THE NEW ERA OF MEGA-PLANS

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Narcolepsy is an often misdiagnosed, incurable, chronic and potentially disabling neurologic disorder, and is associated with high medical comorbidity burdens and reduced daily function. Narcolepsy has also been shown to have substantial socioeconomic burden resulting from increased healthcare resource utilization and lower work productivity relative to those without narcolepsy.

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References:

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In This Corner, Weighing In At....

By Peter Wehrwein

Sometimes images just stick with you like the tune that you can’t get out of your head. After editing our cover story this month about insurance company mergers by Susan Ladika (page 18), the image I can’t get out of mind is a pair of sumo wrestlers going at it. Susan interviewed Tim Greaney, a professor at St. Louis University School of Law, and Greaney compared the current consolidation of both providers and payers to the Japanese wrestlers. The law professor says as one side gets larger, it can counteract the market power of the other side. I wonder if the CEOs of these big-and-getting-bigger provider and payer organizations would agree to settle their disputes in a dohyo instead of at the negotiating table, wearing mawashis instead of expensive suits.

But I’ve also had a nagging feeling that the sumo wrestler analogy is off because, as Susan reports, the insurance mergers are partly a response to the growing role of the government payer. About 1 in 3 Americans now get their health insurance through a public health plan of some kind. CMS actuaries predict that federal, state, and local government dollars will finance nearly half (47%) of national health care spending by 2024 because of the ACA and baby boomers aging into Medicare. The plot thickens, though. An increasing share of those public dollars are managed by private entities. The trend lines for Medicare Advantage and Medicaid managed care plans continue to go up and up.

So maybe it’s not really private payers grappling with private providers, sumo-style, but a complicated cage match of government, employer, and personal funds, managed by private companies, going to larger providers. Let’s just hope the health and well-being of the American people emerges the winner. ☞

CONTACT E-MAIL ADDRESSES:
Editorial: fdiamond@medimedia.com
Circulation: jott@medimedia.com
Advertising: mliberti@medimedia.com
Reprints: mecurry@medimedia.com
Cover Story

The Urge to Merge Continues to Surge

Health plan consolidation is nothing new. The Supreme Court’s decision in King v. Burwell, however, which for now halts legal challenges to the ACA, seems to have given insurers the certainty they need to buy and/or join. Deals proposed this summer amount to about $100 billion.

‘The Young and the Rest of Us’, Starring the ACA

Even as the law withstands legal challenges and signs up millions of uninsured, there’s still concern that “young invincibles” will not participate enough to help dilute the risk. Perhaps more subsidies and the introduction of a copper plan would reinforce the foundation.

Narrow Networks Under Scrutiny

As health plans pick and choose the higher performing providers, state insurance commissioners worry about “surprise billing” to consumers who do not know that their favorite physician is no longer part of the panel. Meanwhile, specialists argue that they are underrepresented.

Original Research

Minimally Invasive Surgery Saves Money

According to Milliman researchers, minimally invasive surgery costs less than open surgery for four procedures: colectomy ($11,698), ventral hernia repair ($5,041), thoracic resection ($12,278), and noncancer hysterectomy ($749).

Departments

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Merger madness creates daunting foes.

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JEFF GOLDSMITH, PhD  
President, Health Futures Inc.  
Charlottesville, Va.

ALICE G. GOSFIELD, Esq.  
Principal, Gosfield & Associates, P.C.  

MICHAEL T. HALPERN, MD, PhD  
Associate Professor of Public Health  
College of Public Health  
University of Arizona  
Tucson, Ariz.

JAN HIRSCH, PhD  
Associate Professor of Clinical Pharmacy, Scaggs School of Pharmacy and Pharmaceutical Sciences  
University of California–San Diego  
San Diego, Calif.

GEORGE J. ISHAM, MD  
Senior Adviser  
HealthPartners  
Minneapolis, Minn.

LUCY JOHNS, MPH  
Independent Consultant  
Health Care Planning and Policy  
San Francisco, Calif.

ROBERT C. JOHNSON, MS  
President, R.C. Johnson & Associates  
American Pharmaceutical Association  
Scottsdale, Ariz.

THOMAS KAYE, RPh, MBA  
Pharmacy Consultant  
Louisville, Ky.

RANDALL CRAUWER, MD, FACP, FACR  
Vice President, National Medical Director, Medical Strategy  
Aetna  
Princeton, N.J.

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PR Kongsvedt Co.  
McLean, Va.

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Press Ganey Associates  
Wakefield, Mass.

ATEEV MEHROTRA, MD, MPH  
Associate Professor of Medicine and Health Care Policy  
Department of Health Care Policy  
Harvard Medical School  
Boston, Mass.

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Health Quality Advisors LLC  
Highland Park, Ill.

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Next IT  
Spokane, Wash.

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Pharmacy Care Support Services  
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President  
BioCare Consultants  
Westport, Conn.

STEVEN R. PESKIN, MD, MBA, FACP  
Associate Clinical Professor of Medicine  
University of Medicine and Dentistry of New Jersey  
Robert Wood Johnson Medical School  
New Brunswick, N.J.

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James Madison Professor of Political Economy  
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Princeton, N.J.

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JAMES M. SCHIBANOFF, MD  
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Milliman USA  
San Diego, Calif.

STEPHEN W. SCHONDELMEYER, PharmD, PhD  
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medSolis  
Frisco, Texas

THOMAS D. SNOOK, FSA, MAAA  
Principal & Consulting Actuary  
Milliman Inc.  
Phoenix, Ariz.

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Chief Medical Officer, The Access Group  
Jefferson College of Population Health  
Thomas Jefferson University  

F. RANDY VOGENBERG, PhD, RPh  
Partner  
Access Market Intelligence  
Greenville, S.C.

JONATHAN P. WEINER, DrPH  
Professor and Director of the Center for Population Health  
Johns Hopkins University  
Bloomberg School of Public Health  
Baltimore, Md.
Urine Test Seems to Spot Pancreatic Cancer Earlier

One of the reasons pancreatic cancer is so deadly is because it sidesteps early detection. “Despite considerable progress in our understanding of the disease at the molecular level, novel findings have not yet translated into clinical benefits and the majority of patients are still faced with a grim median survival of 5 to 6 months,” states a study in the August 1 issue of *Clinical Cancer Research* that provides hope for early detection.

Researchers at Barts Cancer Institute of Queen Mary University of London say that they have discovered a novel, three-protein biomarker panel that might be able to detect patients with early-stage pancreatic cancer using urine specimens. It's an early study, though, and clinical application of the assay, if it ever happens, is years away.

Urine as a source of biomarkers for cancer has advantages over blood. It is far less complex and can be sampled repeatedly and noninvasively. What's more, as the authors point out, urine is an “ultrafiltrate” of blood, so some biomarkers might be found in higher concentrations.

For this study, the researchers initially analyzed six urine samples (three males and three females) from healthy patients with chronic pancreatitis and pancreatic cancer patients—18 samples in total—and found about 1,500 proteins. They ended up zeroing in on three: LYVE1, REG1A, and TFF1.

Tatjana Crnogorac-Jurcevic, the senior author, says those three were selected based on both “their functional roles as well as the statistical difference when compared to the experimental groups.”

They looked for the three proteins in urine samples from 87 healthy people, 92 patients with chronic pancreatitis, and 192 with pancreatic cancer patients. The combination identified early stage pancreatic cancer with 90% accuracy.

“To our knowledge, a panel with such performance has not been reported as yet,” the study states, “although this will need to be confirmed in a larger, independent study.”

Currently, the diagnosis of pancreatic cancer is usually made by contrast-enhanced CT after late symptoms such as jaundice and weight loss have already appeared.

“Such procedures are expensive and involve radiation; novel, highly accurate and noninvasive diagnostic tests would thus fill a major clinical need for screening high-risk populations and patients with suggestive symptoms,” says Crnogorac-Jurcevic.

However, the road to this experimental test actually being used is long and barriers, high. Crnogorac-Jurcevic and her colleagues have already hit a stumbling block.

“Despite a proof of principle study where we showed that signatures of this malignancy can be found in urine, we were still unable to secure the funding to continue work for several years,” Crnogorac-Jurcevic tells *Managed Care*.

Patient Handoffs Hit Communication Snag

Transferring patients efficiently and safely from the emergency department to other parts of the hospital takes good communication, but too often clinical data wind up missing in action.

Surveys of the emergency medicine department and five medical admitting services at a 627-bed tertiary care academic medical center found that ineffective communication hobbles handoffs and endangers patients.

Researchers at the University of Nebraska Medical Center College of Medicine noted that most research into handoffs has focused on the process within units so their research into handoffs among units explores some less charted territory.

Their study, published in the July issue of the *Journal of Hospital Medicine*, identified tension between emergency medicine physicians and those on the admitting units.

Ninety-four percent of emergency physicians felt defensive at least sometimes—and perhaps with good reason.

“EM physicians frequently felt that admitting physicians did not trust their clinical decisions, a perception supported by the fact that over 25% of admitting respondents’ usually disagreed with decisions in the ED,” the study states.

One of the problems is a fundamental lack of trust. Another is that physicians often don’t know the experience level of the doctors that they are handing off to. The study states that “less experienced clinicians may
require explicit information that a more experienced provider may infer. “

The number of handoffs in American hospitals has increased partly because of rules limiting the number of hours that residents can work. But computer-based tools that standardize patient information and handoffs have been found to reduce medical errors and preventable adverse events.

The Nebraska researchers say that they want to work out a better handoff system and are “pilot testing a standardized approach for ED-to-hospital handoffs....”

**Autism Screening Suffers a Setback**

There’s not enough evidence to merit universal screening for autism of toddlers (children ages 18 to 30 months old), according to a draft recommendation by the U.S. Preventive Services Task Force (USPSTF).

The prevalence of autism spectrum disorder (ASD) is now about 1 in 68 American children compared with 1 in 150 children 15 years ago. The reasons for autism becoming more common are unclear, although some research suggests that the rise may have more to do with the way the condition is being defined and diagnosed than a true increase.

In explaining its decision, the USPSTF cited the lack of randomized controlled trials directly addressing the question of whether screening reduces autism on a population basis. The prevention experts also mentioned the lack of evidence for early intensive treatment benefiting a screened population.

USPSTF’s recommendation not to screen is at odds with what many physician groups say should be done. The American Academy of Pediatrics recommends universal screening for ASD in all children at ages 18 and 24 months.

The American Academy of Neurology wants developmental surveillance at all well-child visits from infancy through school age. And the American Academy of Child and Adolescent Psychiatry recommends that questions about ASD be included in routine developmental assessment of young children and the psychiatric assessment of all children.

The USPSTF points to some potential harm from screening that include “the time, effort, and anxiety associated with further testing after a positive screening result, particularly if confirmatory testing is delayed because of resource limitations. Behavioral treatments are generally thought to not be associated with significant harms but can place a large time and financial burden on the family.”

The American Academy of Pediatrics (AAP) worries that the task force’s statement will be interpreted as saying that there’s no benefit to screening. The AAP stresses that early detection is crucial to early intervention and effectiveness of early intervention therapies for children with ASD.

“Parents who have concerns about their child’s development, especially about the way their child plays, learns, speaks, acts or moves, should talk with their child’s doctor,” Sandra Hassink, MD, the AAP’s president, said in a press release. “A child who has developmental delays can begin therapy before a formal diagnosis has been made.”

**Medicare Advantage Takes On 3-Day Rule**

Medicare Advantage (MA) allows for experimentation that traditional Medicare can’t indulge in. For instance, experimenting with the longstanding rule that for skilled nursing care to be covered the beneficiary must have a three-day inpatient hospital stay first.

As authors of a study in the August issue of *Health Affairs* point out, however, the rule dates from a time when the average hospital stay was two weeks, and evaluations to come up with discharge plans took much longer than three days.

MA plans can waive the three-day rule. The Brown University researchers who conducted this study compared 14 MA plans that waived the three-day rule with 14 that didn’t. The researchers looked at the period between Jan. 1, 2006, and March 31, 2011.

They found that hospital length of stay (LOS) for the group that waived the rule declined from 6.9 days to 6.7 days while it increased from 6.1 to 6.6 days for those that stuck with the rule. The researchers estimated that the 0.7
day difference would translate into a cost savings of about $1,500 for every hospital admission that involved a transfer to a skilled nursing facility.

A piece of history hovering over the three-day rule is the Medicare Catastrophic Coverage Act of 1988. When that law eliminated the three-day requirement, Medicare spending on nursing home care more than doubled, noted the authors. But they didn’t see any great influx of people into nursing homes when the MA plans eliminated the three-day rule. Why? In addition to tighter management, the MA plans did not reduce copayments for hospital and skilled nursing facilities, as happened with the 1988 law.

### Briefly Noted

**Fewer than 50%** of medical practices are prepared to handle ICD-10, according to a survey by the Workgroup for Electronic Data Interchange (WEDI). But nearly 90% of hospitals and 60% of health plans are good to go. The group wants HHS to further ease the transition from ICD-9 in part by divulging how far along every Medicaid agency in the country is on this effort. The people who run wellness programs should not ask if a woman is pregnant, argues the National Women’s Law Center. Kaiser Health News reports that the center wants the federal government to ban the question from employee wellness questionnaires, saying that it may encourage discrimination and violates the Pregnancy Discrimination Act of 1978.

**Adolescents with major depression** or bipolar disease are also more likely to face early heart disease, according to a scientific statement from the American Heart Association. Pathophysiologic mechanisms (inflammation, oxidative stress) may be to blame as well as known cardiovascular risk factors (high blood pressure, for example). Nine percent of adolescents have major depressive disorder, while 2.6% have bipolar disorder.

—Frank Diamond

### Racial disparities seen in both fetal and infant deaths

For the first time, there were more fetal deaths than infant deaths in the United States in 2013, according to CDC data. The difference was about 1%, with 23,595 fetal deaths (intrauterine deaths at 20 weeks of gestation or more) and 23,446 infant deaths.

Overall, the fetal death rate has been steady since 2006 while the infant mortality rate fell by 11% during that period. Significant racial disparities exist in both categories. The number of fetal deaths for black women was 10.53 per 1,000 pregnancies, more than twice the number for white women and Asian or Pacific Islander women. The number of infant deaths for black women was 10.75, which was, again, more than twice the number of the other groups.

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<td><strong>Fetal mortality</strong></td>
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**Fetal and perinatal mortality rates** by race (2013)

- **Non-Hispanic white**: 4.88, 5.25, 10.53, 10.75
- **Non-Hispanic black**: 6.22, 6.72
- **American Indian or Alaska native**: 4.68, 4.79
- **Asian or Pacific Islander**: 5.22, 5.58
- **Hispanic**: 5.96, 6.24
- **Total**: 4.94, 5.18

*20 weeks of gestation or more

†Includes infant deaths under age 7 days

CDC researchers refer to fetal mortality as a major, but little known, public health problem. “Much of the public concern surrounding reproductive loss has focused on infant mortality, due in part to a lesser knowledge of the incidence, etiology, and prevention strategies for fetal mortality,” the study states.

