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Great expense, true economy

By Peter Wehrwein

Putting Medicaid aside for a moment, so much of health care reform has circled around the individual, or non-group market. Mark Pauly, a right-of-center University of Pennsylvania health care economist, made the point at a forum at the Philadelphia Inquirer earlier this year that the non-group market is actually a relatively small part (7% in 2015, according to the Kaiser Family Foundation) of the health insurance market. Many more Americans still experience health insurance as an employer-provided benefit (Kaiser puts it at 49% of the insurance market) or as Medicare (14%).

These proportions don’t make the debate about fixing the troubled non-group market unimportant. But they may mean that the underlying political temperature of health care reform is actually a bit cooler than one might expect. Many Americans can view the non-group debate as something that’s not going to affect them directly.

Still, isn’t it time that we grew up and had universal coverage? Walter McClure and Tim McDonald of the Center for Policy Design and Alain Enthoven, the famous Stanford health economist, made an eloquent case for it in a Health Affairs blog post published in late July. They compared universal health coverage to universal public education and deployed the Edmund Burke quote: “Mere parsimony is not economy. Expense, and great expense, may be an essential part in true economy.”

Yet great, bloated expense is what ails American health care, they argued, and if the right needs to stop fighting universal coverage, the left needs to recognize the need for cost containment.

Their preferred method is changing “perverse incentives” with objective ratings of providers and rewards for consumers who pick less costly, but high-quality providers.

That is a familiar prescription and there are problems with it, not the least of which is getting people to shop for health care, but not with the goal of finding that sweet spot of universal coverage and cost containment. 

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To Save a Bundle, These Payments Need To Change

Bundled payment systems have been with us a long while and maybe it’s time to tweak them, according to an opinion piece in *JAMA*. The authors argue that bundled payments can be even more cost-effective if their durations are lengthened, if some of the bundled services can be performed outside a hospital, and if they can be integrated with ACOs.

Bundled payment systems pay providers for an episode of care based on how well they keep costs in check relative to benchmarks based on how much was spent in the past. The authors—Amol S. Navathe, MD, Zirui Song, MD, and Ezekiel J. Emanuel, MD—say that the current structure of bundled payment systems limit their effectiveness. Emanuel, who is now on the faculty of the University of Pennsylvania, was a health official in the Obama administration and had a hand in shaping the ACA.

Bundled payments have retained the fee-for-service incentive to do more, especially for conditions without well-defined criteria for intervention, they wrote in *JAMA*. Another trouble spot: an unintended incentive to select for healthier patients and potentially increasing low-value care that offsets efficiency savings.

One change these authors want to see is restricting bundled payment to conditions with a clear starting point and those in which there is only limited physician and patient discretion.

Including services outside of the expensive hospital setting would involve allowing primary care physicians to take on some of the financial responsibility. The authors cite Medicare’s oncology bundle care model as an example. It lets outpatient practices share in the risk.

“Similarly, allowing ambulatory surgery centers or orthopedic practices to serve as the risk-bearing entity for hip replacements would incentivize a shift in surgical procedures out of the hospital, potentially generating substantial cost savings,” the authors write.

One of the biggest problems with the current structure of bundled payments is that, for the most part, they cover services up to 90 days after hospital discharge. That should be extended a year, they say.

Maternity bundled care, for instance, could include prenatal care, delivery, and subsequent neonatal care.

“For chronic diseases such as atrial fibrillation, the bundle may include physician visits, laboratory measurements for anticoagulation such as the international normalized ratio, diagnostic services such as electrocardiograms, medications, therapeutic procedures such as cardioversion and ablation, and associated hospitalizations.”

Bundled payments could work with ACOs if every provider involved has the same information on a patient. “The simplest approach is to count episodes for patients in ACOs in the bundle program by including the actual episode costs for assigned beneficiaries within the global costs of ACOs,” the authors write. This contrasts with current CMS policy for ACOs that “counts the historical target price for the bundle against the global costs of ACOs.”

Bundled payment care could be evaluated separately from the calculations of total cost at ACOs, according to the letter. “This structure would not allow the ACO program to offset the incentive to do more within the bundled payment and would potentially reduce savings for ACOs by allowing clinicians to cherry-pick more profitable cases,” the authors write.

**Briefly Noted**

An aging population and the associated higher incidence of lung disease fuels a demand for pulmonologists, according to the recruiting company Merrit Hawkins. Demand for the specialists increased by about 150% since 2012–2013. Another fact: For only the second time in the 24 years that Merrit Hawkins has conducted a review of the recruiting requests it gets from clients, psychiatrists were second on the list of the most requested recruiting assignments….

A wellness program in Gaston County, N.C., appears to be working rather, er, well, according to the *Gaston Gazette*. Hundreds of employees of the county near Charlotte have incorporated wellness into their lives. “Their efforts … have translated into measurable achievements, such as weight loss, smoking cessation, a decrease in sick leave, and a savings to the county in sick time hours, which all benefits taxpayers as a whole,” the newspaper reports. For about $172,000 per year, CaroMont Health System is providing biometric screening and wellness profiles to participating employees.

