will likely stretch across multiple years to allow for investment and improvement. Savings will take time. Likewise, payers will want more information on just what it is they're paying for.

"It's no longer just about numbers," Ambres says. "How can we change the way payments are made and move out to three-year contracts that are longer and establish a commitment between the payer and provider that was not there before?"

Over the next few years, payers must make a bridge for providers as they move from higher revenue to higher margin. Providers' revenue is going to decrease under many innovative contract arrangements, and "that's not a conversation they like to have," Ambres says. **MHE**

*—Julie Miller*

### FUTURE ACO MARKET EXPANSION




**Source:** Meyer Consulting

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# CUBICIN® (daptomycin for injection)

**Brief Summary of Prescribing Information**

**INDICATIONS AND USAGE** CUBICIN is indicated for the treatment of the following infections. **Complicated Skin and Skin Structure Infections** (cSSSI) caused by susceptible isolates of the following Gram-positive bacteria: *Staphylococcus aureus* (including methicillin-resistant isolates), *Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus dysgalactiae* subsp. *equisimilis,* and *Enterococcus faecalis* (vancomycin-susceptible isolates only). ***Staphylococcus aureus*** **Bloodstream Infections (Bacteremia), Including Those with Right-Sided Infective Endocarditis, Caused by Methicillin-Susceptible and Methicillin-Resistant Isolates. Limitations of Use** CUBICIN is not indicated for the treatment of pneumonia. CUBICIN is not indicated for the treatment of left-sided infective endocarditis due to *S. aureus*. The clinical trial of CUBICIN in patients with *S. aureus* bloodstream infections included limited data from patients with left-sided infective endocarditis; outcomes in these patients were poor [see *Clinical Trials* in full prescribing information]. CUBICIN has not been studied in patients with prosthetic valve endocarditis. **Usage** Appropriate specimens for microbiological examination should be obtained in order to isolate and identify the causative pathogens and to determine their susceptibility to daptomycin. To reduce the development of drug-resistant bacteria and maintain the effectiveness of CUBICIN and other antibacterial drugs, CUBICIN should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy. Empiric therapy may be initiated while awaiting test results.