They add that the racial disparities in fetal deaths are not well understood. “Factors frequently mentioned as contributing to the black-white fetal and perinatal mortality gap are racial differences in maternal preconception health, infection, income, access to quality health care, stress and racism, and cultural factors; however, much of the black-white disparity in perinatal mortality remains unexplained.”

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Legislation & Regulation

‘21st Century Cures’ Isn’t a Cure for Everything
The NIH would get a $9 billion shot in the arm, but some fear the FDA provisions will mean lax oversight of drugs and devices.

By Richard Mark Kirkner

Something very strange happened in the House of Representatives a few days after the July 4 recess: The chamber passed legislation to increase funding for medical research by almost $9 billion over the next five years—and with overwhelming bipartisan support.

Let me repeat that: The House voted to spend nearly $9 billion more on medical research with overwhelming bipartisan support amid the run-up to next year’s presidential election.

Now that you’ve picked yourself up off the floor, the legislation—titled 21st Century Cures—would give an additional $1.75 billion over each of the next five years to the NIH, but it would also tinker with FDA oversight of drugs and medical devices.

The legislation isn’t a sure thing; the Senate still has to pass a version, and that’s where opponents will focus their attention over the next few months. There’s a chance that the full Senate may not get to the bill until next year.

Pushback on FDA provisions
The drug industry trade group PhRMA has gone all in on 21st Century Cures—would give an additional $1.75 billion over each of the next five years to the NIH, but it would also tinker with FDA oversight of drugs and medical devices.

The legislation isn’t a sure thing; the Senate still has to pass a version, and that’s where opponents will focus their attention over the next few months. There’s a chance that the full Senate may not get to the bill until next year.

Support for the increased NIH funding is almost universal, but enthusiasm for the overall legislation is not. A coalition that includes the National Physicians Alliance (NPA), Consumers Union, and AIDS United sent a letter to House and Senate members expressing their dismay and opposition to the legislation. “Rather than addressing the true scientific bottleneck in drug and device development, the bill includes unnecessary, costly, and potentially harmful regulatory changes and financial incentives for pharmaceutical and medical device companies that would put patient safety at risk and undermine public health,” the letter states.

The critics take issue with several provisions. Among them: allowing the FDA to approve “high-risk” medical devices based on case studies or journal articles alone rather than clinical trials in which the devices are tested in hundreds of live patients; a framework to consider “patient experience” for drug approvals; lower standards for approving antibiotics and antifungals; and incentives for hospitals to use new antibiotics—a provision that “would hasten the rise of resistant superbugs,” the coalition letter states.

Things like “patient experience” and journal articles might seem hazy medical evidence to scientists and clinicians more accustomed to randomized controlled trials. “In talking to other people who like this bill, do they really think we should allow clinical experience and anecdotal evidence to be evidence for drug approvals?” asks Lisa Plymate, MD, a Seattle internist and co-chair of the NPA FDA Task Force.

The FDA’s critics in Congress and their powerful allies, the drug and device industries, have complained that the agency is too slow in approving new drugs and devices, but the NPA has evidence to the contrary. “We have fast-track mechanisms for new drug approvals already in place, and it’s not a bottleneck,” Plymate says. From 2002 to 2013, 56% of the drugs approved by the FDA used at least one of the accelerated new-approval pathways, according to Plymate.

“We are approving most drugs faster than our European and Canadian counterparts, and most of the reviews are just taking 6 to 10 months,” she says.

Scant evidence
Two studies that looked at cardiac devices found scant evidence of an onerous FDA. A
January 2014 report in *JAMA* found that most implantable cardiac devices were approved through a supplemental process, not a full FDA review. A 2009 *JAMA* study of cardiac devices concluded that “premarket approval of cardiovascular devices by the FDA is often based on studies that lack adequate strength and may be prone to bias.”

Ameet Sarpatwari, an instructor at Harvard Medical School and member of the Program On Regulation, Therapeutics, and Law at Brigham and Women’s Hospital, explains the importance of randomized controlled trials in the drug-approval process.

“Federal law permits drugs to be approved on the basis of a single adequate and well-controlled investigation,” he says. “The FDA prefers that this investigation be a randomized controlled trial—and for good reason. Such trials are extraordinarily important for evaluating safety and effectiveness because they distribute both measured and unmeasured variables equally between the trial arms, allowing researchers to isolate the effect of the investigational drug.

“If science has taught us anything, it’s that we should have an element of humility regarding what we don’t know or understand. These unmeasured variables can oftentimes be very critical.”

**Climbing out of a hole**

The concern is that short-circuiting the clinical trial pathway would eventually drive up health care costs. It may be faster and cheaper to get a product on the market, but that may come at the expense of patient safety and public safety, says Sarpatwari. “The last thing we want to be doing is paying for treatments that are unsafe or ineffective,” he says.

Critics of the FDA provisions say increased funding for the NIH should address many of the concerns about the lack of innovation and FDA inertia, but that’s a deep hole from which to climb out of. Overall NIH funding has dropped 22% over the last 10 years when inflation is factored in, according to Dick Woodruff, vice president of federal affairs for the American Cancer Society Cancer Action Network (ACS CAN), one group that pushed for the additional NIH funding.

“**Show me the money!**”

In 2013, the chance of a clinical investigator getting an NIH grant reached an all-time low of around 16%, about half of what the rate was at the turn of the century, according to NIH data. “That increases the chances that someone isn’t going to receive a grant to begin with,” says Jon Retzlaff, director of science policy and government affairs for the American Association for Cancer Research.

The 21st Century Cures still faces some hurdles. The House-approved version came out of the Energy and Commerce Committee, to which the health subcommittee reports. “Energy and Commerce has jurisdiction over some of Medicare and all of energy, and they came up with sales of petroleum from the strategic reserve to pay for the NIH Innovation Fund,” says Woodruff.

**Bad timing**

The handling of the bill in the Senate could get interesting, especially if opponents step up their game. The Senate committee that deals with health issues doesn’t have access to the offsets the House counterpart used.

“It would be difficult for the Senate committee to come up with the budget offsets that would match by any stretch what the House was able to do,” Woodruff says.

Timing could also be a problem. Tennessee Republican Sen. Lamar Alexander, chair of the Senate Health, Education, Labor and Pensions Committee, has said his committee doesn’t plan to report out a 21st Century Cures bill until later this year and possibly next year.

Nonetheless, Woodruff at ACS CAN says that some new NIH funding could get included in an end-of-year budget agreement between the two chambers, even if legislation doesn’t make it to the finish line intact.

That would be the best of both worlds for critics of the bill. **MC**
Excluded in 2016: These Drugs Are On the Outside Looking In

Express Scripts and CVS have come out with their national formularies for 2016—and the list of drugs and other products (blood glucose test strips, for example) that didn’t make the cut and are newly excluded from the list of covered drugs.

Express Scripts is excluding 80 medications in 2016, an increase of eight from the number on the 2015 list of excluded drugs. The newly excluded drugs include two diabetes drugs, Kombiglyze XR and Onglyza; Synvisc, the injection for arthritic knees; and Qsymia, the weight-loss drug. The country’s largest PBM (as measured by the number of prescriptions processed) says the exclusions will save its national preferred formulary customers about $1.3 billion in 2016 and that less than 1% of the people covered by those clients will be affected by the change. Express Scripts also put 10 excluded drugs back on its formulary, including Betaseron, a multiple sclerosis drug; Tradjenta, a diabetes drug; and Zohydro ER, the controversial long-acting opioid. CVS has 93 products on its 2015 excluded list and is adding 31 more in 2016 (that count might be slightly misleading because slight variations of a drug sometimes get their own listing). The newcomers to the excluded list include Abilify, an atypical psychotic; Intuniv, an ADHD drug, and Viagra (CVS covers Cialis instead). A spokesman for the company said in an email that CVS “led the PBM industry” when it introduced a formulary strategy in 2012 that excluded “certain expensive branded drugs.” The formulary exclusions, the email continued, allows the company to “deliver significant savings to both the payer and the patient without compromising overall health outcomes.”

Prime Therapeutics, the Minnesota PBM owned by Blues plans, doesn’t publish a single list of drug exclusions because the exclusions vary with the client. “We believe our tailored approach is highly competitive with other PBMs in the industry,” a spokesperson wrote in an email.

Uncovered
Additions to the list of drugs excluded from the 2016 national formularies of Express Scripts and CVS.

<table>
<thead>
<tr>
<th>Express Scripts</th>
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<td>Acuvail (ophthalmic NSAIDs)</td>
<td>Abilify (depression and schizophrenia, atypical antipsychotic)</td>
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<td>Asacol, Asacol HD (inflammatory bowel)</td>
<td>Amitiza (IBD-constipation predominant)</td>
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<td>Delzicol (inflammatory bowel)</td>
<td>Avonex (multiple sclerosis)</td>
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<td>Dipentum (inflammatory bowel)</td>
<td>Bydureon (diabetes)</td>
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<td>doxcycline 40 mg (oral agent for rosacea)</td>
<td>Carac (actinic keratosis)</td>
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<td>Cardizem, Cardizem CD, Cardizem LA [includes generic Cardizem LA] (hypertension-calcium channel blockers)</td>
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<td>Monovisc (osteoarthritis-viscosupplements)</td>
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<tr>
<td></td>
<td>Noritrate (rosacea)</td>
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<td>Plegridy (multiple sclerosis)</td>
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<td>Valcyte (antiviral-cytomegalovirus)</td>
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<td>Viagra (erectile dysfunction)</td>
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<td>Zubsov (opioid dependence)</td>
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</table>
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THE NEW ERA OF

Insurer tie-ups are nothing new. But there’s been a shopping spree lately as uncertainty about the ACA recedes, providers bulk up, and government payers become more important.

By Susan Ladika

It got started just as the dust was settling after the Supreme Court’s momentous King v. Burwell decision in June that effectively kept the ACA intact.

First up was Centene, which on July 2 announced its intention to buy Health Net, for $6.8 billion. The merger would make St. Louis-based Centene the country's largest Medicaid managed care company.

The very next day, Aetna announced it that it would be acquiring Humana for $37 billion. The attraction? Humana’s strong and expanding Medicare Advantage (MA) business.

Then in late July, Anthem announced it was purchasing Cigna in a transaction valued at $53 billion. “I don’t think we’ve seen anything quite like this,” says Jason McGorman, an analyst with Bloomberg Intelligence.

Whether antitrust regulators will allow these deals to go through is an open question. But if they do, it would leave the American health insurance industry with three large, national publicly traded companies—Aetna, Anthem, and UnitedHealthcare—and four smaller ones.

This spate of merger activity is partly just the uncorking of insurers’ pent-up tendencies to get larger, according to Mark Pauly, a professor at the Wharton School at the University of Pennsylvania. “In a different universe,” he says, “this might have happened more gradually.” But King v. Burwell and the end (at least for now) of legal challenges to the ACA gave insurers the certainty they wanted before making any bold merger moves. Moreover, like many large companies these days, insurers have large amounts of cash on their books, so they have the money to spend on large acquisitions. Low interest rates help if they need to borrow to finance a deal. “Now is a good time to go ahead and get these mergers done,” says McGorman.

This year may set a new high-water mark, but the health insurance industry has been consolidating

### AND THEN THERE WERE SEVEN...

Consolidation of publicly traded health insurers

<table>
<thead>
<tr>
<th>Health insurers in 2011</th>
<th>Health insurers in 2015</th>
<th>Health insurers in 2016</th>
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<tbody>
<tr>
<td>Aetna</td>
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Source: Bloomberg Intelligence
MEGA-PLANS

into fewer and fewer companies for some time now. According to Bloomberg Intelligence, there were 14 large health insurers in 2011. Since then, the industry has gotten more concentrated because of a steady stream of acquisitions, including Aetna’s acquisition of Coventry (2013), Humana’s purchase of Metropolitan Health (2012), Anthem’s (when it was still known as WellPoint) purchase of Amerigroup (2012), and Cigna’s purchase of HealthSpring (2011). The combined value of those transactions was about $15 billion, which is peanuts compared with this summer’s deals, which tot up to about $100 billion.

The reasons for this merger and acquisition activity are various, so the best, if vague, answer to the question about what’s behind these mergers may be “all of the above.”

“The name of the game is diversification,” says Ashraf Shehata, a former Anthem executive who heads up KPMG’s advisory group for health plans in the United States. Companies can’t be content just serving the commercial market. Medicare Advantage is an inviting alternative. Baby boomers are aging into Medicare coverage at a rate of about 10,000 beneficiaries per day, and an increasing percentage of newcomers are going right into a Medicare Advantage plan rather than traditional Medicare. About a third (31%) of Medicare beneficiaries—or roughly 16.8 million older Americans—are now insured through Medicare Advantage. Most projections show the MA trend line continuing to head north. According to a Kaiser Family Foundation report, six firms or Blue Cross Blue Shield affiliates now account for 72% of the MA market. UnitedHealthcare has the most enrollees (20%), followed by Humana (19%), Blue Cross Blue Shield (BCBS) affiliated plans (16%), Kaiser Permanente (8%), Aetna (7%), and Cigna (3%). By Kaiser’s reckoning, Humana added 350,000 beneficiaries to its MA plans between 2014 and 2015, more than any other national firm. Insurers want to “build their Medicare Advantage business to offset other books of business,” Shehata says.

From certain angles, MA might not seem like an attractive line of business. For example, a recent KPMG study found that two thirds of those enrolled in Medicare Advantage plans have at least one serious chronic medical condition. But earlier this year, CMS bumped up the reimbursement rate for MA plans that cover patients with more severe medical conditions, creating an incentive to keep those with more severe health issues in Medicare Advantage plans.

Insurers are also eyeing large pieces of the growing Medicaid pie, notes Marianne Udow-Phillips, director of the Center for Healthcare Research & Transformation, a nonprofit partnership between the University of Michigan and Blue Cross Blue Shield of Michigan. Thirty states and Washington, D.C., have signed up for Medicaid expansion under the ACA. Although insurers in the Medicaid managed care market are struggling to keep costs under control, the huge pool of government money available is more than a little tantalizing. Right now, Medicare accounts for a larger share of national health care spending than Medicare Advantage.

Bloomberg Intelligence’s Jason McGorman doesn’t think that both the Aetna-Humana and Anthem-Cigna deals will be approved.

MEDICARE ADVANTAGE MARKET SHARE

Source: Kaiser Family Foundation analysis of CMS enrollment files, 2015
aim (20% vs. 15%), but Medicaid spending has been going up at a faster clip. Government at all levels has turned into a major buyer of health care. Eight short years from now, federal, state, and local government health expenditures combined are expected to add up to $2.5 trillion and constitute about half of all American health care spending. We’re a long way from a single payer system, but one reason insurers want to be behemoths is that they are sitting across the table from large government payers.

If the deal between Centene and Health Net goes through, the company would cover more than 10 million members. They lack the name recognition of the Aetnas and the Humanas, but the two companies are, respectively, the sixth- and seventh-largest publicly traded health insurers by market value.

Aetna touted Humana’s Medicare Advantage business when it announced its intention to buy the Louisville insurer. The new company will cover 33 million people and have revenue of about $115 billion per year, more than half of it coming from government programs.

The Anthem-Cigna merger seems to have a different rationale, with Anthem using Cigna to gain a major foothold in the self-insured market, which is about 80% of Cigna’s business.