—Frank Diamond
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.

For more information about narcolepsy, please contact your Jazz Pharmaceuticals Account Manager.

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10 Notables From Behind the Scenes Of the Health Care Reform Debate

Whether an ACA fix or GOP plans—or neither—prevail, these players are poised to determine what comes next.

By Richard Mark Kirkner, Contributing Editor

On the day before Senate Majority Leader Mitch McConnell released his caucus’s first draft ACA replacement, Politico reported that Marilyn Tavenner, America’s Health Insurance Plans President and CEO, was among a coterie of AHIP officers holed up in his office for about an hour.

The irony of Tavenner negotiating the undoing of the law that she helped parent into existence was obvious.

Since then, Tavenner and AHIP have kept a noticeably low profile—although they did strongly object to the proposal by Sen. Ted Cruz that would make it easier for insurers to sell non–ACA-compliant insurance. Other groups representing health care stakeholders have been far more vocal in their opposition to the GOP plan.

Tavenner and AHIP may continue to operate largely in the background, but that, of course, doesn’t mean that they won’t have a meaningful role in shaping any health care legislation that emerges from the ashes of the GOP’s repeal-and-replace efforts.

And if the legislation stalls, they’ll lobby Congress and the Trump administration in hopes of influencing the legislative tweaks and rule-making that will reshape the ACA.

Tavenner is one of a handful of lobbyists, administration officials, and think tankers who are in a position to sculpt federal health care policy—with or without full-blown repeal-and-replace.

Below, I present a list of 10 of them, not in any order of importance. This is not meant to be “the 10 most important” people in health care policy. It’s a sample from a larger group, and a different group of 10 might have been selected and would have been just as worthy—kind of like admission to a selective college.

If you have suggestions on someone I’ve overlooked, please let me know at richkirkner@gmail.com or via Twitter @rmkeditor. (Yes, this is a shameless bid for fodder for a future column.)

Marilyn Tavenner. As far as health plans getting Washington’s ear, she’s up there, and she understands the inner workings of Washington. From 2011 to 2015, she was CMS administrator, leading the agency through the crash and recovery of the HealthCare.gov website. A nurse by training, Tavenner rose through the ranks of the Hospital Corporation of America to become a regional and group executive. Then she went to work for Tim Kaine when he was the governor of Virginia before the Obama administration lured her to CMS.

Tavenner got off to a rocky start as AHIP chief. UnitedHealth Group bolted, key senior staff handed in their resignations, and then Aetna staged a rather public departure. But the turmoil stopped, AHIP’s membership has held, and the remaining three of the big five insurers—Anthem, Cigna, and Humana—have stayed in the fold.

Although she’s served in Democratic administrations, Tavenner has skillfully navigated the partisan waters of Washington. She has avoided becoming too identified with the ACA. That may explain AHIP laying low for much of the debate about the House and Senate bills. Tavenner and AHIP may be waiting until all the regulations and rules have to be written to implement a repeal-and-replace law or to engage legislators and bureaucrats if the ACA stays on the books.

Grace-Marie Turner. Turner is the president of the Galen Institute, a conservative, free-
Market health think tank she founded in 1995. Just as Tavenner has her Democratic bona fides, Turner has her conservative ones. She’s head of the Health Policy Consensus Group, a panel of analysts from market-oriented think tanks. Former House Speaker John Boehner put her on the Long Term Care Commission in 2013, and before that she served on the advisory council to the Agency for Healthcare Research and Quality (AHRQ). She also served as a member of the Medicaid Commission, a group appointed by the HHS secretary to make recommendations to reform Medicaid. Turner has testified regularly before Congress and writes a health blog for *Forbes*.

Turner has been a staunch defender of the GOP’s repeal-and-replace efforts, even blasting the Congressional Budget Office for getting its numbers wrong on the analyses of both the House and Senate bills as well as its projections for the ACA. She’s laid out the four things any repeal-and-replace plan must do: preserve coverage for millions in the ACA exchanges; give states more flexibility in managing Medicaid; provide subsidies to help people purchase coverage; and give states more say over their health insurance markets—“but with new flexibility and resources.” The GOP plans meet these litmus tests, she says. Her background in Medicaid could give the GOP ideas to soften the blow it would otherwise deliver to the program.

**Stephen T. Parente.** When the Department of Health and Human Services gets fully staffed—or at least more staffed than it is now—Minnesotan Parente will play a vital role as assistant secretary of planning and evaluation. As of this writing, he was still awaiting his Senate confirmation hearing. Once he’s ensconced on Independence Avenue Southwest, Parente will be HHS Secretary Tom Price’s principal adviser on policy development. His portfolio will include legislation development, strategic planning, policy research, and economic analysis.