**CONTRAINDICATIONS** CUBICIN is contraindicated in patients with known hypersensitivity to daptomycin.

**WARNINGS AND PRECAUTIONS** **Anaphylaxis/Hypersensitivity Reactions** Anaphylaxis/hypersensitivity reactions have been reported with the use of antibacterial agents, including CUBICIN, and may be life-threatening. If an allergic reaction to CUBICIN occurs, discontinue the drug and institute appropriate therapy [see *Adverse Reactions*]. **Myopathy and Rhabdomyolysis** Myopathy, defined as muscle aching or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values to greater than 10 times the upper limit of normal (ULN), has been reported with the use of CUBICIN. Rhabdomyolysis, with or without acute renal failure, has been reported [see *Adverse Reactions*]. Patients receiving CUBICIN should be monitored for the development of muscle pain or weakness, particularly of the distal extremities. In patients who receive CUBICIN, CPK levels should be monitored weekly, and more frequently in patients who received recent prior or concomitant therapy with an HMG-CoA reductase inhibitor or in whom elevations in CPK occur during treatment with CUBICIN. In patients with renal impairment, both renal function and CPK should be monitored more frequently than once weekly [see *Use in Specific Populations* in this summary and *Clinical Pharmacology* in full prescribing information]. In Phase 1 studies and Phase 2 clinical trials, CPK elevations appeared to be more frequent when CUBICIN was dosed more than once daily. Therefore, CUBICIN should not be dosed more frequently than once a day. CUBICIN should be discontinued in patients with unexplained signs and symptoms of myopathy in conjunction with CPK elevations to levels >1,000 U/L (~5× ULN), and in patients without reported symptoms who have marked elevations in CPK, with levels >2,000 U/L (≥10× ULN). In addition, consideration should be given to suspending agents associated with rhabdomyolysis, such as HMG-CoA reductase inhibitors, temporarily in patients receiving CUBICIN [see *Drug Interactions*]. **Eosinophilic Pneumonia** Eosinophilic pneumonia has been reported in patients receiving CUBICIN [see *Adverse Reactions*]. In reported cases associated with CUBICIN, patients developed fever, dyspnea with hypoxic respiratory insufficiency, and diffuse pulmonary infiltrates. In general, patients developed eosinophilic pneumonia 2 to 4 weeks after starting CUBICIN and improved when CUBICIN was discontinued and steroid therapy was initiated. Recurrence of eosinophilic pneumonia upon re-exposure has been reported. Patients who develop these signs and symptoms while receiving CUBICIN should undergo prompt medical evaluation, and CUBICIN should be discontinued immediately. Treatment with systemic steroids is recommended. **Peripheral Neuropathy** Cases of peripheral neuropathy have been reported during the CUBICIN postmarketing experience [see *Adverse Reactions*]. Therefore, physicians should be alert to signs and symptoms of peripheral neuropathy in patients receiving CUBICIN. ***Clostridium difficile*–Associated Diarrhea** *Clostridium difficile*–associated diarrhea (CDAD) has been reported with the use of nearly all systemic antibacterial agents, including CUBICIN, and may range in severity from mild diarrhea to fatal colitis [see *Adverse Reactions*]. Treatment with antibacterial agents alters the normal flora of the colon, leading to overgrowth of *C. difficile. C. difficile* produces toxins A and B, which contribute to the development of CDAD. Hypertoxin-producing strains of *C. difficile* cause increased morbidity and mortality, since these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibacterial use. Careful medical history is necessary because CDAD has been reported to occur more than 2 months after the administration of antibacterial agents. If CDAD is suspected or confirmed, ongoing antibacterial use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibacterial treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated. **Persisting or Relapsing *S. aureus* Bacteremia/Endocarditis** Patients with persisting or relapsing *S. aureus* bacteremia/endocarditis or poor clinical response should have repeat blood cultures. If a blood culture is positive for *S. aureus*, minimum inhibitory concentration (MIC) susceptibility testing of the isolate should be performed using a standardized procedure, and diagnostic evaluation of the patient should be performed to rule out sequestered foci of infection. Appropriate surgical intervention (e.g., debridement, removal of prosthetic devices, valve replacement surgery) and/or consideration of a change in antibacterial regimen may be required. Failure of treatment due to persisting or relapsing *S. aureus* bacteremia/endocarditis may be due to reduced daptomycin susceptibility (as evidenced by increasing MIC of the *S. aureus* isolate) [see *Clinical Trials* in full prescribing information]. **Decreased Efficacy in Patients with Moderate Baseline Renal Impairment** There are limited data available from the cSSSI clinical trials regarding clinical efficacy of daptomycin treatment in patients with CrCL <50 mL/min; only 6% (31/534) patients treated with daptomycin in the intent-to-treat (ITT) population had a baseline CrCL <50 mL/min. In the ITT population of the Phase 3 cSSSI trials, the clinical success rates in daptomycin (4 mg/kg q24h)-treated patients with CrCL 50-70 mL/min and CrCL 30-<50 mL/min were 66% (25/38) and 47% (7/15), respectively. The clinical success rates in comparator-treated patients with CrCL 50-70 mL/min and CrCL 30-<50 mL/min were 63% (30/48) and 57% (20/35), respectively. In a subgroup analysis of the ITT population in the *S. aureus* bacteremia/endocarditis trial, clinical success rates, as determined by a treatment-blinded Adjudication Committee [see *Clinical Trials* in full prescribing information], in the daptomycin-treated patients were lower in patients with baseline CrCL <50 mL/min. A decrease of the following magnitude was not observed in comparator-treated patients. In the ITT population of the *S. aureus* bacteremia/endocarditis trial, the Adjudication Committee clinical success rates at the test-of-cure visit in daptomycin (6 mg/kg q24h)-treated bacteremia patients with CrCL >80 mL/min, CrCL 50-80 mL/min, and CrCL 30-50 mL/min were 60% (30/50), 46% (12/26), and 14% (2/14), respectively. The clinical success rates in daptomycin (6 mg/kg q24h)-treated right-sided infective endocarditis (RIE) patients with CrCL >80 mL/min, CrCL 50-80 mL/min, and CrCL 30-50 mL/min were 50% (7/14), 25% (1/4), and 0% (0/1), respectively. The clinical success rates in comparator-treated bacteremia patients with CrCL >80 mL/min, CrCL 50-80 mL/min, and CrCL 30-50 mL/min were 45% (19/42), 42% (13/31), and 41% (7/17), respectively. The clinical success rates in comparator-treated RIE patients with CrCL >80 mL/min, CrCL 50-80 mL/min, and CrCL 30-50 mL/min were 46% (5/11), 50% (1/2), and 100% (1/1), respectively. Consider these data when selecting antibacterial therapy for use in patients with baseline moderate to severe renal impairment. **Drug-Laboratory Test Interactions** Clinically relevant plasma concentrations of daptomycin have been observed to cause a significant concentration-dependent false prolongation of prothrombin time (PT) and elevation of International Normalized Ratio (INR) when certain recombinant thromboplastin reagents are utilized for the assay [see *Drug-Laboratory Interactions*]. **Non-Susceptible Microorganisms** The use of antibacterials may promote the overgrowth of non-susceptible microorganisms. If superinfection occurs during therapy, appropriate measures should be taken. Prescribing CUBICIN in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