If the Anthem-Cigna deal goes through and the new entity comes to be, it will have bragging rights to being the largest health insurer in the country by membership with roughly 53 million members compared with UnitedHealthcare’s 46 million. If revenue is the gauge, UnitedHealthcare will likely stay the top dog. In 2014, UnitedHealthcare had revenues of $130 billion, which is more than the $115 billion in revenue that the putative Anthem-cum-Cigna company is expected to pull in.

The sumo wrestling theory
As insurers have merged and gotten bigger, so have providers. According to Dealogic, there were 631 mergers in the health care industry (all aspects) through July that were worth about $364 billion, which tops the record merger volume of $326.4 billion in the health care sector set last year. Tim Greaney, a professor at Saint Louis University School of Law and an expert on health care and antitrust law, calls the consolidation on both sides the “sumo wrestler theory”: Payers have to bulk up if they are to be effective in bargaining down prices with supersize providers. “There’s some evidence when the buyer side gets bigger, it can counteract the price effect on the seller side," says Greaney. "It doesn’t necessarily work out that way. In some cases, the wrestlers agree to shake hands and protect each other’s interest, with higher prices resulting for both.”

A 2012 Robert Wood Johnson study found that hospital consolidation typically results in higher prices. It’s particularly true in highly concentrated markets, where price increases can surpass 20%.

Another factor propelling the mergers is technology, according to Shehata, at KPMG. Call centers, data security, claims processing, data analytics, consumer outreach—they’re costly to establish and to run. Scale can help dilute the expense. Anthem CEO Joseph Swedish said in a conference call with industry analysts that the merger with Cigna would have “the scale to drive greater efficiency and affordability for our customers,” and would be able to “accelerate improvements in the total cost of care,” according to an account in the Wall Street Journal. His views were echoed by Aetna CEO Mark Bertolini in an interview with USA Today: “You need to have enough power and enough presence at the local market level to be able to create relationships and efficiencies that are to consumers’ advantages,” Bertolini told the newspaper. To do so, he said, requires “larger organizations, more capital, more technology and more intellectual property. That’s what’s driving the consolidation.”

But some research shows that limited health insurer choices may actually push up prices—which isn’t all that surprising, all the upbeat talk about the benefits of scale notwithstanding. A study published earlier this year in the American Journal of Health Economics examined the participation of insurers in health insurance marketplaces during 2014. On average, four insurance companies participated in each of the areas in the 34 states with federally facilitated marketplaces. The researchers calculated premiums would have been 11% lower if all of the insurers that had been active in each state’s individual market in 2011 had sold insurance on the exchanges. The lead author, Leemore Dafny, a professor of strategy in Northwestern University’s Kellogg School of Management, was also the lead author of a 2012 study of the merger of Aetna and Prudential in 1999. That study found that...
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post-merger premiums rose by 7 percentage points.

Pauly, at Wharton, is among those who doubt that insurer mergers will lower prices. “As a consumer,” he says, “I’d keep my hand on my wallet.”

**Divestment a possibility**

The *Wall Street Journal* ran a strong story about the anticompetitive consequences of the mergers in late June when it was still unclear which companies would combine (a UnitedHealthcare-Aetna deal that didn’t happen was being talked about). By using state and federal data, the reporters showed that Aetna’s acquisition of Humana will mean 180 more counties where the combined company will control at least 75% of the Medicare Advantage business.

The concern over prices and competition will mean regulatory and legal scrutiny of this summer’s proposed mergers—and proposed should be emphasized. “There’s plenty of uncertainty here when it comes to how the courts will view this,” Greaney says, and he expects it will take months before decisions are made.

If history is a guide, Greaney expects antitrust regulators to look at each segment (Medicare Advantage, Medicaid managed care, large employers) of health insurance separately. It’s possible that the merged companies will be ordered to divest portions of their business when their tie-up would lead to a market share—either by market segment or geographic location—that the regulators deem too large.

The proposed mergers also are coming under Congressional scrutiny. The House Judiciary Committee is scheduled to hold a hearing this month on the mergers, the role that the ACA has played in consolidation, and the effect that fewer and larger insurers might have on consumers.

The American Medical Association doesn’t have the clout that it once had, so its opposition to the mergers may not have much practical effect. Still, the organization’s statement about its stance is a concise expression of what many fear: “The lack of a competitive health insurance market allows the few remaining companies to exploit their market power, dictate premium increases and pursue corporate policies that are contrary to patient interests.” An AMA study of the 2008 merger involving UnitedHealth Group and Sierra Health Services found that premiums increased after the merger by almost 14% relative to a control group.

Udow-Phillips foresees more provider-sponsored health plans as they try to control “the whole supply chain.” For example, Ascension Health in St. Louis, which bills itself as the country’s largest not-for-profit provider, is buying U.S. Health and Life Insurance for $50 million. The Michigan-based insurance company is licensed in 20 states.

Perhaps the consolidation of the large health insurers will have run its course if all of these deals are approved and the number of large publicly traded insurers dwindles to three. But experts agree that there’s still plenty of room for smaller players and regional players.

Shehata believes the next wave in mergers will be regional consolidation among not-for-profit Blue Cross Blue Shield Association members. Many are strong players in their home markets and have contracts with local and rural providers. But with a strong national network, they might have some of the same appeal as a national insurer. In smaller states, the Blues may join forces to share some services, such as a claim system.

**PBM purchases**

One success has been Kaiser Permanente, McGorman says. The managed care consortium has all the pieces in place, including hospitals, health plans, and outpatient care. That’s helped them to keep prices a bit lower than their competition.

Shehata expects more health plans to followed UnitedHealthcare’s lead and acquire pharmacy benefit management services because drugs are some a major area for spending. “It’s a very important part of the puzzle that health plans want to have.”

Susan Ladika is a freelancer writer in Tampa, Fla., with 30 years of experience covering health and other issues.
The ACA as a Survivor

The law has withstood legal challenges. More Americans have health insurance. But are more subsidies and new “copper” plans needed to make it work over the long haul?

By Robert Calandra

When the ACA marketplaces reopen for business on November 1 it will be the first time since the law’s rollout that the law isn’t facing a credible legal challenge.

Notwithstanding the “repeal and replace” mantra of Republican presidential candidates, this summer’s favorable Supreme Court ruling, plus the millions of Americans who now have health insurance because of the ACA, has given the law at least the sheen of success that may help deflect attempts to rescind it, even by a Republican president.

Actually, Republicans probably won’t try. At least that’s what Joel Ario, a managing director at Manatt Health Solutions, says he is hearing. Their focus, he says, will shift from “repeal and replace” to “reform” around the edges by giving people more choices and flexibility to buy what they want.

“When push comes to shove, opponents of the law will not have a better solution,” says Ario, who served as Pennsylvania insurance commissioner under Gov. Ed Rendell, a Democrat. “There is a lot of talk on the Republican side about reforming the law to make it more consistent with Republican principles and to use the subsidy money in different ways.”

With legal attacks in its rearview mirror—at least for now—and solid enrollment numbers, the ACA may have bought a little breathing room. But there are still some problems that, if not adequately addressed, could accomplish what the legal challenges have failed to do—pull the plug on the ACA or, at the very least, marginalize it.

Fewer uninsured

If reducing the number of Americans without health insurance is the ACA’s chief reason to be, then the law does seem to be fulfilling its purpose. According to the CDC’s National Health Interview Survey, which dates back to 1957 and uses data gathered by the Census Bureau, 9.2% (29 million) of Americans didn’t have health insurance at the time they were interviewed sometime during the first three months of this year compared with 11.5% (36 million) in 2014. Among adults 18 to 64, the group targeted by the ACA, the proportion of those without health insurance has dropped to 13%, a 3.3% percentage point decline from 16.3% in 2014. And the number of people under 65 using state or federal marketplaces to purchase health insurance grew from 6.7 million in the first three months of 2014 to 9.7 million in 2015, according to the survey data collected by the CDC.

But dig deeper and you’ll understand why ACA supporters are a little nervous and the skeptics unimpressed. The CDC report found that adults 25 to 34, the “young invincibles,” were twice as likely as adults 45 to 64 to be uninsured. The report doesn’t break out raw numbers, but the percent decreases suggest that gains in insurance coverage have been larger among Americans with low incomes.

“If you read into what people who are not buying insurance are saying, it’s that they will buy something that costs them less that gives them a little less protection,” says Joel Ario, former Pa. insurance commissioner.

“There has been some pretty sophisticated polling about the people who are not buying,” Ario says. “Some people just flat out cannot afford it, while others who could pay something do not want to pay too much.”

But some young people are making the value judgment that health insurance, especially exchange policies where they pay higher premiums for something they are unlikely to use so their elders can pay less, just isn’t a good financial deal. Of course, it’s not such a bad financial deal if invincibility fails them.

The success of the law has always hinged on healthy millennials who have aged out of coverage on their parents’ plans buying insurance on the ACA public exchanges to balance the risk pool and keep premiums affordable. While some of these younger people just don’t see the need, for most it’s just not in the budget. They are not alone. Middle class people, especially those in their 50s and early 60s who lost their jobs
during the recession, have been among the hardest hit when it comes to health insurance, says Terry Stone, global managing partner for health and science with Oliver Wyman, the consulting firm.

Because subsidy amounts wane as income approaches 400% of the federal poverty level (FPL)—$47,080 for an individual and $97,000 for a family of four—people near or at 400% of the FPL receive little or no help paying their monthly premium.

“They don’t qualify for Medicaid and they are not poverty stricken enough to necessarily qualify for big subsidies,” Stone says. “They are the ones who incur more cost personally when they go to the doctor and are not covered. How do we get them care and coverage?”

Supporters of the law are optimistic that the affordability issue can be resolved. Some ideas floating around call for raising the subsidy ceiling above the 400% of the FPL cap or creating a new, low-premium, high cost-sharing copper tier plan, with premium prices below the bronze plans, which are currently the cheapest.

Others would focus on changing the care and business models as a way to reduce the cost of medicine in America. “I think the long-term challenge is whether coverage will be affordable for people,” says Larry Levitt, a health policy expert at the Kaiser Family Foundation.

But with the number of people enrolled expected to only climb higher, most people expect the ACA in some shape, form, or fashion to be around for a long time to come. “I think that we’re in the messy early stages,” Stone says. “I don’t think people should despair over whether every aspect of the ACA is perfect. It’s just the starting stages. If we focus on the ultimate goal there are ways to get there.”

Number of uninsured dwindles as ACA takes hold

Government and other surveys are showing that the number of Americans without health insurance is dwindling, with credit going to the expansion of Medicaid and the ACA insurance exchanges. Nothing is free in this world, however. After a lull, related in part to the 2008 recession, health care spending is picking up again partly because the ACA has successfully expanded insurance coverage. In July, CMS actuaries projected that health care spending will increase, on average, by 5.8% over the next decade.

**Medicaid expansion plus an exchange decreases uninsured rates the most**

Data collected in the CDC’s National Health Interview Survey show that the percentage of adult Americans, ages 18 to 64, without insurance decreased from 22.3% in 2010 to 13% during the first three months of this year.

The CDC data show a shift toward public insurance, which includes Medicaid, Medicare, the CHIP program, and military plans. Of those with insurance this year, 18.1% had public insurance compared with 15.9% in 2010.

This survey data also shows that young adults are twice as likely to be without insurance as middle-aged adults (18.3% vs. 9%). That tilt is not surprising but is a problem for insurance markets because young people are less expensive to insure and their participation can help keep premium costs down.

A survey done for the Gallup-Healthways Well-Being Index paints a picture similar to that of the CDC. The survey shows that the percentage of Americans without health insurance fell from 17.3% in 2013 to 11.7% in the first half of this year. Randomly selected adults were asked: “Do you have health insurance coverage?” Sample sizes ranged from 232 in Hawaii to 8,600 in California.

States that went all-in and expanded Medicaid as well as set up an exchange by Dec. 31, 2014, saw the greatest decrease in the uninsured rate: 7.1 percentage points collectively. For the 28 states that implemented only one or neither of these options, the uninsured rate dropped 5.3 percentage points collectively.

The effectiveness of expanding Medicaid and participating in an exchange becomes even more noticeable when Gallup-Healthways looked at the 10 states with the largest reductions in the percentage of uninsured. Seven of those did both. (Arkansas installed a private option program that uses federal Medicaid funds to purchase private insurance for low-income residents.)
Before the ACA marketplace opened on Oct. 1, 2013, insurance companies didn’t have a lot of information about who their clients would be. So they guessed.

“The risk pool ended up being different than what the carriers anticipated and they had no prior experience covering that population,” says Deborah Dorman-Rodriguez of Freeborn & Peters law firm.

Insurers had years to prepare for the ACA. The biggest companies hired consultants to set up and run mock exchanges to identify the people likely to enroll, what plans they would buy, and at what price points they would buy them. The raw data was handed over to armies of actuaries who sliced, diced, and shaped the information into ACA Qualified Health Plans.

And they still got it wrong.

Apparently Voltaire was right: Common sense is not common. Who wouldn’t expect the first wave of enrollees in a health insurance program designed to expand access and provide coverage to those who previously had neither, just might be the sickest people with the lowest incomes and highest subsidies?

“The risk pool ended up being different than what the carriers anticipated and they had no prior experience covering that particular population,” says Deborah Dorman-Rodriguez, a partner in the law firm of Freeborn & Peters in Chicago and the leader of its health care practice. “They thought

### States with largest reductions in uninsured

<table>
<thead>
<tr>
<th>State</th>
<th>% uninsured, 2013</th>
<th>% uninsured first half of 2015</th>
<th>Change in uninsured (percentage points)</th>
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<tr>
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<tr>
<td>North Dakota</td>
<td>15.0</td>
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Results based on telephone interviews conducted on Jan. 2 to Dec. 30, 2013 (random sampling of 178,072 adults) and Jan. 2 to June 30, 2015 (88,667).

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PAZEO™ Solution: Safety Profile

- Well tolerated
- The safety and effectiveness of PAZEO™ Solution have been established in patients two years of age and older
- The most commonly reported adverse reactions, occurring in 2% to 5% of patients, were blurred vision, dry eye, superficial punctate keratitis, dysgeusia, and abnormal sensation in eye

Once-daily dosing

INDICATION AND DOSING
PAZEO™ Solution is indicated for the treatment of ocular itching associated with allergic conjunctivitis. The recommended dosage is to instill one drop in each affected eye once a day.

IMPORTANT SAFETY INFORMATION
As with any eye drop, care should be taken not to touch the eyelids or surrounding areas with the dropper tip of the bottle to prevent contaminating the tip and solution. Keep bottle tightly closed when not in use.

Patients should not wear a contact lens if their eye is red. PAZEO™ Solution should not be used to treat contact lens-related irritation. The preservative in PAZEO™ Solution, benzalkonium chloride, may be absorbed by soft contact lenses. Patients who wear soft contact lenses and whose eyes are not red should be instructed to wait at least five minutes after instilling PAZEO™ Solution before they insert their contact lenses.