Parente has been director of the Medical Industry Leadership Institute at the University of Minnesota’s Carlson School of Management, but he’s well known in Washington, where he serves as chair of the Health Care Cost Institute, a not-for-profit group that uses private insurers’ data to track factors affecting health costs. He also serves as a CBO health adviser and works with the conservative American Enterprise Institute and American Action Forum.

As an adviser to Sen. John McCain’s 2008 presidential campaign, Parente was the architect of three key components of the candidate’s health policies, including removal of the employer-sponsored insurance tax exclusion, allowing interstate purchase of health insurance, and use of high-risk insurance pools. But he’s worked on the other side of the aisle as an aide to former West Virginia Democratic Sen. John D. Rockefeller IV during the Bush and Clinton administrations’ health reform initiatives.

**Thomas Miller.** A resident fellow at the American Enterprise Institute, Miller co-authored an ACA replacement plan—along with the likes of AEI’s James Capretta, current FDA Commissioner Scott Gottlieb, and former George H.W. Bush health adviser Gail Wilensky—that called for capping deductions on employer-paid premiums and a few ideas that made it into the most recent House and Senate plans, including greater reliance on health savings accounts and Medicaid block grants.

Miller was a senior health economist for the Joint Economic Committee in Congress, where he organized a number of hearings that focused on reforms in private health care markets, such as information transparency and consumer-driven health care. He served HHS as a member of the AHRQ advisory council in the latter years of the George W. Bush administration, and in 2011 coauthored *Why ObamaCare Is Wrong for America* with Capretta, Grace-Marie Turner, and Robert Moffitt.

**Rick Pollack.** While AHIP may be keeping relatively quiet, a number of other trade and professional associations—the AMA, state hospital associations, the American College of...
of Physicians, and the Catholic Health Association among them—have weighed in with raspberries aimed at the GOP’s ACA replacement plans. The American Hospital Association, under President and CEO Pollack, has led the Bronx cheers. Pollack decried the Medicaid cuts in the original Senate bill as “unsustainable” and called for the Senate to craft a bill that would continue coverage “to all Americans who currently have it.”

The AHA is no lightweight. It has 5,000 members, including community and rural hospitals, nursing homes, teaching and public hospitals, and health care systems. It’s a safe bet that every member of Congress has an institution represented by the AHA in his or her district. Pollack’s members have a lot to lose if the CBO estimates are right and the number of Americans without insurance goes up by 20 million or more as a result of the Republican legislation. He's poised to have a big voice if the GOP plans get retooled so hospitals don’t take such a big hit.

Keith Hall. With its scathing reports on the House and Senate GOP plans, the nonpartisan CBO has come under fire from the Trump administration and advocates of the GOP plans. Keith Hall, its director, is a conservative economist with a PhD from Purdue University. In 2008 George W. Bush appointed him commissioner of the Bureau of Labor Statistics, and he served a full four-year term, including three years under President Obama. Before that, he’d been chief economist for Bush’s White House Council of Economic Advisers.

Hall’s Republican pedigree has not kept Republicans from attacking him and CBO scorekeeping. Politico reported that Republican Senators went at him in a closed-door meeting the day McConnell decided to delay a vote on the original health care bill. Hall did not take the top job at the CBO until April 2015. CBO scoring was important when the ACA was being crafted, but it has become even more so. And with so much at stake in these partisan times, it’s not surprising that Hall was pulled into the fray.

Chris Jennings. If the GOP has to go back to the drawing board on ACA repeal and replace, Democratic operative and former Obama health care adviser Jennings may find a seat at the table. Although a Democrat—he served as a senior health policy adviser to six presidential campaigns, including Hillary Clinton’s—Jennings has embraced the private sector as a driver of health care innovation and cost control. He recently co-wrote a Health Affairs blog post on such with Capretta, a Bipartisan Policy Center colleague. Since he left the Obama White House in 2014, Jennings runs the health care consulting firm Jennings Policy Strategies.

Jennings helped implement the ACA’s access and delivery reform provisions and played key roles in other signature legislation including the Children’s Health Insurance Program, the Health Insurance Portability and Accountability Act (HIPAA), the Prescription Drug User Fee Act of 1997 and major Medicare reforms in the Balanced Budget Act (BBA) of 1997. Jennings could be a go-to for cobbling together an ACA fix if Republican health care efforts fizzle out.

Elizabeth MacDonough. The Senate Parliamentarian is playing a pivotal role in determining how the upper chamber tackles health care legislation. In late July, MacDonough ruled that a number of important provisions in the Senate legislation would have to be stripped out for it to meet the filibuster-proof budget reconciliation standard that requires only 50 votes (plus Vice President Mike Pence to break the tie).

As of this writing, the Senate had voted, by the narrowest of margins, to debate the repeal-and-replace legislation, kicking off a marathon of votes with an uncertain outcome. MacDonough’s umpiring made a limited, “skinny” repeal a distinct possibility; the tangled politics—and parliamentary rulings—of replacement would be left for another day.