**ADVERSE REACTIONS** The following adverse reactions are described, or described in greater detail, under *Warnings and Precautions:* anaphylaxis/hypersensitivity reactions, myopathy and rhabdomyolysis, eosinophilic pneumonia, peripheral neuropathy. The following adverse reaction is described in greater detail under *Warnings and Precautions* and *Drug-Laboratory Test Interactions:* increased International Normalized Ratio (INR)/prolonged prothrombin time. Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared with rates in the clinical trials of another drug and may not reflect the rates observed in practice. **Clinical Trials Experience** Clinical trials enrolled 1,864 patients treated with CUBICIN and 1,416 treated with comparator. Complicated Skin and Skin Structure Infection Trials In Phase 3 complicated skin and skin structure infection trials, CUBICIN was discontinued in 15/534 (2.8%) patients due to an adverse reaction, while comparator was discontinued in 17/558 (3.0%) patients. The incidence (%) of adverse reactions, organized by body system, that occurred in ≥2% of patients in the CUBICIN 4 mg/kg (N=534) treatment group and ≥ the comparator (N=558) treatment group in Phase 3 cSSSI trials was as follows [comparators were vancomycin (1 g IV q12h) and anti-staphylococcal semi-synthetic penicillins (i.e., nafcillin, oxacillin, cloxacillin, flucloxacillin; 4 to 12 g/day IV in divided doses)]: *Gastrointestinal disorders:* diarrhea 5.2% and 4.3%; *Nervous system disorders:* headache 5.4% and 5.4%; dizziness 2.2% and 2.0%; *Skin/subcutaneous disorders:* rash 4.3% and 3.8%; *Diagnostic investigations:* abnormal liver function tests 3.0% and 1.6%; elevated CPK 2.8% and 1.8%; *Infections:* urinary tract infections 2.4% and 0.5%; *Vascular disorders:* hypotension 2.4% and 1.4%; *Respiratory disorders:* dyspnea 2.1% and 1.6%. Drug-related adverse reactions (possibly or probably drug-related) that occurred in <1% of patients receiving CUBICIN in the cSSSI trials are as follows: *Body as a Whole:* fatigue, weakness, rigors, flushing, hypersensitivity; *Blood/Lymphatic System:* leukocytosis, thrombocytopenia, thrombocytosis, eosinophilia, increased International Normalized Ratio (INR); *Cardiovascular System:* supraventricular arrhythmia; *Dermatologic System:* eczema; *Digestive System:* abdominal distension, stomatitis, jaundice, increased serum lactate dehydrogenase; *Metabolic/Nutritional System:* hypomagnesemia, increased serum bicarbonate, electrolyte disturbance; *Musculoskeletal System:* myalgia, muscle cramps, muscle weakness, arthralgia; *Nervous System:* vertigo, mental status change, paresthesia; *Special Senses:* taste disturbance, eye irritation. *S. aureus* Bacteremia/Endocarditis Trial In the *S. aureus* bacteremia/endocarditis trial, CUBICIN was discontinued in 20/120 (16.7%) patients due to an adverse reaction, while comparator was discontinued in 21/116 (18.1%) patients. Serious