The most commonly reported adverse reactions in a clinical study occurred in 2%-5% of patients treated with either PAZEO™ Solution or vehicle. These events were blurred vision, dry eye, superficial punctate keratitis, dysgeusia, and abnormal sensation in eye.

For additional information on PAZEO™ Solution, please refer to the brief summary of the full Prescribing Information on the following page.


From Alcon, committed to providing treatment options for patients.
PATIENTS AT RISK FOR DEVELOPING ALLERGIC CONJUNCTIVITIS RECEIVED ONE DROP OF EITHER PAZEO (N=330) OR VEHICLE (N=169) IN BOTH EYES FOR 6 WEEKS. THE MEAN AGE OF THE POPULATION WAS 32 YEARS (RANGE 2 TO 74 YEARS). THIRTY-FIVE PERCENT WERE MALE. FIFTY-THREE PERCENT HAD BROWN IRIS COLOR AND 23% HAD BLUE IRIS COLOR. THE MOST COMMONLY REPORTED ADVERSE REACTIONS WERE MALE. FIFTY-THREE PERCENT HAD BROWN IRIS COLOR AND 23% HAD BLUE IRIS COLOR. THE MOST COMMONLY REPORTED ADVERSE REACTIONS OCCURRED IN 2-5% OF PATIENTS TREATED WITH EITHER PAZEO OR VEHICLE. THESE EVENTS WERE BLURRED VISION, DRY EYE, SUPERFICIAL PUNCTATE KERATITIS, DYSGEUSIA AND ABNORMAL SENSATION IN EYE.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There are no adequate or well-controlled studies with PAZEO in pregnant women. Olopatadine caused maternal toxicity and embryofetal toxicity in rats at levels 1,080 to 14,400 times the maximum recommended human ophthalmic dose (MRHOD). There was no toxicity in rat offspring at exposures estimated to be 45 to 150 times that at MRHOD. Olopatadine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Animal Data

In a rabbit embryofetal study, rabbits treated orally at 400 mg/kg/day during organogenesis showed a decrease in live fetuses. This dose is 14,400 times the MRHOD, on a mg/m² basis. An oral dose of 600 mg/kg/day olopatadine (10,800 times the MRHOD) was shown to be maternally toxic in rats, producing death and reduced maternal body weight gain. When administered to rats throughout organogenesis, olopatadine produced cleft palate at 60 mg/kg/day (1080 times the MRHOD) and decreased embryofetal viability and decreased fetal weight in rats at 600 mg/kg/day. When administered to rats during late gestation and throughout the lactation period, olopatadine produced decreased neonatal survival at 60 mg/kg/day and reduced body weight gain in offspring at 4 mg/kg/day. A dose of 2 mg/kg/day olopatadine produced no toxicity in rat offspring. An oral dose of 1 mg/kg olopatadine in rats resulted in a range of systemic plasma area under the curve (AUC) levels that were 45 to 150 times higher than the observed human exposure [9.7 ng/hr/mL] following administration of the recommended human ophthalmic dose.

Nursing Mothers

Olopatadine has been identified in the milk of nursing rats following oral administration. Oral administration of olopatadine doses at or above 4 mg/kg/day throughout the lactation period produced decreased body weight gain in rat offspring; a dose of 2 mg/kg/day olopatadine produced no toxicity. An oral dose of 1 mg/kg olopatadine in rats resulted in a range of systemic plasma area under the curve (AUC) levels that were 45 to 150 times higher than the observed human exposure [9.7 ng/hr/mL] following administration of the recommended human ophthalmic dose. It is not known whether topical ocular administration could result in sufficient systemic absorption to produce detectable quantities in the human breast milk. Nevertheless, caution should be exercised when PAZEO is administered to a nursing mother.

Pediatric Use

The safety and effectiveness of PAZEO have been established in pediatric patients two years of age and older. Use of PAZEO in these pediatric patients is supported by evidence from adequate and well-controlled studies of PAZEO in adults and an adequate and well controlled study evaluating the safety of PAZEO in pediatric and adult patients.

Geriatric Use

No overall differences in safety and effectiveness have been observed between elderly and younger patients.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenicity

Olopatadine administered orally was not carcinogenic in mice and rats in doses up to 500 mg/kg/day and 200 mg/kg/day, respectively. Based on a 35 µL drop size and a 60 kg person, these doses are approximately 4,500 and 3,600 times the MRHOD, on a mg/m² basis.

Mutagenesis

No mutagenic potential was observed when olopatadine was tested in an in vitro bacterial reverse mutation (Ames) test, an in vitro mammalian chromosome aberration assay or an in vivo mouse micronucleus test.

Impairment of fertility

Olopatadine administered at an oral dose of 400 mg/kg/day (approximately 7,200 times the MRHOD) produced toxicity in male and female rats, and resulted in a decrease in the fertility index and reduced implantation rate. No effects on reproductive function were observed at 50 mg/kg/day (approximately 900 times the MRHOD).

PATIENT COUNSELING INFORMATION

• Risk of Contamination: Advise patients to not touch dropper tip to eyelids or surrounding areas, as this may contaminate the dropper tip and ophthalmic solution.

• Concomitant Use of Contact Lenses: Advise patients not to wear contact lenses if their eyes are red. Advise patients that PAZEO should not be used to treat contact lens-related irritation. Advise patients to remove contact lenses prior to instillation of PAZEO. The preservative in PAZEO solution, benzalkonium chloride, may be absorbed by soft contact lenses. Lenses may be reinserted 5 minutes following administration of PAZEO.

Patents: 8,791,154
it would be a different mix, and in insurance it’s all about balancing the risks.”

**Years of pent up medical needs**
Since the launch of the exchanges, the biggest drop among the uninsured has been with poorer Americans whose incomes are at or below 200% of FPL ($23,540 for an individual and $48,500 for a family of four). Not surprisingly, those people, with years of pent up medical needs, used their plans.

The ACA opened up the floodgates, Stone says: “You would expect poorer people who are sicker people are going to be the ones with the greatest motivation to get care and access first. That’s logical.”

When open enrollment opened up November 2014 for 2015 coverage, insurers had to make up for their miscalculation and premium prices jumped—for some plans, as much 38%. Plans were also rejiggered to bring costs into line. Deductibles, copays, and coinsurance went up and drug formularies were made more restrictive.

When rates for 2016 are released later this month, it will be the first time they will be based on actual claims data. In the end, the carriers’ misplaced optimism may have compounded the affordability issue. But contrary to what some may think, insurance companies are not stuffing their pockets with cash, at least not most of them. “There is this whole fallacy that somehow plans are minting money in the basement,” says Stone at Oliver Wyman, which has clients that sell plans on the ACA exchanges. “These guys (insurers) make anywhere from minus 1% to 5% most of the time” from health insurance plans on the exchange.

Mark Pauly, a professor of health care management at the University of Pennsylvania’s Wharton School, believes that premium growth will mirror growth in health care spending, which most recently was in the 6% to 8% range.

“I do not have a prediction of premium growth myself since I do not have a prediction for health spending growth long term, other than it will exceed GDP growth,” says Pauly.

To put health insurance’s projected yearly increase into perspective, it will be two to three times more than the average 3% salary raise most American workers will receive this year, according to Mercer, the human resource consulting firm.

No one really expects the number of people covered by exchange policies at the end of 2016 to reach the Congressional Budget Office’s 20 million projection. But fans of the ACA still expect the number to continue climbing. Expanding enrollment is the quickest and easiest way to address affordability. But no one knows for sure what the profile of the new enrollees will be: their age, economic, and subsidy status. What is known is that, so far, enrollment has been dominated by people at 200% of the FPL and below.

Almost none of the people buying insurance on the public ACA exchanges have incomes above the subsidy limit of 400% of the FPL, notes Pauly. As incomes rise and subsides fall, “there is a very steep drop off in the population of people who should be buying insurance on exchanges.”

There are some ideas about how to fix that problem and the low participation of young people. One route is financial help, which could mean increasing subsidy amounts and raising the ceiling so more Americans would be eligible for the tax credits. But the ACA’s detractors, a group that includes most of the Republican party, would see this as simply throwing money at the problem. Chances of it happening hover near zero.

Congress might, however, be more amenable to a new copper tier plan that would cover 50% of medical expenses but have a low premium. These new copper plans would function much like catastrophic insurance but with an important difference because they would still be required to cover the ACA’s 10 essential health benefits, which include maternity care and some preventive services.

The problem is how many takers would there be with the high cost sharing and deductibles in the range of $8,000 to $9,000. Levitt, for one, is skeptical that there would be much of a demand—or political appeal—if the goal is to fix the ACA. “The premium for a copper plan would be lower but people would be getting less coverage,” he says. “The cost sharing in bronze plans is already quite high. I’m not sure (Congress) would perceive that as the solution.”

**A financially viable risk pool is crucial**
Ario, however, thinks it just might be what a segment of the non-poor uninsured are looking for. “Some people need help with routine expenses, but some
healthier people are looking primarily for financial protection and would prefer lower premiums and higher cost sharing,” Ario says. “The challenge is how to serve different preferences while still getting enough premium from everyone to have a financially viable risk pool.”

Expanding the number of people insured by the marketplace would also encourage more competition among carriers. Industry giants have already enlarged their exchange footprints. UnitedHealthcare is currently in 24 markets while Aetna, Humana (before it was targeted for acquisition by Aetna), and Anthem have a presence on more than a third of state and federal exchanges. Cigna (now an Anthem acquisition target) was doing business in 10 states (see story on page 18). “These are big companies,” says Pauly. “They are over the teething pain of figuring out this new market.”

More competition usually means lower prices for consumers, and a July 2015 report from HHS on health insurance markets bears this out. The report says that rates are 8.4% lower on exchanges where three or more companies are competing. The mergers of the major insurers could spell more trouble for the ACA and competitive, well-functioning insurance markets. Less competition is rarely better for consumers, notes Levitt. But with health insurance, it gets complicated, he adds, because big insurers may be able to strike better deals with providers, which are also consolidating into bigger and bigger groups.

Both Dorman-Rodriguez and Stone think the consolidation is more about synergies and efficiencies rather than getting a chokehold on the individual health insurance market. The goal, they say, is to reduce administrative costs, which, in the long run could lower premium prices.

“We’re really talking about technology and the things that go along with running something as complex as this type of coverage,” Dorman-Rodriguez says. “I think the efficiencies that analysts have written about will actually improve the marketplace.”

Ario, who once kiboshed a deal between Highmark and Independence Blue Cross when he was Pennsylvania’s insurance commissioner, is skeptical but intrigued by the merger talks. He says state regulators and the Department of Justice should take a long hard look at how the mergers will affect competition regionally and nationally.

On the other hand, “It’s a good thing that a carrier has both an exchange product and a Medicaid product,” he says. “Having cross-market capability is very important and Medicare should be added into that mix because there are transitions with Medicare as well.”

If the first two years of the ACA were about access and encouraging competition (the announced mergers notwithstanding), then the next few years will be about the great white whale of American health care—controlling costs.

Optimists see good news in more collaboration between providers and payers. Pessimists see narrow networks that saddle many Americans with huge out-of-network medical bills (see story on page 30). Count Stone at Oliver Wyman among the optimists. Narrow networks and ACOs will help make providers and payers do their part reeling in costs. But sooner or later consumers will have to step up and share the responsibility. Yes, the proverbial skin in the game. “If we want to get more affordable care we have to get the cost of care per person less expensive,” Stone says. “The way to do that is to drive more focus and attention on wringing out excess and waste. The next step is to get consumers to change.”

That next step will be part of the ACA’s continuing evolution. After all, the law is about to begin its third enrollment. Like Social Security and Medicare before it, the ACA may take years and several course corrections to find its level.

Robert Calandra is a freelancer writer in Philadelphia with more than 20 years experience writing about health care.

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For Narrow Networks, Fresh Scrutiny: Can They Pass the Adequacy Test?

Narrow networks mean lower premiums. Now, state insurance commissioners are wrestling with how they should be regulated so that insurers stay solvent and consumers are protected.

By Jan Greene

St ate legislators and insurance regulators are refereeing the latest power struggle between providers and insurers—the design of provider networks.

Insurers are narrowing networks to better control costs; creating “high quality” networks to include providers that rank well on quality metrics; and introducing tiered networks in which consumers pay more for high-cost providers. These changes may please the providers who are fortunate enough to be chosen for the networks, but are threatening to those left out, such as higher-cost academic medical centers or specialty providers such as children’s hospitals or cancer centers.

As the networks narrow and change, there’s been backlash from specialty providers who complain about being neglected, and from consumers who may be surprised to find their health plan’s provider list is shorter than expected or that a hospital specialist such as an anesthesiologist or pathologist is out of network. Both groups are looking to their state legislators for relief.

All of this has been laid at the feet of the National Association of Insurance Commissioners (NAIC), which handed the mess to its Network Adequacy Subgroup, 12 hardy souls who have endured dozens of conference calls since mid-2014. The subgroup is working out the details, word by painful word, of a new model network adequacy law. The effort updates a 1996 version that has become badly outdated as insurance products have evolved and the narrow network

States with marketplace plans subject to 1 or more quantitative standards for network adequacy, as of January 2014

State network-adequacy standards may apply broadly to all network plans or more narrowly to specified network designs (e.g., HMOs) or plan types (e.g., marketplace plans). The 16 states identified in dark purple have one or more quantitative standards that apply to all marketplace plans specifically or to all network plans in general. By contrast, the quantitative standards in effect in the 11 states identified in lighter purple apply only to particular types of network plans (usually HMOs) and generally do not regulate all marketplace plans.

Source: Commonwealth Fund
has become increasingly common. As obscure as this panel’s work is, it is actually at the heart of some of health care’s most heartfelt public debates about how consumers interact with their health plans and with providers. News coverage has highlighted compelling stories of innocent patients facing thousands of dollars in unexpected medical bills.

**Regulating network adequacy**

The NAIC conference calls are meant for the insurance commissioner representatives to hammer out language, working from a November 2014 draft and public comments collected in January 2015. But the calls are open to the public and lobbyists for health plans, providers, consumers, and any other “interested party” are welcome to join in and have a chance to comment on wording. About 100 people usually dial in to each call.

Currently, state regulation of network adequacy is all over the map. Some states have general guidelines to ensure health plan consumers can see the doctors they need to, while other states prescribe specific quantitative standards, such as how long it takes for most health plan members to travel to an in-network hospital. A Commonwealth Fund examination noted that as of January 2014, 23 states mandated maximum travel time or distance; 11 had a maximum appointment wait time; and 10 had provider-to-enrollee ratios.

States generally regulate networks by responding to complaints, according to a report by NAIC’s consumer advocacy group. Almost half (42%) of states carry out a regularly scheduled periodic review of network adequacy for HMOs, and most (70%) review network adequacy when a health plan files notice of a significant change to its network.

The NAIC process is being closely watched by officials at HHS. Federal regulators have generally left network adequacy reviews of exchange plans to the states, but have said they may conduct network reviews in the future. The ACA establishes the first national standard for network adequacy, requiring that plans sold on the exchanges maintain a provider network that is “sufficient in numbers and types of providers, including providers that specialize in mental health and substance abuse services, to assure that all services will be accessible without unreasonable delay.” The law also requires exchange plans to include essential community providers that serve predominantly low-income, medically underserved patients.