The provisions that MacDonough said went beyond budget reconciliation concerned hot-button issues like coverage of abortion as well as more granular ones, such as a waiting period for people who have lapses in coverage.

McConnell could overrule MacDonough (and, indeed, might have by the time this gets
published). But McConnell would be opening a Pandora’s box: a reconsideration of the so-called Byrd rule that created the budget reconciliation path around the filibuster.

Paul Spitalnic. Overlooked in all the attention on the CBO scores was a report CMS actuary Spitalnic issued in June on the House bill. Spitalnic is not a political appointee. He’s been with CMS since 2003, when he led the actuarial efforts to implement the new Part D program, then headed up the Parts C and D Actuarial Group, where he has responsibility for the review of Medicare Advantage and Part D plan bids, preparing budget estimates for the Parts C and D programs, and calculating the Medicare Advantage benchmark rates. Before working at CMS, he was a consulting actuary specializing in retiree health insurance.

Spitalnic’s projection for the House bill wasn’t as bad as the CBO’s but still wasn’t very rosy. He estimated that the ranks of the uninsured would be 13 million larger by 2026 under the House bill than if the ACA was left intact. If critics shoot holes in the CBO estimates, Spitalnic’s work at CMS could provide ACA defenders with a fallback.

Andrew Bremberg. Trump’s Domestic Policy Council chief, Bremberg is the White House’s low-key point person on health care legislation. Bremberg used to be a senior aide to McConnell and worked at HHS from 2001 to 2009 in the Bush administration. He was also policy adviser for the 2016 Republican Party Platform and advised Wisconsin Gov. Scott Walker’s short-lived presidential campaign.

Bremberg reports to Trump senior adviser Stephen Miller, who made a name for himself in the early days of the administration by being the on-camera defender of Trump’s travel ban.

One former colleague of Bremberg’s told The Hill: “His experience in policymaking process has got to be important to them. There aren’t too many people in Trump’s senior circle who have done this before.”

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Outcomes-based Pricing Program Puts Money in Beneficiaries’ Pockets

Harvard Pilgrim’s program gives rebates to beneficiaries if Repatha doesn’t help them avoid a heart attack or stroke.

By Ed Silverman

Last May, Harvard Pilgrim Health Care inked a deal with Amgen in which the health plan will receive a full rebate if patients taking Repatha, the cholesterol-lowering medicine, suffer either a heart attack or stroke. The move came shortly after the biotech company released study data showing that its injectable treatment, which has a list price of $14,000, was effective in reducing those serious cardiovascular events.

This was only the latest in a growing number of outcomes-based pricing agreements in which an insurer may get an extra discount from a drugmaker if a medication does not help patients as much as expected. Harvard Pilgrim, New England’s second-largest health plan, has been at the forefront of the trend. The not-for-profit insurer has signed several of these deals over the past two years with Novartis, Eli Lilly, and AstraZeneca.

But this particular deal with Amgen has an extra twist—Harvard Pilgrim beneficiaries will receive a full refund for their out-of-pocket costs for Repatha if the drug fails to work. This would be defined as a stroke or heart attack suffered by a patient who was on the drug for at least six months.

Right thing to do

“Our approach has been to use money that we get back, including rebates, to keep premiums affordable for everyone,” says Michael Sherman, MD, the plan’s chief medical officer. “This is the first deal in which it starts to get too close to a member’s health plan costs. The right thing to do is to make sure they get their cost share back.”

Of course, the downside is that the patient suffered a heart attack or stroke.

The insurer does not offer such refunds with its other deals, he explains, because rebates are much smaller, so the money involved is not large enough to return to beneficiaries. In some cases, for instance, the administrative costs to refund a small rebate would not be efficient, so the plan prefers to spread the dollars around in hopes of reducing premiums. “We are not pocketing the money, though,” Sherman says.

Whether other such deals will materialize is uncertain.

Regardless, interest in outcomes-based contracts is increasing. About 70% of health plans view these deals favorably, 24% already have one, and another 30% are currently negotiating at least one contract, according to a survey by Avalere Health, a consulting firm that queried 45 different health plans representing 183 million insured people earlier this year.

But contracts that benefit beneficiaries—they’re likely to be the exception.” “The bottom line is that plans expect to see a reduction in total cost of care from these agreements,” says Dan Mendelson, who heads Avalere Health, “but savings are typically not directly passed to consumers in the form of lower copays for drugs.”

For that reason, one consumer advocate argues these agreements—which drugmakers and health plans like to talk up—really aren’t such a good deal from the consumer/beneficiary/patient perspective.

The challenge facing patients is high drug prices. “These discounted arrangements don’t address prices or lower the cost to patients or the system,” says David Mitchell, who heads Patients for Affordable Drugs. “And even if you tell me that you are going to pass through any rebates, I’m still in a bad place, because I don’t want to receive a drug that doesn’t work.”