Gram-negative infections (including bloodstream infections) were reported in 10/120 (8.3%) CUBICIN-treated and 0/115 comparator-treated patients. Comparator-treated patients received dual therapy that included initial gentamicin for 4 days. Infections were reported during treatment and during early and late follow-up. Gram-negative infections included cholangitis, alcoholic pancreatitis, sternal osteomyelitis/mediastinitis, bowel infarction, recurrent Crohn's disease, recurrent line sepsis, and recurrent urosepsis caused by a number of different Gram-negative bacteria. The incidence [n (%)] of adverse reactions, organized by System Organ Class (SOC), that occurred in ≥5% of patients in the CUBICIN 6 mg/kg (N=120) treatment group and ≥ to the comparator (N=116) treatment group in the *S. aureus* bacteremia/endocarditis trial was as follows [comparators were vancomycin (1 g IV q12h) and anti-staphylococcal semi-synthetic penicillins (i.e., nafcillin, oxacillin, cloxacillin, flucloxacillin; 2 g IV q4h), each with initial low-dose gentamicin]: *Infections and infestations:* sepsis not otherwise specified (NOS) 6 (5%) and 3 (3%); bacteremia 6 (5%) and 0 (0%); *Gastrointestinal disorders:* abdominal pain NOS 7 (6%) and 4 (3%); *General disorders and administration site conditions:* chest pain 8 (7%) and 7 (6%); edema NOS 8 (7%) and 5 (4%); *Respiratory, thoracic, and mediastinal disorders:* pharyngolaryngeal pain 10 (8%) and 2 (2%); *Skin and subcutaneous tissue disorders:* pruritus 7 (6%) and 6 (5%); sweating increased 6 (5%) and 0 (0%); *Psychiatric disorders:* insomnia 11 (9%) and 8 (7%); *Investigations:* blood creatine phosphokinase increased 8 (7%) and 1 (1%); *Vascular disorders:* hypertension NOS 7 (6%) and 3 (3%). The following reactions, not included above, were reported as possibly or probably drug-related in the CUBICIN-treated group: *Blood and Lymphatic System Disorders:* eosinophilia, lymphadenopathy, thrombocythemia, thrombocytopenia; *Cardiac Disorders:* atrial fibrillation, atrial flutter, cardiac arrest; *Ear and Labyrinth Disorders:* tinnitus; *Eye Disorders:* vision blurred; *Gastrointestinal Disorders:* dry mouth, epigastric discomfort, gingival pain, hypoesthesia oral; *Infections and Infestations:* candidal infection NOS, vaginal candidiasis, fungemia, oral candidiasis, urinary tract infection fungal; *Investigations:* blood phosphorous increased, blood alkaline phosphatase increased, INR increased, liver function test abnormal, alanine aminotransferase increased, aspartate aminotransferase increased, prothrombin time prolonged; *Metabolism and Nutrition Disorders:* appetite decreased NOS; *Musculoskeletal and Connective Tissue Disorders:* myalgia; *Nervous System Disorders:* dyskinesia, paresthesia; *Psychiatric Disorders:* hallucination NOS; *Renal and Urinary Disorders:* proteinuria, renal impairment NOS; *Skin and Subcutaneous Tissue Disorders:* pruritus generalized, rash vesicular. Other Trials In Phase 3 trials of community-acquired pneumonia (CAP), the death rate and rates of serious cardiorespiratory adverse events were higher in CUBICIN-treated patients than in comparator-treated patients. These differences were due to lack of therapeutic effectiveness of CUBICIN in the treatment of CAP in patients experiencing these adverse events [see *Indications and Usage*]. Laboratory Changes *Complicated Skin and Skin Structure Infection Trials* In Phase 3 cSSSI trials of CUBICIN at a dose of 4 mg/kg, elevations in CPK were reported as clinical adverse events in 15/534 (2.8%) CUBICIN-treated patients, compared with 10/558 (1.8%) comparator-treated patients. Of the 534 patients treated with CUBICIN, 1 (0.2%) had symptoms of muscle pain or weakness associated with CPK elevations to greater than 4 times the upper limit of normal (ULN). The symptoms resolved within 3 days and CPK returned to normal within 7 to 10 days after treatment was discontinued [see *Warnings and Precautions*]. The incidence [n (%)] of CPK elevations from Baseline through End of Therapy, organized by change in CPK, that occurred in either the CUBICIN 4 mg/kg (N=430) treatment group or the comparator (N=459) treatment group in all patients in the Phase 3 cSSSI trials was as follows [comparators were vancomycin (1 g IV q12h) and anti-staphylococcal semi-synthetic penicillins (i.e., nafcillin, oxacillin, cloxacillin, flucloxacillin; 4 to 12 g/day IV in divided doses)]: *No increase:* 390 (90.7%) and 418 (91.1%); *Maximum Value >1× Upper Limit of Normal* (ULN; defined as 200 U/L): 40 (9.3%) and 41 (8.9%); *Max Value >2× ULN:* 21 (4.9%) and 22 (4.8%); *Max Value >4× ULN:* 6 (1.4%) and 7 (1.5%); *Max Value >5× ULN:* 6 (1.4%) and 2 (0.4%); *Max Value >10× ULN:* 2 (0.5%) and 1 (0.2%). In patients with normal CPK at baseline, the incidence [n (%)] of CPK elevations, organized by change in CPK, that occurred in either the CUBICIN 4 mg/kg (N=374) treatment group or the comparator (N=392) treatment group was as follows: *No increase:* 341 (91.2%) and 357 (91.1%); *Max Value >1× ULN:* 33 (8.8%) and 35 (8.9%); *Max Value >2× ULN:* 14 (3.7%) and 12 (3.1%); *Max Value >4× ULN:* 4 (1.1%) and 4 (1.0%); *Max Value >5× ULN:* 4 (1.1%) and 0 (0.0%); *Max Value >10× ULN:* 1 (0.2%) and 0 (0.0%). Note: Elevations in CPK observed in patients treated with CUBICIN or comparator were not clinically or statistically significantly different. *S. aureus Bacteremia/Endocarditis Trial* In the *S. aureus* bacteremia/endocarditis trial, at a dose of 6 mg/kg, 11/120 (9.2%) CUBICIN-treated patients, including two patients with baseline CPK levels >500 U/L, had CPK elevations to levels >500 U/L, compared with 1/116 (0.9%) comparator-treated patients. Of the 11 CUBICIN-treated patients, 4 had prior or concomitant treatment with an HMG-CoA reductase inhibitor. Three of these 11 CUBICIN-treated patients discontinued therapy due to CPK elevation, while the one comparator-treated patient did not discontinue therapy [see *Warnings and Precautions*]. **Post-Marketing Experience** The following adverse reactions have been identified during postapproval use of CUBICIN. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to estimate their frequency reliably or establish a causal relationship to drug exposure. *Immune System Disorders:* anaphylaxis; hypersensitivity reactions, including pruritus, hives, shortness of breath, difficulty swallowing, truncal erythema, and pulmonary eosinophilia [see *Contraindications* and *Warnings and Precautions*]; *Infections and Infestations: Clostridium difficile*–associated diarrhea [see *Warnings and Precautions*]; *Musculoskeletal Disorders:* myoglobin increased; rhabdomyolysis (some reports involved patients treated concurrently with CUBICIN and HMG-CoA reductase inhibitors) [see *Warnings and Precautions* and *Drug Interactions* in this summary, and *Clinical Pharmacology* in full prescribing information]; *Respiratory, Thoracic, and Mediastinal Disorders:* cough, eosinophilic pneumonia [see *Warnings and Precautions*]; *Nervous System Disorders:* peripheral neuropathy [see *Warnings and Precautions*]; *Skin and Subcutaneous Tissue Disorders:* serious skin reactions, including Stevens-Johnson syndrome and vesiculobullous rash (with or without mucous membrane involvement); *Gastrointestinal Disorders:* nausea, vomiting.