Ever since the ACA went into effect five years ago, state and federal insurance authority has been mingled in new and sometimes uncomfortable ways. In the case of the network adequacy issue, a model state law would likely cover all health plans regulated by a state, including those sold in a state exchange, along with plans in the commercial and individual markets. It would not cover health plans provided by self-insured employers, which are still covered under ERISA. Medicare and Medicaid managed care plans are generally covered under their own sets of rules.

Health plans may also be subject to accreditation standards; in July 2015 the National Committee for Quality Assurance said it would address narrow networks and provider directories in its 2016 standards. These include a new Network Management section that provides “a more comprehensive assessment of plan network and focus on specialty areas,” NCQA said in a news release.

Complaints and concerns about narrow networks started to bubble up in 2013, and reports and analyses from consulting firms and other groups followed in their wake.

A McKinsey analysis of health plans offered on the exchanges in 2014 determined that broad networks are available to nearly 90% of the population even if consumers are tending to buy less expensive narrow network plans; narrow networks make up about half of all networks in exchange plans across the U.S. and 60% of the networks in the largest cities in each state. The study found broad networks carried premiums a median of 13% to 17% higher than narrow networks.

A study of California’s marketplace found that its plans may have hospital networks narrower than those of commercial plans, but they haven’t reduced geographic access or quality, according to a study in the May 2015 Health Affairs.

For certain specialty providers, the outlook is less promising. A July 2014 Avalere study of access to heart care in 10 regions of the country found that the share of specialist physicians who were included in exchange plan networks was highly variable, ranging from an average of 8% in Los Angeles to 83% in Philadelphia. “The wide variation in inclusion of providers … suggests the need for specific quantitative standards to evaluate whether an adequate number of providers are available to exchange plan consumers,” the study said.

“The NAIC process creates a really important dynamic because everyone involved is focused on the same goal, according to Claire McAndrew of Families USA.
being included to ensure that consumers can access their covered benefits,” said Stephanie Mohl, senior government relations adviser for the American Heart Association at a 2014 Alliance for Health Reform briefing. The association commissioned the study.

Consumers don’t necessarily see narrow networks as a bad thing if they keep costs down, and they have been relatively popular in the ACA exchanges so far, accounting for about 70% of health plan sales in 2014. A Kaiser Family Foundation survey in February 2015 showed that people buying their own insurance (as opposed to employer-sponsored coverage) often like the option to spend less for a smaller-scale plan; that 54% dropped to 35%, though, when those respondents were told they might lose access to their usual providers. Consumers may be lured in by the lower premium, but attitudes may change once they learn that they can’t see certain specialists or when they get a big medical bill from an out-of-network provider that they didn’t know was out of network.

Ox goring
One of the NAIC subgroup’s ground rules is that it does not take sides in contracting tussles between insurers and providers. The competing financial interests of powerful groups such as insurers and physicians makes the whole issue of regulating network adequacy fraught with difficulty for state officials, notes Kevin Lucia, a senior research fellow at the Georgetown University Health Policy Institute’s Center on Health Insurance Reforms.

To the extent that the subpanel addresses thorny issues, it tries to do so with some balance, says its chairman, J.P. Wieske, legislative liaison/public information officer for Wisconsin’s insurance commissioner. “The hope here is that we are goring everybody’s ox to a certain degree,” Wieske said during one NAIC subgroup call.

While the model law’s language will continue to be tweaked as various committees within NAIC work on it this fall, its core became clear after two rounds of intensive work by the network adequacy subgroup over nearly two years. Here are some of the main issues that an August draft of the model law focuses on:

- **Network adequacy.** Network adequacy would be determined by insurance commissioners on the basis of several factors but without including specific metrics for them; that if a network is insufficient to provide a covered benefit then a nonparticipating provider will be covered at an in-network coverage level.

- **Access plans.** Health carriers would file with the insurance commissioner an access plan for any new network. The plan would include the factors it used in building the network, how it addresses the needs of all covered persons, and how it will monitor ongoing access to specialty providers.

- **Tiering.** The model law addresses tiering specifically, stating that it cannot be discriminatory against high-risk populations, and the carriers must make its standards for selecting networks and tiering available to the public.

- **Balanced billing/out-of-network services.** Health care facilities and insurers would be required to provide the patient with notice that out-of-network services may be provided during a scheduled nonemergency procedure, and the facility notice would include a range of the charges for which the patient may be responsible. The law would also limit balance billing by alerting patients that they can use an insurer’s mediation process for out-of-network, facility-based provider bills, and requires insurers to set up a mediation process that is paid for 50/50 by the insurer and the provider.

- **Continuity of care.** The carrier must establish “reasonable procedures” to transition a covered person who is in an active course of treatment to an in-network provider if that person’s provider leaves or is removed from a network. Insurers must make a “good faith effort” to provide written notice to regular patients of providers who are removed from or leave a network.

- **Provider directories.** Insurers would be required to post an electronic provider directory for each network plan and update it monthly. The directory would need to periodically audit a “reasonable sample size” for accuracy. Directories would need to note which network plan they apply to.

In determining network adequacy, consumer representatives had hoped that the model law might require that a state have in place some type of quantifiable...
standards on wait time, time and distance, “but that’s not exactly where things seem to be going,” said Claire McAndrew, private insurance program director for Families USA.

The working document said adequacy would be determined using “reasonable criteria” that may include provider-covered person ratios by specialty, geographic accessibility of providers, waiting times, hours of operation, and ability of the network to meet the needs of people with specific needs, and the volume of specialty services available; but the section does not establish what those ratios should be. An accompanying drafting note mentioned some specific quantitative standards such as limits on travel distance, travel times or waiting times; America’s Health Insurance Plans, the industry trade association, as well as the Blue Cross Blue Shield Association were supportive of the adequacy language in general, but urged the removal of these specific standards.

The subgroup seems more interested in expanding rules that would improve transparency for health care consumers, such as more accurate provider directories and notice before being seen by out-of-network providers in a hospitalization.

Given the huge health literacy problem in the United States, even these disclosures may not be enough to bridge the gap so consumers know what they are getting, says Lucia of Georgetown. “I’m not sure the average consumer necessarily has a great sense of the tradeoffs” between premium and size of network, he says. Educating consumers, Lucia notes, is a huge challenge and should be a goal for exchanges and for state and federal regulators.

Nix “surprise billing”
The issue of people receiving a bill for an out-of-network provider they didn’t know was involved in their care, sometimes referred to as “surprise billing,” has put pressure on state legislatures to act as horror stories abound across the country.

States have tried stepping into this; 13 states ban balance billing. In California, the state assembly has passed a bill that is now awaiting state senate action. Some states have set up a mediation process to resolve consumer complaints about a balance bill, bringing provider and insurer representatives together on a phone call to negotiate. Texas includes the consumer on the mediation call with provider and insurer. New York’s process uses a pricing database from Fair Health, a not-for-profit corporation dedicated to bringing transparency to health care costs, as a starting point in negotiations. Florida’s process hasn’t been used very much, which is consistent with study by the NAIC’s consumer group that found that the mediation processes aren’t often used. “This is a battle between providers and insurers, and they use consumers to make their points,” says Lucia. “Laws like New York’s recognize there’s a tension that has to be resolved for the appropriate reimbursement level, but removes the consumer from the fight. There seems to be more interest in that kind of model.”

The NAIC subgroup began its deliberations trying to take the consumer out of the middle of out-of-network billing disputes, but also not simply dumping the problem completely on either the insurer or provider. The group spent many hours working on language that all parties could live with; the working draft would give patients notice before a nonemergency hospitalization if certain of their providers are out-of-network, and would require carriers to establish a mediation process with providers for disputes.

‘The doctor is in. (Isn’t she?)’

Keeping provider directories and network information up to date is difficult because of the varying contract dates for the individual market and group plans. Changes that physician groups make that are unrelated to insurance can also affect a directory’s accuracy. Say a practice moves its office or a physician leaves the practice or retires. Insurers can’t count on practice groups, which deal with multiple insurers, to contact them every time something like that happens. But from the consumer’s point of view, an inaccurate directory with bad network information can be, at the very least, aggravating and might lead to unwitting use of an out-of-network provider and a huge out-of-network bill.

States vary by how often they require directories to be updated. It can be anywhere between 15 days and six months. Regulations are changing to reflect the shift to web-based listings. Some require monthly updates, which is the requirement for plans sold on the ACA exchanges. The NAIC draft would require carriers to maintain directories online, update them monthly, and make clear what health plan network the directory applies to.

Covered California, the California ACA exchange, got some bad press when consumers kept on finding bad information about providers in the directories for the plans sold on the exchange. Director Peter Lee told an Alliance for Health Reform briefing in July 2015 that his organization made a concerted effort in its second year of operation to improve the accuracy of its online directory, noting “provider directories have been pretty bad for a long time.” The exchange sent letters jointly with exchange health plans, working with medical societies, to tell providers “it’s your job to make sure you know what network you’re in.” Lee said he is “optimistic” the directories would improve; in case an inaccuracy affects a consumer’s health plan choice, Covered California will allow them to change plans after enrollment.
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NAIC sausage making
The NAIC released a draft network adequacy model law for comment in November 2014 and received responses from 90 parties. In April 2015, the group embarked on a series of more than 30 conference calls and an in-person meeting in Chicago. The version that comes out of the subgroup gets two more rounds of committee-level review before going before the NAIC plenary in Washington in November; there, it requires a two-thirds vote to become NAIC policy. There is no obligation on the part of any state to adopt the final model law. In fact, just 10 states adopted the 1996 version of NAIC’s network adequacy model law.

When specific approaches are discussed in the NAIC calls, they are sometimes left out of the legal language of the model law and relegated to “drafting language” to offer states some guidance if they choose to regulate there. NAIC also has the option of developing a draft regulation for states to use along with the model law.

The subgroup’s conference calls, while time-consuming, are a useful exercise in weighing all points of view, says McAndrew. “The NAIC process creates a really important dynamic because everyone involved is focused on the shared goal of completing the model act,” she says. “Even though it has been a very long process, it is very impressive in the ways people are willing to compromise.”

Quality not quantity
State regulators, while motivated to protect consumers, are stepping carefully, particularly considering that one of their main roles is ensuring the solvency of the insurers they license.

Overly aggressive regulation of networks could also impede some of the creativity going into innovations to improve the efficiency and quality of the health care system, argued Gary Cohen, a consultant and former administrator at CMS, in a 2014 Health Affairs blog. “Consumers might be better served if regulators focus initially on transparency,” he wrote.

As health plans evolve in the new era of value, optimists say focus on networks is likely to shift away from quantity and toward quality. “Plans will increasingly be selling the plans based on the quality of their networks,” says Wieske, the Wisconsin insurance official. But if put together poorly, narrow networks could be more cost shifting to consumers in another guise. The hope is that thoughtful legislation and regulation will keep that from happening—and hope, especially in health care, springs eternal.

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Jan Greene is a veteran health care journalist based in northern California. Her work has appeared in the Los Angeles Times, Health magazine, Hospitals & Health Networks, and many other publications.

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Cabozantinib reduced the risk of disease progression or death by 42% in patients with metastatic renal cell carcinoma (RCC), compared with everolimus (Afinitor), according to results of the METEOR trial. The 658 patients who were enrolled had disease progression following treatment with a VEGF receptor tyrosine kinase inhibitor. METEOR met its primary endpoint, a statistically significant increase in progression-free survival (PFS), in the first 375 randomized patients.

The CheckMate-025 study evaluating nivolumab (Opdivo) in previously treated patients with advanced or metastatic RCC was stopped early when the study met its endpoint, superior overall survival (OS), in patients receiving nivolumab compared with the control arm. CheckMate-025 is an open-label study in which patients were randomized to receive either nivolumab 3 mg/kg intravenously every two weeks or everolimus 10 mg tablets daily until documented disease progression or unacceptable toxicity.

Two previous CheckMate trials demonstrated statistically significant one-year survival rates in patients given nivolumab versus those on chemotherapy regimens. Nivolumab currently has indications for metastatic squamous non–small-cell lung cancer (NSCLC) and metastatic melanoma.

Lung cancer trial stopped
Adding tivantinib to erlotinib (Tarceva) improved progression-free survival (PFS) but not OS in patients with previously treated nonsquamous NSCLC. OS was the primary endpoint of the 1,048-patient study, which was discontinued for futility at an interim analysis. Results were published in the Journal of Clinical Oncology.

In a subgroup of 211 patients with high MET tumor expression, researchers did see a trend toward improved OS, with a median OS of 9.3 months in patients given the combination therapy and 5.9 months in those who received only erlotinib. Tivantinib is a selective inhibitor of the MET receptor tyrosine kinase, helping to slow cell proliferation and induce apoptosis in cancer cells that express MET.

Setback in uveal melanoma
Selumetinib combined with dacarbazine chemotherapy for treatment of metastatic uveal melanoma, an orphan disease in which cancer cells grow in eye tissues, failed to improve PFS compared with dacarbazine alone, according to results of the SUMIT study. SUMIT was a randomized, double-blind, placebo-controlled trial carried out in 45 centers in 11 countries.

Selumetinib is an oral, small-molecule MEK inhibitor in late-stage development, discovered by Array BioPharma and licensed to AstraZeneca. The drug is also being investigated in phase 3 studies for KRAS-mutant advanced NSCLC and differentiated thyroid cancer, as well as in a phase 2 registration study in patients with type 1 neurofibromatosis.

Uveal melanoma is rare but is the most common form of malignancy in the eye. According to the National Cancer Institute, uveal melanoma incidence is about 4.3 cases per 1 million people.

In other trials involving diseases of the eye:
Xoma’s Phase 3 EYEGUARD-B study of gevokizumab to treat Behçet’s uveitis failed to meet the primary endpoint of time to first acute ocular exacerbation, although it appeared to be well tolerated in the trial. Behçet’s uveitis is a systemic condition that originates with inflammation in the eye and, untreated, can promote cataracts and optic atrophy, lead to vascular injury multiple organs, produce ulcers in
the mouth, and genital lesions. In rare cases, it can be fatal, though literature suggests that symptoms “burn themselves out” after about 10 years.

A benefit-risk analysis trial data supports the favorable profile of Genentech’s ranibizumab (Lucentis) 0.5 mg as-needed dosing compared with laser therapy for treatment of diabetic macular edema. A comparative benefit-risk assessment was conducted using the Benefit Risk Action Team Software Tool (BRAT), which includes steps for selection, summarization, organization, and interpretation of data.

**Alzheimer’s trials revisited**

Two presentations at the Alzheimer’s Association International Conference, in Washington, showed flickers of hope against the frustration researchers face in trying to unlock the secrets of Alzheimer’s disease.

In a posthoc exploratory analysis of gantenerumab, researchers suggested that dosing in the two-year SCarlet RoAD trial in people with early symptoms of Alzheimer’s may have been too low to be clinically effective. Roche stopped the SCarlet RoAD trial last December after preliminary results indicated that the chance of successful completion was very low, but patients in the study continued to be followed. The drug produced non–statistically significant, dose-related reductions on amyloid levels but statistically significant reductions in tau, a protein marker of brain cell degeneration that can be measured in the cerebrospinal fluid.