One Wall Street analyst, meanwhile, contends that value-based pricing is something of a smokescreen that is allowing the pharmaceutical industry to deflect meaningful legislative action toward high prices.

“This has been the drug industry’s preferred solution to the question of drug costs,” Sanford Bernstein analyst Ronny Gal wrote in a recent investor note.

“While the argument, in principle, is logical—drugs
should be priced to the value they provide—it turns every debate on drug costs into a convoluted economic calculation,” Gal said, “and the drug industry has so far run circles around payers in developing an economic model for the value of drugs they provide. To the extent value-based pricing is adopted as the main way to address drug costs, the industry will likely be in the clear on the drug issue for roughly a decade.”

An article published jointly by ProPublica and the New York Times in July mentioned the Italian health care system’s experience with outcomes-based pricing. Researchers who studied the program described the amount of money returned by drug companies as “trifling,” the article said.

Others have a more optimistic take on the situation. Roger Longman, who heads Real Endpoints, a research firm that tracks reimbursement issues, believes outcomes-based pricing deals will be “hugely important” and will soon cover anywhere from 20% to 30% of new drugs.

“I think this is a new way of thinking about contracting,” he explains. “Yes, there are plenty of challenges, but it does start to change the dialogue between pharma and payers. It forces payers, on one hand, to come clean about what value they’re really looking for—is it clinical or economic value? And on the pharma side, it forces them to do the kind of guarantees that virtually every other industry has to do with its customers.”

But, as Mitchell points out, “Why don’t we just lower the price at the outset?”

Ed Silverman founded the Pharmalot blog and has covered the pharmaceutical industry for 20 years.

“The bottom line is that plans expect to see a reduction in total cost of care from these agreements,” but the savings don’t always result in lower costs for consumers, says Dan Mendelson of Avalere Health.
As a congressman, Tom Price led the charge in Republican efforts to repeal the ACA. Year after year, Price introduced bills to undo the health care reform legislation. It seemed more like a bit of political theater than a real bid for change.

Now as HHS secretary, Price could be presiding over the reality of the less regulated, post-ACA health care system that he agitated for—if the GOP-dominated Senate and House make good on the party’s repeal-and-replace campaign promises.

Price, 62, with pure white hair, rimless glasses, and an easy, slightly cherubic smile, comes across like a friendly, family doctor, not the ambitious, politically-minded orthopedic surgeon that he is.

Congressional colleagues view him as a brainy mentor with the just-right blend of policy smarts and wisdom from decades of being a practicing physician. Rep. Diane Black, a registered nurse and fellow Republican who represents the suburbs east of Nashville, says Price is a “true policy wonk” but one who has a real-world perspective on health policy.

She credits him with guiding her through the knotty details of legislation—and through the maze of tunnels under the Capitol complex that are “the bane of every freshman member of Congress’s existence.”

His affable manner belies Price’s staunch conservatism. Gail Wilensky, a Republican health economist who served in both the Bush 41 and Bush 43 administrations, describes Price as a “harder conservative” than her: “He is regarded as a conservative Republican from Georgia, and that is obviously different than being a Republican from other parts of the country.” The conservative Association of American Physicians and Surgeons, a physician group formed during World War II to oppose socialized medicine, gave Price its Shining Scalpel award in 2009 for “cutting through the rhetoric regarding ‘health care reform’ and fighting for patient- and physician-centered health care legislation.”

Price was a Daniel in the lion’s den in June when he was interviewed at the Aspen Institute’s Ideas Festival. Jeffrey Goldberg, editor in chief of the Atlantic, asked Price whether the House repeal-and-replace bill is, as his boss has described it, “mean.” Price adroitly deflected the question about a bill that is a direct legislative descendant of his anti-ACA legislation. “I think what’s mean is [a health system] that has 6.5 million Americans paying $3 billion in taxes or penalties so they have the right to purchase health coverage. That mean system might work for government, but it doesn’t work for patients.”

Third-generation physician
Price grew up in Dearborn, Mich. Both his grandfather and his father were doctors, which may explain some of his strong feelings about the patient-physician relationship. He has described seeing his father take care of all patients, insured or not, and how he likewise has cared for all comers. Price received his bachelor and medical degrees from the University of Michigan in Ann Arbor, completed his orthopedic surgery residency at Emory University, and then opened a solo medical practice. Eventually, he came to be a founding board member of Resurgens Orthopaedics. With almost 100 orthopedic surgeons and physiatrists, it claims to be the largest orthopedic practice in Georgia.

Price entered elective politics in 1996 when he was elected to the Georgia Senate. When he opposed tort reform legislation in 2003 because it didn’t put a cap on noneconomic damages in malpractice cases, Mark Taylor, then Georgia’s Democratic lieutenant governor, told the Washington Post that Price is a right-wing doctor before anything else. “Whether it be liability or any policy issues about how health care is delivered, how it is paid for, how it is ac-
cessed, it is doctors—all day, every day,” said Taylor.