**DRUG INTERACTIONS HMG-CoA Reductase Inhibitors** In healthy subjects, concomitant administration of CUBICIN and simvastatin had no effect on plasma trough concentrations of simvastatin, and there were no reports of skeletal myopathy [see *Clinical Pharmacology* in full prescribing information]. However, inhibitors of HMG-CoA reductase may cause myopathy, which is manifested as muscle pain or weakness associated with elevated levels of creatine phosphokinase (CPK). In the Phase 3 *S. aureus* bacteremia/endocarditis trial, some patients who received prior or concomitant treatment with an HMG-CoA reductase inhibitor developed elevated CPK [see *Adverse Reactions*]. Experience with the coadministration of HMG-CoA reductase inhibitors and CUBICIN in patients is limited; therefore, consideration should be given to suspending use of HMG-CoA reductase inhibitors temporarily in patients receiving CUBICIN. **Drug-Laboratory Test Interactions** Clinically relevant plasma concentrations of daptomycin have been observed to cause a significant concentration-dependent false prolongation of prothrombin time (PT) and elevation of International Normalized Ratio (INR) when certain recombinant thromboplastin reagents are utilized for the assay. The possibility of an erroneously elevated PT/INR result due to interaction with a recombinant thromboplastin reagent may be minimized by drawing specimens for PT or INR testing near the time of trough plasma concentrations of daptomycin. However, sufficient daptomycin concentrations may be present at trough to cause interaction. If confronted with an abnormally high PT/INR result in a patient being treated with CUBICIN, it is recommended that clinicians: 1. Repeat the assessment of PT/INR, requesting that the specimen be drawn just prior to the next CUBICIN dose (i.e., at trough concentration). If the PT/INR value obtained at trough remains substantially elevated above what would otherwise be expected, consider evaluating PT/INR utilizing an alternative method. 2. Evaluate for other causes of abnormally elevated PT/INR results.