Meanwhile, a delayed-start analysis produced evidence of slower cognitive decline in some Alzheimer’s patients when solanezumab was taken for a longer period of time than in the original clinical trials. Two initial phase 3 trials of solanezumab—the 18-month EXPEDITION and EXPEDITION2 placebo-controlled studies—failed to reach statistical significance on primary endpoints in patients with mild to moderate disease. But patients with only mild disease and who were given placebo in the initial trials were allowed to cross over to solanezumab in an extension study. In a pooled analysis of 1,322 patients from the two original trials, those given solanezumab for two years in the extension study had statistically significant improvements in cognition. Eli Lilly intends to proceed with a new trial of solanezumab, which is expected to enroll 2,100 patients and take several years to complete.

**MS head-to-head trial**

Two pivotal studies (OPERA I and OPERA II) evaluating ocrelizumab in people with relapse-remitting multiple sclerosis met their primary and major secondary endpoints. Ocrelizumab significantly reduced the annualized relapse rate over a two-year period compared with interferon beta-1a (Rebif), the primary endpoint in both studies. Patients treated with ocrelizumab also experienced significantly reduced progression of clinical disability compared with interferon beta-1a, measured by the Expanded Disability Status Scale, and a significant reduction in the number of brain lesions, measured by MRI.

Ocrelizumab, under joint development by Genentech and Biogen, is an anti–CD20 monoclonal antibody that selectively targets CD20-positive B cells. These cells are thought to contribute to myelin and axonal damage.

**PsA mab superior to placebo**

The investigational medicine ixekizumab, a monoclonal antibody that targets interleukin-17A, was statistically superior to placebo in the treatment of patients with active psoriatic arthritis (PsA). Efficacy was demonstrated as the proportion of patients achieving ACR20 in the 24-week SPIRIT-P1 study. Patients who were naive to biologic disease-modifying antirheumatic drugs were treated with one of two different ixekizumab dosing regimens or placebo. In both regimens, ixekizumab-treated patients demonstrated significant improvements versus placebo in signs and symptoms of active PsA.

Izekizumab is also being studied in patients with psoriasis, and if Eli Lilly receives FDA approval for ixekizumab next year, the drug would be 1 of 2 IL-17s available for treatment of immunomodulatory diseases. Novartis’s secukinumab (Cosentyx) received FDA approval earlier this year. Amgen ceased development of a third IL-17, brodalumab, in May, after reports surfaced of suicidal thoughts and behavior in patients taking the drug in clinical trials.

**Have you heard?**

Two large trials both reported marginal or no improvement in OS in women with early-stage breast cancer who were treated with regional nodal irradiation in addition to whole-breast irradiation, but the addition of nodal irradiation did reduce the risk of recurrence and metastatic disease. Because these trials began in 1996 and 2000, some of the currently used therapies, such as trastuzumab (Herceptin) or taxane chemotherapies, were not systematically included in the trial protocols. Results of both trials were published in the New England Journal of Medicine.

— Katherine T. Adams

All clinical studies mentioned in this article are phase 3 unless otherwise stated.
<table>
<thead>
<tr>
<th>Date (type)</th>
<th>Manufacturer</th>
<th>Drug (trade) name; administration</th>
<th>Indication</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>July 2 (NDA)</td>
<td>Vertex</td>
<td>ivacaftor/lumacaftor (Orkambi); oral tablet</td>
<td>Cystic fibrosis (CF) in patients age≥12 with two copies of the F508del mutation</td>
<td>Combination tablet adds lumacaftor to ivacaftor (Kalydeco, approved in 2012 for patients age ≥6 with 1 of 9 CFTR mutations). Orkambi had a “breakthrough” designation because of preliminary evidence of a “substantial improvement” over existing CF therapies. The $259,000/year WAC called “egregious” by several prominent CF specialists.</td>
</tr>
<tr>
<td>July 24 (NDA)</td>
<td>Bristol-Myers Squibb</td>
<td>daclatasvir (Daklinza); oral tablet</td>
<td>In combination with sofosbuvir (Sovaldi) for the treatment of chronic hepatitis C, genotype 3 (HCV-3) infection</td>
<td>NS5A inhibitor is first to treat HCV-3 without coadministration of interferon or ribavirin. Safety and efficacy demonstrated in an open-label trial of 152 treatment-naive and -experienced patients. WAC is $63,000, but because Daklinza must be prescribed with Sovaldi ($84,000), a 12-week course comes at a total cost of $147,000.</td>
</tr>
<tr>
<td>July 24 (NDA)</td>
<td>AbbVie</td>
<td>ombitasvir, paritaprevir and ritonavir (Technivie); oral tablet</td>
<td>In combination with ribavirin for the treatment of chronic hepatitis C, genotype 4 (HCV-4) infection without cirrhosis</td>
<td>Fixed-dose combination NS5A inhibitor is first to treat HCV-4 without coadministration of interferon. Two-arm study included patients with or without coadministration of ribavirin. 100% of patients in Technivie-ribavirin group achieved SVR, vs. 91% in the Technivie-only group.</td>
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<tr>
<td>July 24 (BLA)</td>
<td>Sanofi-Aventis/Regeneron</td>
<td>alirocumab (Praluent); subcutaneous injection</td>
<td>Adjunct to maximally tolerated statin in adults with HeFH or clinical atherosclerotic CV disease who need extra help lowering LDL cholesterol</td>
<td>First PCSK9 inhibitor to market is injected to help the body clear excess LDL. HeFH is a genetic disorder that can elevate LDL &gt;200 mg/dL and makes LDL reductions difficult to achieve. WAC price is $40/day.</td>
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<td>July 24 (NDA)</td>
<td>Novartis</td>
<td>sonidegib (Odomzo); oral tablet</td>
<td>Recurrent locally advanced basal cell carcinoma</td>
<td>For use only in patients who are not candidates for surgery or radiation therapy, Odomzo inhibits the hedgehog pathway. Approval is based on demonstration of ORR in a randomized trial that compared dosage strengths.</td>
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<tr>
<td>July 14 (NDA)</td>
<td>AstraZeneca</td>
<td>gefitinib (Iressa); oral</td>
<td>First-line treatment of metastatic NSCLC with EGFR exon 19 deletions or exon 21 (L858R) substitution mutations, as detected by an FDA-approved test</td>
<td>Approval is concurrent with labeling expansion of the therascreen EGFR RGQ PCR kit, a companion diagnostic for the detection of EGFR oncogene mutations. Iressa was withdrawn from the market in 2011 after confirmatory trials failed to verify clinical benefit. This approval is for a different population than for Iressa’s initial approval in 2003.</td>
</tr>
<tr>
<td>July 24 (sNDA)</td>
<td>Onyx</td>
<td>carfilzomib (Kyprolis); intravenous injection</td>
<td>Relapsed MM. Prescribed with len/dex in patients who have received 1–3 prior lines of therapy, or as monotherapy for patients with ≥2 prior therapies including bortezomib and an IMiD</td>
<td>Approval is based on demonstration of improved progression-free survival in the PX-171-009 ASPIRE trial. The revised labeling includes new warnings and precautions for VTE, cardiac toxicities, acute renal failure, pulmonary toxicities, and hypertension.</td>
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A Google search on “$1,000 pill” and you will get nearly 500,000 results, with most of them being about new hepatitis C antivirals. And it’s a safe bet that almost everyone in health care has seen or read something about the $1,000 pill.

Now search on “$1 million injection” and you will find a number of articles about injections (of cash or capital) into companies or government programs, not humans.

But in the next year, somebody at some health plan in this country will likely receive a bill for $1 million for a single injection (or depending on which drug is approved first, a single patient visit for numerous injections). In fact, bills for this level of care are already being received in Europe.

The European Commission in November 2012 granted its first marketing authorization of a gene-based therapy called alipogene tiparvovec (Glybera), and the treatment has now been commercialized in parts of Europe. The pricing for alipogene tiparvovec came to light in November 2014 when uniQure, an Amsterdam-based company, and its marketing partner, Chiesi, based in Italy, filed a document in Germany that put the price at about $1.4 million per treatment. Although alipogene tiparvovec isn’t on the American market, it’s probably just a matter of time before uniQure seeks FDA approval. The company operates a 55,000-square-foot facility in a suburb of Boston.

Glybera was designed to treat familial lipase deficiency (LPLD), also called type 1 hyperlipidemia, a disorder that affects a very small number of people—about one or two individuals out of every million. Lipoprotein lipase is an important enzyme in the metabolic cascade involved in the generation and regulation of triglycerides. People with the deficiency suffer recurrent abdominal pain, acute and potentially life threatening episodes of pancreatitis, hepatosplenomegaly (enlarged liver and spleen) and cutaneous xanthomata (fatty deposits in the skin).

Glybera uses an adeno-associated viral vector, a small nonenveloped virus that carries a genetic snippet designed to correct the lipase deficiency. Adeno-associated viral vectors are used in gene therapy because they don’t provoke a strong immune response and can transfer their therapeutic genetic cargo into many different types of cells. Glybera is injected into multiple sites in the muscles of the leg because legs are accessible and a site of lipoprotein lipase expression.

Fixing retinal dystrophy

On this side of the ocean, a therapy to correct an inherited eye disorder might be the first gene therapy to get FDA approval and hit the market. The therapy, which is being called SPK-RPE65 for the time being, is a treatment for inherited retinal dystrophies caused by defects in the RPE65 gene. Retinitis pigmentosa is the most common form of inherited retinal dystrophy, and Leber congenital amaurosis, the most severe. Patients with Leber congenital amaurosis often have severe vision loss and abnormal eye movements (nystagmus) starting when they are infants or very young children.

Spark Therapeutics, a Philadelphia company, is now conducting the trials of SPK-RPE65, but other groups are also investigating treatments that fix RPE65-related retinal dystrophies at the genetic level. Yet this is very much a niche area of
medicine. Spark estimates that only about 3,500 people in the United States and five major European markets could benefit from its gene therapy treatment, a group that includes people with the subtypes of retinitis pigmentosa (RP type 20) and Leber congenital amaurosis (LCA type 2) that can be traced back to RPE65 mutations.

On the other hand, Spark is testing the same basic gene therapy technology in other trials with other diseases as the target. SPK-RPE65 is its leading product. If it pans out and is shown to be effective in clinical trials that may bode well for its other gene therapy products and for gene therapy in general.

The RPE65 gene is expressed in the retinal pigment epithelium—thus the RPE of RPE65. The retinal pigment epithelium nourishes the retina’s photoreceptor cells—the rods and cones—and provisions important steps in the metabolic cycle that make vision possible. RPE65 is especially important for rods, so people lose most if not all of their night vision if the gene is mutated in a way that adversely affects its expression.

Like uniQure’s Glybera, Spark’s SPK-RPE65 uses an adenov-associate viral vector to ferry the therapeutic genetic material to the target tissue. One reason that gene therapy for this obscure eye disease has come so far along is researchers had a good animal model to work with. The Briard breed of dog suffers from a RPE65-related condition that is very much like human Leber congenital amaurosis.

Positive results in those dogs led to human trials, and results from those trials have been encouraging. An initial report in Lancet in 2009 said all 12 patients in a phase 1 trial that involved treating just one eye with SPK-RPE65 experienced improvement in subjective and objective measures of vision. A 2012 article in Science Translational Medicine described successful efforts to treat the second eye of three people who were in the initial study.

Spark Therapeutics appears to have some momentum going that would win it the distinction of having the first-ever gene therapy product on the American market. It finished recruiting 28 patients for the pivotal phase 3 trial of SPK-RPE65 two years ago and received FDA breakthrough therapy status for the treatment last year. The company says on its website that it will report data from the phase 3 study in the later half of this year with an expectation of filing a biologic licensing application with the FDA in 2016.

But there’s also reason to keep a finger on the pause button. Earlier this year, a British group reported results for gene therapy for Leber congenital amaurosis in the New England Journal of Medicine (NEJM) that showed the benefits to people’s vision to be modest and, more troubling, the improvements in vision wore off. Spark Therapeutics says there are important differences between its product and what the British researchers used, but the NEJM report does sow doubt. And gene therapy as a field suffered a significant setback earlier this year when Mydical, a gene therapy product for heart failure, did not meet primary and secondary endpoints in a phase 2b study.

Some may remember when gene therapy seemed poised to take off in the ’90s. A patient death effectively shut the field down and it’s only recently gotten into recovery mode.

Managed care implications
Restoring vision, albeit limited in existing published studies, will garner a lot of attention, especially since the studies show improvement in children. If SPK-RPE emerges from its phase 3 trial with positive results and gains FDA approval, managed care companies will be hard pressed to deny coverage for a therapy for a disease that causes blindness in later decades. How it will be priced isn’t known. But the million-dollar syringe may soon make the thousand-dollar pill seem quaint, and again prove that Tomorrow’s Medicine will always be newsworthy—and sometimes very expensive!

ADVERTISING INDEX

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Cost Differences Between Open and Minimally Invasive Surgery
Kathryn Fitch, RN, MEd1; Tyler Engel, ASA, MAAA1; Andrew Bochner, ASA, MAAA1
1Milliman, Inc

INTRODUCTION

Despite evidence supporting the benefits of MIS, its use varies widely by region and hospital (Cooper 2014). High utilization of MIS has been correlated with urban location, large hospital size, teaching hospitals, and specific US regions (Cooper 2014). Surgeon preference, reimbursement considerations, and resident training convention have been shown to be factors in the choice of surgical approach (Fullum 2010, Roumm 2005).

ABSTRACT
Purpose: To analyze the cost difference between minimally invasive surgery (MIS) and open surgery from a commercial payer perspective for colectomy, ventral hernia repair, thoracic resection (resection of the lung), and hysterectomy.

Design: A retrospective claims data analysis was conducted using the 2011 and 2012 Truven Health Analytics MarketScan Commercial Claims and Encounter Database. Study eligibility criteria included age 18–64 years, pharmacy coverage, ≥1 month of eligibility in 2012, and a claim coded with 1 of the 4 surgical procedures of interest; the index year was 2012.

Methodology: Average allowed facility and professional costs were calculated during inpatient stay (or day of surgery for outpatient hysterectomy) and the 30 days after discharge for MIS vs open surgery. Cost difference was compared after adjusting for presence of cancer, geographic region, and risk profile (age, gender, and comorbidities).

Results: In total, 46,386 cases in the 2012 MarketScan database represented one of the surgeries of interest. The difference in average allowed surgical procedure cost (facility and professional) between open surgery vs adjusted MIS was $10,204 for colectomy; $3,721, ventral hernia repair; $12,989, thoracic resection; and $1,174, noncancer hysterectomy ($<.001 for all comparisons). The difference in average allowed cost in the 30 days after surgery between open surgery vs adjusted MIS was $1,494 for colectomy, $1,320 for ventral hernia repair, negative $711 for thoracic resection, and negative $425 for noncancer hysterectomy ($<.001 for all comparisons, except $=.487 for thoracic resection).

Conclusion: MIS was associated with statistically significantly lower costs than open surgery for all 4 analyzed surgeries.