A year later, Price was elected to Congress, representing Georgia’s 6th district, the suburban Atlanta district that sent Newt Gingrich to Congress. As a congressman, Price sponsored more than 70 pieces of legislation, but he was best known for his implacable opposition to the ACA.

Called for tax credits
He first introduced his alternative, Empowering Patients First Act, in 2009, a year before the ACA was signed into law. Price called for tax credits to offset the cost of individual health coverage based on age rather than income and premium price, expanding health savings accounts, and the sale of health insurance across state lines—all of which eventually made its way into the House and Senate bills now under consideration.

Price’s nomination to be HHS secretary got a mixed reception. The AMA gave its blessing, even though it has been a supporter of the ACA. The AMA has long encouraged physicians of all political stripes to participate in government; remarkably, Price is only the third physician to serve as HHS secretary. Patrice Harris, MD, the former chair of the AMA and a psychiatrist in Atlanta, sang his praises as a leader of patient-choice and market-based solutions and reducer of burdensome regulations. Daniel “Stormy” Johnson, MD, past president of the AMA, who has known Price since he was a Georgia delegate to the AMA’s policy-setting House of Delegates, was unstinting: “I can’t imagine a more qualified person to be in that job.”

But Price was also accused of buying and selling health care stocks when he was in Congress in a way that, at the very least, looked to be unethical because he was in a position to influence company profits. Price insisted he had done nothing improper and that virtually all of his health care trades were managed by his broker. The one exception was his investment in Innate Immunotherapeutics, an Australian company partly owned by Rep. Chris Collins, a New York Republican. Politico reported that Price sold his Innate shares for $250,000 earlier this year after an initial investment of $94,000.

The public face
As HHS secretary, Price has often been the public face of the anti-ACA effort, even though a single POTUS tweet or off-the-cuff remark completely overshadows anything Price might have said during the good-soldier hours he has logged testifying before Congress and talking at think tanks and events like the Aspen Ideas
Festival. Price has also had to walk a fine line between criticizing the ACA while assuring the public—and insurers—that it won’t be undone recklessly.

“Nobody is interested in sabotaging the system,” said Price in testimony before Congress on June 8. Previously, Price said during a budget hearing in the House in March, “so long as the law is on the books, we at the department are obliged to uphold the law.” Still, as David Nather and Sam Baker at Axios pointed out last month, Price and others will have to switch gears from talking up the ACA’s failures to trying to make it work. Either that—or work to undermine it.

In late June, Price spoke at a roundtable about the Senate bill in Sandy, Utah, a suburb of Salt Lake City. The Deseret News covered the event.

“The bill itself that is now before the Senate, we believe is a step in the right direction,” Price said, noting that the bill’s Medicaid provisions offer “greater flexibility” and “more choice.” “You don’t want a system that works best for Florida. You want a system that works best for Utah,” Price said to the Utah audience. He defended the bill’s reduction in Medicaid spending, saying it will ensure that “small businesses once again are able to afford the ability to provide health coverage for their employees.” The ACA has led to more people being insured, but Price said the coverage is useless because of high deductibles.

Wilensky, the Republican health economist, said Price has some advantages that should help him be an effective HHS secretary. He has a good relationship with many members of Congress. His background as an orthopedic surgeon gives his views added credibility. It’s too soon to judge Price, she says. “The question of how effective will he be trying to manage a sprawling enterprise like HHS or thinking about the broader public health aspects involved in population health is something that we’ll have to wait and see. They will be new areas for him and so we’ll have to give him some time to see how he grows into those positions.”

Mark Bertolini Wants To Take The ‘Nasty’ out of Insurance
His roots are modest. His ideas for Aetna, health care, and even capitalism are not.

By Richard Mark Kirkner
Contributing Editor

For a person of modest means who says he never really followed a defined career path, Mark Bertolini has had one resume, said he never looked for a job, and went to Cornell for his MBA because it was the “cheapest.” Now all he wants to do is tear down and rebuild the corporate model and the nation’s health care delivery system.

For the CEO and chairman of Aetna, that’s meant a series of maneuvers not quite as modest as his roots as a Detroit autoworker’s son: a high-profile departure from the industry’s leading trade association, America’s Health Insurance Plans; a move to acquire another big-five insurer, Humana, before a federal judge blocked it on anti-trust grounds; raise pay and benefits of Aetna’s lowest-paid employees and offer incentives to others to take yoga; pull Aetna out of state exchange markets; and relocate the company’s headquarters from Hartford, Conn., to New York next year. All the while, Aetna’s adjusted per share earnings jumped 17% in the first quarter this year while its stock trades at an all-time high. Bertolini is richly compensated for his efforts. According to a tabulation by Axios, his 2016 compensation totaled $41.7 million.

Stephen Hemsley of UnitedHealthcare and Joseph Swedish at Anthem may lead larger companies, but Bertolini stands out among today’s health insurance executives. He has a penchant for bold moves, and his candor when talking about what’s wrong with health insurance, health care, corporate America, and anything else have made him a media darling. To paraphrase the beer commercial, he is American health insurance’s most interesting man in the world.