**USE IN SPECIFIC POPULATIONS Pregnancy** Teratogenic Effects: Pregnancy Category B. Reproductive and teratology studies performed in rats and rabbits at doses of up to 75 mg/kg (2 and 4 times the 6 mg/kg human dose, respectively, on a body surface area basis) revealed no evidence of harm to the fetus due to daptomycin. There are, however, no adequate and well-controlled trials in pregnant women. Because animal reproduction studies are not always predictive of human response, CUBICIN should be used during pregnancy only if the potential benefit outweighs the possible risk. **Nursing Mothers** It is not known whether daptomycin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when CUBICIN is administered to nursing women. **Pediatric Use** Safety and effectiveness of CUBICIN in patients under the age of 18 years have not been established. **Geriatric Use** Of the 534 patients treated with CUBICIN in Phase 3 controlled clinical trials of complicated skin and skin structure infections (cSSSI), 27% were 65 years of age or older and 12% were 75 years of age or older. Of the 120 patients treated with CUBICIN in the Phase 3 controlled clinical trial of *S. aureus* bacteremia/endocarditis, 25% were 65 years of age or older and 16% were 75 years of age or older. In Phase 3 clinical trials of cSSSI and *S. aureus* bacteremia/endocarditis, clinical success rates were lower in patients ≥65 years of age than in patients <65 years of age. In addition, treatment-emergent adverse events were more common in patients ≥65 years of age than in patients <65 years of age. The exposure of daptomycin was higher in healthy elderly subjects than in healthy young subjects. However, no adjustment of CUBICIN dosage is warranted for elderly patients with creatinine clearance ($CL_{CR}$) ≥30 mL/min [see *Dosage and Administration* in full prescribing information and *Clinical Pharmacology* in full prescribing information]. **Patients with Renal Impairment** Daptomycin is eliminated primarily by the kidneys; therefore, a modification of CUBICIN dosage is recommended for patients with $CL_{CR}$ <30 mL/min, including patients receiving hemodialysis or continuous ambulatory peritoneal dialysis (CAPD). In patients with renal impairment, both renal function and creatine phosphokinase (CPK) should be monitored more frequently than once weekly [see *Dosage and Administration* in full prescribing information, *Warnings and Precautions* in this summary, and *Clinical Pharmacology* in full prescribing information].