METHODS
Data Source
We performed a retrospective claims data analysis using the 2011 and 2012 Truven Health Analytics MarketScan Commercial Claims and Encounter Database (MarketScan), a large dataset containing the inpatient, outpatient, and prescription drug healthcare service use of individuals nationwide who are covered by the benefit plans...
of large employers, health plans, and governmental and public organizations. MarketScan includes the annual enrollment and paid health care claims generated by approximately 50 million commercially insured lives from approximately 100 private sector payers. All MarketScan data used in our analysis were de-identified and comply with Health Insurance Portability and Accountability Act confidentiality requirements.

Study Population Identification
We used 2012 MarketScan data to identify the study population; our index year was 2012. Study eligibility criteria for the study population included age 18-64 years, pharmacy coverage, ≥1 month of eligibility in 2012, and a claim coded with 1 of the 4 procedures of interest (ie, colectomy, ventral hernia repair, thoracic resection (resection of the lung), or hysterectomy). Individuals enrolled in capitaled plans were not eligible because of the potential for incomplete claims.

MIS and open surgical procedure cases were identified using International Classification of Diseases Ninth Edition (ICD-9) and/or Current Procedural Terminology/Healthcare Common Procedure Coding System (CPT) codes (Table 1). The ICD-9 procedure code was required to be in the primary position of the claim. In cases that converted to open from MIS, we assigned the case and all costs to the MIS cohort. Robotics cases in which a claim included certain add-on codes (ICD-9 procedure codes

### KEY POINTS
- Minimally invasive surgery using laparoscopic, endoscopic, or catheter-based techniques has become an increasingly common alternative to traditional open surgery.
- Studies comparing minimally invasive to open surgery have shown that minimally invasive surgery is associated with shorter stays in intensive care and in the hospital overall; lower rates of transfusion, readmission, surgical site infections, pain, and mortality; and less time taken off before returning to normal activities or work.
- This study made cost comparisons between a minimally invasive approach and an open approach for four procedures: colectomy, ventral hernia repair, thoracic resection, and hysterectomy.
- Cost per episode (inclusive of professional, facility, and costs incurred 30 days after the surgery) was lower for the minimally invasive approach for all four types of surgery.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Open ICD-9 procedure codes</th>
<th>MIS ICD-9 procedure codes</th>
<th>Open CPT codes</th>
<th>MIS CPT codes</th>
<th>DRGs for IP Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colectomy</td>
<td>53.61, 53.69, 53.51, 53.59</td>
<td>53.62, 53.63</td>
<td>49560, 49561, 49565, 49566</td>
<td>49652, 49653, 49654, 49655, 49656, 49657</td>
<td>353, 354, 355</td>
</tr>
<tr>
<td>Hysterectomy (noncancer)</td>
<td>58570, 58571, 58572</td>
<td>58573, 58548</td>
<td>49650, 49651, 49655, 49656, 49657</td>
<td>353, 354, 355</td>
<td>329, 330, 331</td>
</tr>
</tbody>
</table>

**TABLE 1**
Codes used for procedure identification and IP case inclusion

Source: Authors' analysis of 2012 Truven MarketScan database.
CPT = Current procedural terminology, DRG = Diagnosis Related Group, ICD-9 = International classification of diseases ninth edition, IP = Inpatient, MIS = Minimally invasive surgery. ICD-9 procedure codes were required to be in the primary position of the claim.
IP cases were required to be coded with specified DRGs.
without MCCs/CCs, and outpatient MIS hysterectomy. The MIS and open surgery cases remaining after meeting all specified criteria were used to calculate the incidence and cost of these procedures in a commercial population. The denominator population for calculating the incidence rates was also required to have pharmacy coverage, ≥1 month of eligibility in 2012, and not be enrolled in capitated plans.

We split cases within the colectomy and thoracic resection cohorts into cancer and noncancer cases based on the following ICD-9 codes appearing in any position of the index surgery claim: colon cancer codes 153.x, 197.5, 209.10, 209.13-209.16, 230.3, 235.2, and 197.5; and lung cancer codes 162.2-162.9, 197.0, 231.2, 235.7, and 197.0.

Cost Analysis

We calculated the average allowed facility and professional costs during the inpatient stay (or day of surgery for outpatient hysterectomy procedures) and all costs in the 30 days after discharge (or 30 days after the outpatient hysterectomy procedure date), including those for inpatient, outpatient, and professional services and prescription drugs. We identified readmissions that initiated within 30 days of discharge for each case and calculated a rate of readmissions per surgical cohort and the cost contribution of readmissions per case. To adjust for outlier costs, we capped each 30-day readmission allowed amount at $100,000.

To compare the cost between open and MIS cohorts by surgery, we adjusted for potential explanatory variables, including age, gender, comorbidities, presence of cancer (colectomy and thoracic surgery only), and US census region. To account for differences in the contribution of cancer cases when comparing the cost of MIS to open surgery, the MIS cancer case contribution in the thoracic surgery and colectomy cohorts was adjusted to reflect the same contribution as the open surgery cancer case contribution. An adjustment was also made to account for regional reimbursement differences when comparing MIS and open surgery costs. The adjustment, which was made for both procedure costs (inpatient stay or outpatient surgery day) and postprocedure 30-day costs, was based on member residence by major geographic census region. A specific region was not identified for 2% of cases, so we also included an “Unidentified” category region. MIS costs were adjusted to reflect the same contribution of cases per region as open surgery cases.

We used a publicly available, federally certified risk adjustment methodology developed by the US Department of Health and Human Services (HHS) to account for differences in age, gender, and comorbidity when comparing the cost of MIS to open surgery. The methodology uses a hierarchical condition category (HCC) system to categorize diagnosis codes by severity for calculating “metal-level” risk scores (ie, platinum, gold, silver, bronze, and catastrophic) (CDC 2013). The risk scores are intended to predict cost in the subsequent year. Using 2011 MarketScan data, we calculated a HHS-HCC gold metal level risk score for each individual using 12 months of claims data prior to the surgery admission date or outpatient procedure date. The gold metal level was chosen to best reflect the risk score for an average commercially insured population. Using individual risk scores, we calculated the mean risk score for each surgery cohort. Using linear regression, we modeled the relationship between post-procedure 30-day costs (after applying a $100,000 outlier cap to readmissions) and the risk score for each surgery cohort. For each surgery cohort, we calculated the ratio between the open surgery and MIS postprocedure 30-day costs.
predicted by the regression analysis. We adjusted the MIS postprocedure 30-day costs by multiplying this ratio by the MIS costs that already included the adjustments for regional and cancer differences and readmission outliers. We did not make an adjustment to the inpatient costs, as the type of procedure (open vs MIS) impacts the DRG assignment.

**Cost Difference of Shifting Open Surgery to MIS**

Based on the total cost of all 2012 cases in each of the 8 surgical cohorts, along with the denominator population’s total 2012 annual costs and member months of eligibility, we calculated the cost per member per month (PMPM) contribution of each cohort to the total population. We modeled the difference in cost from the starting baseline PMPM if 25%, 50%, and 75% of open cases were shifted to MIS for each surgery cohort, assuming the mean cost of the open cases would be replaced with that of the MIS cases.

**RESULTS**

We identified 46,386 cases in the 2012 MarketScan database meeting the inclusion criteria for the eight surgical cohorts of interest in the 2012 index year (Table 2). Of these, 3113 cases were thoracic resection (open, n = 1040; MIS, n = 2073); 28,953 cases, noncancer hysterectomy (open, n = 11,136; MIS, n = 17,817); 11,542 cases, colectomy (open, n = 6056; MIS, n = 5486); and 2778 cases, ventral hernia repair (open, n = 2073; MIS, n = 705). We excluded 23,525 cases that did not meet the inclusion criteria, including 10,260 hysterectomy cases (inpatient open non-cancer with MCCs/CCs, n = 3759; inpatient open cancer, n = 1161; outpatient open, n = 583; inpatient MIS, n = 3497; outpatient MIS cancer, n = 1260) and 13,265 ventral hernia repair cases (outpatient open, n = 9216; outpatient MIS, n = 4049). Outpatient colectomy and thoracic resection cases were not identified in the data.

More patients were identified with open surgery than MIS for colectomy (52.5% vs 47.5%, respectively) and ventral hernia repair (74.6% vs 25.4%, respectively), whereas fewer patients were identified with open surgery than MIS for thoracic resection (33.4% vs 66.6%, respectively) and noncancer hysterectomy (38.5% vs 61.5%, respectively).

The average length of stay for inpatient cases was found to be statistically significantly lower with MIS than open surgery in patients undergoing thoracic resection (4.7 vs 6.6 days, respectively; P < .001), colectomy (4.9 vs 7.4 days, respectively; P < .001), and ventral hernia repair (2.7 vs 3.6 days, respectively; P < .001); the comparison could not be made with noncancer hysterectomy, as MIS was performed on an outpatient basis.

The mean age of patients was significantly different when comparing thoracic resection and hysterectomy open and MIS cohorts (P < .001), but not when comparing colectomy and ventral hernia repair open and MIS cohorts (P = .107 and P = .386, respectively). The gender distribution was significantly different when comparing thoracic resection open and MIS cohorts (P < .001), but not when comparing colectomy and ventral hernia repair open and MIS cohorts (P = .169 and P = .434, respectively). The difference in the distribution of cases from the 10 geographic regions was statistically significant when comparing the open and MIS colectomy, thoracic resection, and hysterectomy cases (P < .001) but not the ventral hernia repair cases (P = .665). The cancer distribution was significantly different when comparing the thoracic resection open and MIS cohorts (P < .001) but not when comparing the colectomy open and MIS cohorts (P = .032).

After adjusting for age, sex, comorbidities, geographic region, and cancer, average allowed surgical procedure costs (facility and professional costs) were statistically significantly lower for all MIS cohorts vs open cohorts (Table 3). The difference in average allowed surgical procedure costs (facility and professional) between open surgery vs adjusted MIS was $10,204 for colectomy; $3721, ventral hernia repair; $12,989, thoracic resection; and $1174, noncancer hysterectomy (P < .001 for all comparisons). The difference in average allowed cost between open surgery vs adjusted MIS in the 30 days after surgery was $1494 for colectomy; $1320, ventral hernia repair; negative $711, thoracic resection; and negative $425, noncancer hysterectomy (P < .001 for all comparisons, except P = .487 for thoracic resection). Readmission per 100 cases was lower with MIS than open surgery for colectomy, ventral hernia repair, and thoracic resection, but higher for MIS noncancer hysterectomy than inpatient hysterectomy (P < .001 for colectomy and ventral hernia repair; P = .091, thoracic resection; P = .004, noncancer hysterectomy). The adjusted readmission average allowed cost was lower with MIS vs open surgery for colectomy and ventral hernia repair but higher with MIS vs open surgery for thoracic resection and noncancer hysterectomy (P < .001 for ventral hernia repair, P = .041, colectomy; P = .496, thoracic resection; and P = .226, noncancer hysterectomy).

We provided the cost difference if the costs for a portion of the open cases in each surgical cohort were shifted to the costs of the MIS cases. We used the baseline distribution of open and MIS cases and baseline 2012 costs. The contribution of the 4 surgeries was $3.58 to the total population PMPM of $404.46. A shift of 25%, 50%, and 75% of open surgery to MIS resulted in allowed PMPM
### TABLE 2
Patient characteristics for surgery cohorts

<table>
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<th>Characteristic</th>
<th>Colectomy Open IP (n = 6,056)</th>
<th></th>
<th>MIS IP (n = 5,486)</th>
<th></th>
<th>P value</th>
<th>Colectomy Open IP (n = 2,073)</th>
<th></th>
<th>MIS IP (n = 705)</th>
<th></th>
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<td><strong>Case distribution</strong></td>
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<tr>
<td>Case distribution</td>
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<td>74.6%</td>
<td></td>
<td>25.4%</td>
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<tr>
<td>Incidence</td>
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<td></td>
<td></td>
<td></td>
<td>6/100,000</td>
<td></td>
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<td><strong>Average length of stay</strong></td>
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<td>&lt;.001*</td>
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<tr>
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<td><strong>DRG distribution for IP cases</strong></td>
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<tr>
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<td>331: Major small &amp; large bowel procedures w/o CC/MCC</td>
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<td></td>
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<td>N/A</td>
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<td>N/A</td>
<td></td>
<td>N/A</td>
<td></td>
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<tr>
<td>354: Hernia procedures except inguinal &amp; femoral w CC</td>
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<td></td>
<td>N/A</td>
<td></td>
<td>N/A</td>
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<td></td>
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<tr>
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<td></td>
<td>N/A</td>
<td></td>
<td>N/A</td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>Cancer distribution</strong></td>
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<td>.03**</td>
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</tr>
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<td></td>
</tr>
</tbody>
</table>

Source: Authors’ analysis of 2012 Truven MarketScan database.

* T-Test. ** Chi-Square Test. ***Hysterectomy MIS cases were OP only.

CC, complication or comorbidity; MCC, major complication or comorbidity; MIS, minimally invasive surgery; IP, inpatient; OP, outpatient.
# Table 2