Progressive ... Pinocchio
Bertolini, 61, who declined an interview for this article, has made some lasting impressions. The New York Times calls his ideas progressive while the New York Post gave him its “Post Pinocchio” for saying that Aetna was leaving several state exchanges because it was losing money when, in fact, it was turning a profit.

Wilensky, the Republican health economist, said Price has some advantages that should help him be an effective HHS secretary. He has a good relationship with many members of Congress. His background as an orthopedic surgeon gives his views added credibility. It’s too soon to judge Price, she says. “The question of how effective will he be trying to manage a sprawling enterprise like HHS or thinking about the broader public health aspects involved in population health is something that we’ll have to wait and see. They will be new areas for him and so we’ll have to give him some time to see how he grows into those positions.”
that broke his neck in five places and left him in a coma for five days. He checked himself out of the hospital—“because I was sure they would kill me if I stayed there,” he told Times's Alan Murray at Fortune magazine’s Brainstorm Health conference in May—and oversaw his own rehab at home. The injury left him partially disabled, but in 2007, he donated a kidney to his son. Today, he’s back on skis and continues to ride bicycles and motorcycles. “It’s sort of like if you tried it once and it didn’t kill you, why not?” he told Murray.

That could apply to his vision for remaking Aetna, which involves addressing four forces changing health care. “First, global populations are aging rapidly,” Bertolini said at the Detroit Economic Club in June. “The second point I point out is that chronic disease is more prevalent as nations develop. Third, there is a growing shortage of medical professionals to keep up with care demand. And then finally, internet mobile adoption will change how consumers make health care decisions.”

Insurance is a “nasty” word
At the Detroit Economic Club, Bertolini talked about Aetna’s mission in a way that could’ve come out of any health care CEO’s playbook: “Aetna’s mission is to build a healthier world,” he said. His business strategy for Aetna also seems straightforward and was a key element in the decision to acquire Humana for $34 billion: Get into every Medicare Advantage market possible.

A federal judge blocked the deal, but Bertolini is undeterred. “Our strategy is still our strategy and our whole acquisition logic was built about supporting our strategy and getting there quicker than we otherwise would have if we had built it organically,” he said in an interview in February.

He’s strayed further from the CEO playbook with other comments. “I think insurance is a nasty word,” he told Bloomberg’s David Gura at Bloomberg’s “The Year Ahead” summit last October. “We may not even call it that when we’re done with it.”

Last year, Aetna brokered a plan with Apple to provide Apple watches to selected customers and nearly all 50,000 Aetna employees to monitor and manage their own health. “Machine learning and artificial intelligence are going to be the base of what the big Aetna does,” Bertolini told Bloomberg’s Gura.

A matter of ZIP code
The Apple deal is an outgrowth of Bertolini’s fixation on social determinants as a driver of an individual’s health status. “We have social determinants that drive 60% of the health status of the U.S. population, where clinical care is only driving 10% and the other 30% is
New capitalism
When Bertolini became Aetna’s CEO in 2010, he found that some employees were on public assistance. “How can we let this happen?” he said to ABC’s Diane Sawyer. “Here we are, a major Fortune 50 company with employees who are suffering every day to make ends meet.” So in 2015 he jacked up the minimum wage for U.S. employees to $16 an hour, then improved other employee benefit programs.

He even added what he’s called “yoga mindfulness” that 16,000 employees signed up for with a $3,000 return per employee—all without passing costs onto customers. “We’ve improved the bottom line doing it,” Bertolini said.

That involves reinventing the corporation. “Eighteen percent of the American public actually believes corporations are good,” he told Sawyer. “Eighteen percent? So how much lower do we need to go before we figure out this doesn’t work? And instead of waiting for it to go away, why don’t we step forward with some courage and conviction to make it better?” Sawyer interjected, “A new capitalism.” “Yeah, let’s reinvent it,” Bertolini said. “I mean we’re the captains of it. Why shouldn’t we be the ones that say, ‘Here’s the new way’? Let’s all as a group of people stand for something and say we’re going to do something about this.”

Nothing modest about that.

Scott Gottlieb Believes a Nimbler, Speedier FDA Can Spur Competition, Lower Prices
Critics see danger in loosening rules and a new FDA chief who might not be tough enough on those he is supposed to regulate.

By Joseph Burns
Contributing Editor

As the newly appointed commissioner of the FDA, Scott Gottlieb, MD, might as well be starring alongside Tom Cruise in the latest installment of Mission Impossible. Since being named commissioner in May, Gottlieb has said he wants the FDA to speed the approval process for generic drugs, introduce competition to drive down prices, and get the opioid crisis under control.

That’s a lot more than one Mission Impossible.