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CUBICIN IS IN THE 2010 IDSA GUIDELINES FOR MRSA cSSSI AND BACTEREMIA[1]

# For suspected MRSA cSSSI or bacteremia, consider CUBICIN first

- Rapid bactericidal activity against MRSA *in vitro**
- Over 99% of *Staphylococcus aureus* isolates are susceptible to CUBICIN *in vitro** according to U.S. surveillance studies[2]
- More than 1.6 million patients have been treated with CUBICIN[2]
- Does not require drug-level monitoring; monitor CPK levels
- Once-a-day, 2-minute IV injection or 30-minute IV infusion

2 MINUTE IV INJECTION

*Clinical relevance of *in vitro* data has not been established.

**Indications and Important Safety Information**

**INDICATIONS**

- CUBICIN® (daptomycin for injection) is indicated for the following infections:

  Complicated skin and skin structure infections (cSSSI) caused by susceptible isolates of the following Gram-positive bacteria: *Staphylococcus aureus* (including methicillin-resistant isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae* subspecies *equisimilis*, and *Enterococcus faecalis* (vancomycin-susceptible isolates only).

  *S. aureus* bloodstream infections (bacteremia), including those with right-sided infective endocarditis, caused by methicillin-susceptible and methicillin-resistant isolates.

**LIMITATIONS OF USE**

- CUBICIN is not indicated for the treatment of left-sided infective endocarditis due to *S. aureus*. The clinical trial of CUBICIN in patients with *S. aureus* bloodstream infections included limited data from patients with left-sided infective endocarditis; outcomes in these patients were poor. CUBICIN has not been studied in patients with prosthetic valve endocarditis.
- CUBICIN is not indicated for the treatment of pneumonia.