## Patient characteristics for surgery cohorts (cont.)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Thoracic resection</th>
<th>Hysterectomy non-cancer</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Open IP (n = 1040)</td>
<td>MIS IP (n = 2073)</td>
</tr>
<tr>
<td>Case distribution</td>
<td>33.4% 66.6%</td>
<td>38.5% 61.5%</td>
</tr>
<tr>
<td>Incidence</td>
<td>3/100,000 6/100,000</td>
<td>32/100,000 52/100,000</td>
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<tr>
<td>Average length of stay</td>
<td>6.6 4.7</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>52.4 48.8</td>
<td>44.7 43.8</td>
</tr>
<tr>
<td>Median</td>
<td>55 53</td>
<td>45 44</td>
</tr>
<tr>
<td>Range</td>
<td>18–64 18–64</td>
<td>21–64 18–64</td>
</tr>
<tr>
<td>Distribution</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18–24</td>
<td>2.8% 8.4%</td>
<td>0.1% 0.2%</td>
</tr>
<tr>
<td>25–34</td>
<td>4.4% 7.3%</td>
<td>7.3% 10.5%</td>
</tr>
<tr>
<td>35–44</td>
<td>9.1% 12.0%</td>
<td>40.3% 43.5%</td>
</tr>
<tr>
<td>45–54</td>
<td>29.9% 29.2%</td>
<td>45.2% 38.3%</td>
</tr>
<tr>
<td>55–64</td>
<td>53.8% 43.1%</td>
<td>7.1% 7.5%</td>
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<tr>
<td>Gender distribution</td>
<td></td>
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<tr>
<td>Male</td>
<td>45.8% 50.5%</td>
<td>0.0% 0.0%</td>
</tr>
<tr>
<td>Female</td>
<td>54.2% 49.5%</td>
<td>100.0% 100.0%</td>
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<tr>
<td>Regional distribution (Census regions)</td>
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<td></td>
</tr>
<tr>
<td>East North Central</td>
<td>23.2% 20.7%</td>
<td>17.4% 17.2%</td>
</tr>
<tr>
<td>East South Central</td>
<td>8.7% 6.8%</td>
<td>9.7% 12.9%</td>
</tr>
<tr>
<td>Middle Atlantic</td>
<td>9.4% 11.8%</td>
<td>7.5% 4.0%</td>
</tr>
<tr>
<td>Mountain</td>
<td>4.3% 6.1%</td>
<td>5.2% 6.9%</td>
</tr>
<tr>
<td>New England</td>
<td>4.8% 7.0%</td>
<td>2.5% 2.0%</td>
</tr>
<tr>
<td>Pacific</td>
<td>8.6% 11.8%</td>
<td>10.9% 6.4%</td>
</tr>
<tr>
<td>South Atlantic</td>
<td>16.4% 18.1%</td>
<td>20.5% 22.6%</td>
</tr>
<tr>
<td>West North Central</td>
<td>6.4% 4.7%</td>
<td>3.9% 6.4%</td>
</tr>
<tr>
<td>West South Central</td>
<td>16.0% 10.9%</td>
<td>21.1% 20.0%</td>
</tr>
<tr>
<td>Unidentified</td>
<td>2.2% 2.1%</td>
<td>1.3% 1.6%</td>
</tr>
<tr>
<td>DRG distribution for IP cases</td>
<td></td>
<td></td>
</tr>
<tr>
<td>163: Major chest procedures w MCC</td>
<td>28.2% 22.8%</td>
<td>N/A N/A</td>
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<td>164: Major chest procedures w CC</td>
<td>67.0% 58.0%</td>
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<tr>
<td>165: Major chest procedures w/o CC/MCC</td>
<td>4.8% 19.2%</td>
<td>N/A N/A</td>
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<tr>
<td>735: Pelvic evisceration, rad hysterectomy &amp; rad vulvectomy w/o CC/MCC</td>
<td>N/A N/A</td>
<td>0.4% N/A</td>
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<tr>
<td>738: Uterine &amp; adnexa proc for ovarian or adnexal malignancy w/o CC/MCC</td>
<td>N/A N/A</td>
<td>1.2% N/A</td>
</tr>
<tr>
<td>741: Uterine, adnexa proc for non ovarian/adnexal malig w/o CC/MCC</td>
<td>N/A N/A</td>
<td>0.1% N/A</td>
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<td>743: Uterine &amp; adnexa proc for non-malignancy w/o CC/MCC</td>
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</tr>
<tr>
<td>No</td>
<td>22.9% 54.7%</td>
<td>100.0% 100.0%</td>
</tr>
</tbody>
</table>

Source: Authors' analysis of 2012 Truven MarketScan database.

* T-Test. ** Chi-Square Test. ***Hysterectomy MIS cases were OP only.

CC, complication or comorbidity; MCC, major complication or comorbidity; MIS: minimally invasive surgery. IP: inpatient. OP: outpatient.
Furthermore, the statistically significant cost differences between MIS vs open surgery persisted after adjustments were made. Our findings pertaining to the cost of MIS vs open surgery are in general agreement with those in the published literature (Fullum 2010, Swanson 2012, Dor 2012, Warren 2009). For example, in one study based on claims costs moving from a starting $3.58 to $3.50, $3.42, and $3.34, respectively (Table 4).

**DISCUSSION**

The results of our study, which identified cost differences between MIS vs open surgery for colectomy, ventral hernia repair, thoracic resection, and hysterectomy, provide further support for the use of MIS and are directly relevant for health care payers and employers. Our calculations showed that MIS vs open surgery is associated with lower facility and professional costs for the initiating procedure for all 4 analyzed surgeries and that readmission rates are lower with MIS than open surgery for colectomy, ventral hernia repair, and thoracic resection. Furthermore, the statistically significant cost differences between MIS vs open surgery persisted after adjustments were made.

**TABLE 3**

*Comparison of MIS and open average allowed costs*

<table>
<thead>
<tr>
<th>Surgery</th>
<th>Open IP</th>
<th>Unadjusted</th>
<th>Adjusted*</th>
<th>Open IP vs adjusted MIS IP</th>
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<td><strong>Colectomy</strong></td>
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<td>Average allowed episode cost</td>
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<td>$45,348</td>
<td>$48,363</td>
<td>$11,698 &lt; .001</td>
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<td>Anchor Average Allowed Cost</td>
<td>$42,132</td>
<td>$38,348</td>
<td>$38,685</td>
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<td>Facility</td>
<td>$36,043</td>
<td>$32,509</td>
<td>$32,653</td>
<td>$9,390 &lt; .001</td>
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<tr>
<td>Professional</td>
<td>$6,089</td>
<td>$5,309</td>
<td>$5,275</td>
<td>$814 &lt; .001</td>
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<td><strong>30 Day Post-Average Allowed</strong></td>
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<tr>
<td>Cost/Case</td>
<td>$6,250</td>
<td>$5,975</td>
<td>$6,757</td>
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<tr>
<td>Readmissions per 100 Anchor Cases</td>
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<td>7.7</td>
<td>3.9 &lt; .001</td>
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<tr>
<td><strong>Readmission Average Allowed</strong></td>
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<td>$2,751</td>
<td>$1,884</td>
<td>$454 &lt; .001</td>
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<tr>
<td>Cost/Case</td>
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<td></td>
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<td>Ventral hernia repair</td>
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<tr>
<td>Average allowed episode cost</td>
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<td>$21,599</td>
<td>$21,886</td>
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<tr>
<td>Facility</td>
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<td>$16,970</td>
<td>$16,882</td>
<td>$2,741 &lt; .001</td>
</tr>
<tr>
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<td>$3,097</td>
<td>$3,116</td>
<td>$980 &lt; .001</td>
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<td><strong>30 Day Post-Average Allowed</strong></td>
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<td>$1,532</td>
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<td>3.4 &lt; .001</td>
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<tr>
<td>Readmission Average Allowed Cost/Case</td>
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<td>$592</td>
<td>$1,000 &lt; .001</td>
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<td>8.2</td>
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<tr>
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<td>Facility</td>
<td>$11,162</td>
<td>$9,687</td>
<td>$9,829</td>
<td>$1,333 &lt; .001</td>
</tr>
<tr>
<td>Professional</td>
<td>$3,159</td>
<td>$2,636</td>
<td>$2,683</td>
<td>($159) &lt; .001</td>
</tr>
<tr>
<td><strong>30 Day Post-Average Allowed</strong></td>
<td></td>
<td>$3,159</td>
<td>$3,318</td>
<td>($425) &lt; .001</td>
</tr>
<tr>
<td>Cost/Case</td>
<td></td>
<td>2.5</td>
<td>3.1</td>
<td>(0.6) .004</td>
</tr>
<tr>
<td>Readmission Average Allowed Cost/Case</td>
<td></td>
<td>$424</td>
<td>$482</td>
<td>($59) .226</td>
</tr>
</tbody>
</table>

Source: Authors’ analysis of 2012 Truven MarketScan database.

1 Total allowed episode cost includes all claims for the initiating “anchor” surgery case and the 30 days after anchor discharge.

2 Readmission average allowed cost/case reflects the cost of all readmissions spread across all cases – not the average cost of a readmission.

3 For Open cases, this cohort includes IP surgeries that are coded with DRGs without CCs or MCCs. For MIS, this cohort includes OP surgeries only.

4 MIS average cost calculation for each cohort assumes the same regional contribution as Open cases and for thoracic resection and colectomy, MIS assumes the same cancer contribution as Open cases and MIS average cost reflects an adjustment for the difference in 2011 HHS-HCC gold risk score between Open and MIS patients. MIS: minimally invasive surgery; IP: inpatient; OP: outpatient.
data from a single large US care plan, the unadjusted cost of laparoscopic surgery was found to be lower than that for open hysterectomy ($10,868 vs $12,086, respectively), and there was no statistically significant cost difference between the 2 procedures after adjustment was made for differences in patient case mix (Warren 2009). Another study reported that hospital costs in patients undergoing lobectomy were higher with open surgery than video-assisted thoracoscopic surgery ($21,016 vs $20,316, respectively) (Swanson 2012).

The data we reported on length of stay and readmission rates in patients receiving MIS vs open surgery are also consistent with those in the published literature (Delaney 2008, Eisenberg 2010, Swanson 2012, Howington 2012, Juo 2014, Paul 2013). For example, we found that the average length of stay in patients who received colectomy with MIS was 2.5 days shorter ($<.001) than in those who received open surgery, which is similar to published reports showing a median difference of 2.0 days (Juo 2014) and a mean difference of 1.7 days (Eisenberg 2010). Our analysis showed that postprocedure 30-day readmission rate for thoracic resection with MIS and open surgery was 8.2 vs 10.1 per 100 surgery cases, respectively ($= .091). Of interest, in a recent study in which 69% of patients underwent MIS and 31% of patients underwent open thoracotomy for pulmonary lobectomy, readmission was found to be independent of surgical approach (Assi 2015).

We found that the utilization of MIS vs open surgery varied widely by procedure. In our study, <50% of patients undergoing colectomy and ventral hernia repair received MIS (47.5% and 25.4%, respectively), whereas 66.6% and 61.5% of patients undergoing thoracic resection and non-cancer hysterectomy, respectively, received MIS. Recently, Cooper and colleagues retrospectively reviewed the hospital-level utilization of MIS vs open surgery for several commonly performed procedures, including colectomy, hysterectomy, and lung lobectomy (Cooper 2014). In the study, hospitals were stratified into low, medium, and high categories to depict MIS utilization. The average portion of MIS cases in low, medium, and high hospitals for colectomy was found to be 6.7%, 29.0%, and 49.8%, respectively; hysterectomy, 0.0%, 6.2%, and 33.6%, respectively; and lung lobectomy, 3.6%, 26.7%, and 65.7%, respectively. Our findings for colectomy and thoracic resection are close to those reported by Cooper and colleagues in the high hospital category; however, our finding that 61.5% of noncancer hysterectomies were performed by MIS is inconsistent with their data.

We did not analyze lost work time or disability data associated with MIS and open surgery; however, a meta-analysis reported that the number of days to return to work was 26 days less for colectomy, 15 days less for hysterectomy (laparoscopic vs abdominal hysterectomy), and 22 days less for ventral hernia repair with MIS vs open surgery (Roumm 2005). The cost associated with lost work time is an additional consideration for employers when examining MIS vs open surgery outcomes.

We acknowledge several study limitations. First, coding inaccuracies may have biased the results. Second, we were unable to examine clinical outcomes. Third, hospital prices may have been susceptible to managed care penetration and competing hospital dynamics. Fourth, our results remained susceptible to bias despite adjustments. For example, (1) although we adjusted for the regional contribution of cases, outlier hospital or professional reimbursement rates could have biased the results; (2) although we adjusted for cancer vs non-cancer cases, the impact of different disease diagnoses for which the procedures were performed could have biased the results; and (3) although we adjusted for comorbidities, age, and gender, the clinical severity in pa-

| TABLE 4 |
| Total allowed PMPM difference with open to MIS shift scenarios |
|-------------------|-------------------|-------|-------|-------|-------|
| Surgery           | PMPM*             | Baseline Distribution | PMMP after % Shift From Open to MIS |
|                   |                   | Open | MIS   | 25%   | 50%   | 75%   |
| Colectomy         | $1.55             | 52.5%| 47.5% | $1.49 | $1.43 | $1.38 |
| Ventral Hernia Repair | $0.22           | 74.6%| 25.4% | $0.21 | $0.21 | $0.20 |
| Thoracic Resection | $0.47             | 33.4%| 66.6% | $0.46 | $0.45 | $0.44 |
| Hysterectomy Non-Cancer | $1.34           | 38.5%| 61.5% | $1.33 | $1.33 | $1.32 |
| Total             | $3.58             | 35.0%| 65.0% | $3.50 | $3.42 | $3.34 |

Source: Authors’ analysis of 2012 Truven MarketScan database. Costs have not been trended.

*PMPM is the contribution of each surgery episode’s costs to total population PMPM. Total population PMPM = $406.46.
Cost Differences Between Open and Minimally Invasive Surgery

Patients receiving MIS vs open surgery may have been different. Additionally, confounding variables beyond those for which adjustments were made (e.g., socioeconomic or racial differences, type of hospital, skill of the surgeon) could also have biased the results. Finally, our findings may not have been representative of all hospitals, other surgery types, and other payers (e.g., Medicare and Medicaid). In addition, we did not distinguish between emergency vs elective surgery.

CONCLUSION

MIS has become an increasingly common alternative to open surgery for routine procedures, and its use has been linked to numerous patient benefits. Data comparing total hospital costs or total operative costs associated with MIS vs open surgery have generally placed MIS in a favorable light. Despite these benefits, however, MIS remains underutilized in many US regions and hospitals. Our study provides real-world outcomes showing that MIS has statistically significant lower costs than open surgery for the 4 analyzed surgeries.

REFERENCES


Juo Y-Y, Hyder O, Haider AH, Camp M, Lidor A, Ahuja N. Is minimally invasive colon resection better than traditional approaches? First comple-


The number of large employers steering their employees into consumer-directed health plans (CDHPs) isn’t changing very much. But if the ACA’s “Cadillac Tax” goes into effect as planned, that may start to change as employers look for ways to nudge costs below the level where the tax kicks in.

Starting in 2018, a 40% excise tax will be assessed on the cost of coverage for health plans that exceed a certain annual limit ($10,200 for individual coverage and $27,500 for family coverage). So, for example, if family coverage costs $30,000, the Cadillac Tax would be $1,000 (0.4 x $2,500). The Congressional Budget Office has estimated that the tax will bring in $87 billion in revenue from 2016 to 2025, a tidy sum but a fraction of the $1.7 trillion in ACA-related expenses for that period.

If Congress doesn’t repeal the Cadillac Tax, “we believe more employers will adopt a CDHP strategy in the coming years,” the National Business Group on Health says in its “2016 Health Plan Design Survey: Reducing Costs While Looking to the Future.”

Next year, 33% of the employers who answered the survey said they will make a CDHP their only insurance option, and 50% said a CDHP is among the health plans that their employees will be able to choose from.

Meanwhile, a CDC survey found that 13.3% of Americans under the age of 65 are now in a CDHP, compared with 7.7% five years ago. The CDC defined a CDHP as a high-deductible plan that comes with an HSA, HRA, or some other account for paying medical expenses.

Nearly half of the 140 large employers surveyed by the business group say that at least one of their health plans will exceed the Cadillac Tax threshold in 2018 if they do not make any changes to their packages. With the Cadillac Tax threshold set to general inflation, rather than medical inflation, the concern is that all plans—not just those deemed the Cadillacs of health care coverage—will end up having to pay the excise tax at some point.

**2015: Top 3 planned actions to minimize the Cadillac Tax**
1. Add or expand tools to encourage plan participants to be better consumers.
2. Implement or expand account based CDHPs.
3. Add or expand incentives to engage employees in wellness programs.

**2017: Top 3 planned actions to minimize the Cadillac Tax**
1. Add or expand high performance networks, ACOs or other delivery mode.
2. Eliminate high-cost plans.
3. Reduce richness of plans.

*Not shown: The number of employers offering a CDHP either as a choice or as the only option is expected to grow from 73% in 2012 to 83% in 2016. Source: National Business Group on Health, “2016 Health Plan Design Survey: Reducing Costs While Looking to the Future,” August 2015.