**WARNINGS AND PRECAUTIONS**

- Anaphylaxis/hypersensitivity reactions have been reported with the use of antibacterial agents, including CUBICIN, and may be life-threatening. If an allergic reaction to CUBICIN occurs, discontinue the drug and institute appropriate therapy.
- Myopathy, defined as muscle aching or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values to greater than 10 times the upper limit of normal (ULN), has been reported with the use of CUBICIN. Rhabdomyolysis, with or without acute renal failure, has been reported. Patients receiving CUBICIN should be monitored for the development of muscle pain or weakness, particularly of the distal extremities. In patients who receive CUBICIN, CPK levels should be monitored weekly, and more frequently in patients who received recent prior or concomitant therapy with an HMG-CoA reductase inhibitor or in whom elevations in CPK occur during treatment with CUBICIN. In patients with renal impairment, both renal function and CPK should be monitored more frequently than once weekly. In Phase 1 studies and Phase 2 clinical trials, CPK elevations appeared to be more frequent when CUBICIN was dosed more than once daily. Therefore, CUBICIN should not be dosed more frequently than once a day. CUBICIN should be discontinued in patients with unexplained signs and symptoms of myopathy in conjunction with CPK elevations to levels >1,000 U/L (~5× ULN), and in patients without reported symptoms who have marked elevations in CPK, with levels >2,000 U/L (≥10× ULN). In addition, consideration should be given to suspending agents associated with rhabdomyolysis, such as HMG-CoA reductase inhibitors, temporarily in patients receiving CUBICIN.
- Eosinophilic pneumonia has been reported in patients receiving CUBICIN. In reported cases associated with CUBICIN, patients developed fever, dyspnea with hypoxic respiratory insufficiency, and diffuse pulmonary infiltrates. In general, patients developed eosinophilic pneumonia 2 to 4 weeks after starting CUBICIN and improved when CUBICIN was discontinued and steroid therapy was initiated. Recurrence of eosinophilic pneumonia upon re-exposure has been reported. Patients who develop these signs and symptoms while receiving CUBICIN should undergo prompt medical evaluation, and CUBICIN should be discontinued immediately. Treatment with systemic steroids is recommended.
- Cases of peripheral neuropathy have been reported during the CUBICIN postmarketing experience. Therefore, physicians should be alert to signs and symptoms of peripheral neuropathy in patients receiving CUBICIN.
- *Clostridium difficile*–associated diarrhea (CDAD) has been reported with the use of nearly all systemic antibacterial agents, including CUBICIN, and may range in severity from mild diarrhea to fatal colitis. CDAD must be considered in all patients who present with diarrhea following antibacterial use. Careful medical history is necessary because CDAD has been reported to occur more than 2 months after the administration of antibacterial agents.
- Patients with persisting or relapsing *S. aureus* bacteremia/endocarditis or poor clinical response should have repeat blood cultures. If a blood culture is positive for *S. aureus*, minimum inhibitory concentration (MIC) susceptibility testing of the isolate should be performed using a standardized procedure, and diagnostic evaluation of the patient should be performed to rule out sequestered foci of infection. Appropriate surgical intervention (e.g., debridement, removal of prosthetic devices, valve replacement surgery) and/or consideration of a change in antibacterial regimen may be required. Failure of treatment due to persisting or relapsing *S. aureus* bacteremia/endocarditis may be due to reduced daptomycin susceptibility (as evidenced by increasing MIC of the *S. aureus* isolate).
- There are limited data available from the cSSSI clinical trials regarding the clinical efficacy of CUBICIN treatment in patients with creatinine clearance (CrCL) <50 mL/min; only 6% (31/534) patients treated with CUBICIN in the intent-to-treat (ITT) population had a baseline CrCL <50 mL/min. The clinical success rates in CUBICIN (4 mg/kg q24h)-treated patients with CrCL 50-70 mL/min and CrCL 30-<50 mL/min were 66% (25/38) and 47% (7/15), respectively. The clinical success rates in comparator-treated patients with CrCL 50-70 mL/min and CrCL 30-<50 mL/min were 63% (30/48) and 57% (20/35), respectively. In a subgroup analysis of the ITT population in the *S. aureus* bacteremia/endocarditis trial, clinical success rates in the CUBICIN-treated patients were lower in patients with baseline CrCL <50 mL/min.

**ADVERSE REACTIONS**

- The most clinically significant adverse reactions observed with CUBICIN 4 mg/kg (cSSSI trials) and 6 mg/kg (*S. aureus* bacteremia/endocarditis trial) were abnormal liver function tests, elevated CPK, and dyspnea.

**References: 1.** Liu C, Bayer A, Cosgrove SE, et al. Clinical practice guidelines by the Infectious Diseases Society of America for the treatment of methicillin-resistant *Staphylococcus aureus* infections in adults and children. *CID.* 2011;52:e18-e55. **2.** Data on file. Cubist Pharmaceuticals, Inc.

**Please see Brief Summary of Prescribing Information on adjacent page.**

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5158101912 November 2012



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