While few would argue with these goals, Gottlieb’s critics worry that any movement to speed the approval process could put unsafe or unproven medications on the market. Critics also charge that Gottlieb’s ties to pharmaceutical companies are concerning. And Gottlieb himself acknowledges there’s not much the FDA can do directly about drug prices and that instead the agency needs to foster the circumstances in which companies can compete on price.

Believes in markets
A 44-year-old survivor of non-Hodgkin’s lymphoma who once worked as a hospitalist and a clinical professor of medicine, Gottlieb has previously held several different roles in the FDA. In 2003 and 2004, he was a senior advisor to the FDA commissioner and then the FDA’s director of medical policy development. From 2005 to 2007, he served as the agency’s deputy commissioner for medical and scientific affairs. In between those jobs, he left the FDA in the spring of 2004 to help implement the Medicare Part D drug benefit.

When Republicans were out of power during the Obama administration, Gottlieb established himself as a health policy wonk while working as a resident fellow for the conservative-leaning American Enterprise Institute and as a columnist for Forbes. Bearing witness to an abiding faith in markets and competition, he talks fasts and comes across as brainy and energetic, up to the job, with a good handle on the issues, even if you disagree with him.

“While the FDA doesn’t have a direct role in drug pricing, we can take steps to help address this problem by facilitating increased competition in the market for prescription drugs through the approval of lower-cost, generic medicines,” he wrote on the FDA’s blog in June.

Last year, he expressed skepticism about candidate Trump’s endorsement of allowing drug imports as a way to reduce drug prices. In a piece for Forbes, Gottlieb said Trump’s proposal was good politics but would do little for consumers who must comply with health plan rules on where to buy and what those plans cover.

But among all of these challenges, Gottlieb’s first priority is the use and abuse of opioids. During his confirmation hearings in April, he called opioids, “a public health emergency on the order of Ebola and Zika.” In July, he followed up by saying the FDA would require manufacturers of immediate-release opioids (which are 90% of those prescribed) to give...
physicians and other prescribers extensive education about these medications.

On the issue of how to improve access to generics, one lever the FDA could pull is streamlining the approval process. In June, the FDA said new generic drugs would get priority reviews until at least three are available to consumers. When three generic drugs are on the market, prices tend to drop by as much as 85% off the brand-name price, the AP reported. Also, the FDA published a list of 180 drugs that have lost patent protection but have no generic competitors, saying it would be a priority to review applications for generic versions of these medications.

Making it easier for companies to get new generic medications to market would presumably head off future Martin Shkreli and Turing Pharmaceuticals—companies that buy low-cost generics and jack up prices knowing it could take two to four years for new generic drugs to enter that same market.

Another way the FDA can stimulate competition, Gottlieb suggested, is to speed approvals of new drugs under the 21st Century Cures Act, which Congress passed last year. “Congress gave us tools to incentivize the development of novel therapies for rare diseases, and we intend to use these resources to their fullest extent,” he said in June. That same month, the agency announced it would reorganize its drug review staff to eliminate a backlog of requests for rare-disease drug designation.

**Pharma ties criticized**

While Gottlieb has said FDA regulations slow the process to approve new drugs and that such delays keep effective treatments from reaching patients, his critics see a flip side: deregulation and off-label marketing of drugs and devices adding expense and increasing the risk of adverse events.

And some see the critique of the FDA as a slow-moving, nay-saying regulator as political posturing and plain wrong.

“In reality, the FDA has become the fastest drug regulatory agency in the world, going from an average of 30 months per drug review in the 1980s to 8.5 months today,” Judith Garber and Shannon Brownlee of the Lown Institute wrote in a recent Stat commentary.

Other critics have questioned Gottlieb’s ties to the pharmaceutical industry, although Gottlieb has promised to recuse himself from decisions affecting companies to which he had connections. During his confirmation hearing, Sen. Patty Murray, a Democrat from Washington, said he had “unprecedented financial entanglements” with pharma companies.
In April, Public Citizen reported that the federal Open Payments database showed Gottlieb received $414,000 from August 2013 through December 2015 from multiple drug and medical device companies, mostly for consulting and speaking fees.

That same month, the Washington Post reported that in 2006, when Gottlieb was at the FDA, he advocated on behalf of Cephalon to increase the amount of fentanyl the manufacturer could produce. At the time, Cephalon was under federal investigation for advocating that doctors prescribe the painkiller for headaches and back pain when it was meant for patients with late-stage cancer. Fentanyl, a highly potent opioid, has led to many fatal overdoses.

So now the question is how far will Gottlieb push the agency to approve drugs faster and will his critics question his work with pharmaceutical companies as a conflict of interest.

Other questions to answer about Gottlieb include what stand he would take in the debate over whether patients have a right to try a medication before it gets FDA approval. Stat reported that Gottlieb carved out what it called a middle ground. In a letter to Murray, he wrote that he would ensure that the agency has policies in place to balance individual patients’ needs for access to investigational therapies while maintaining “a rigorous clinical trial paradigm for testing investigational products and demonstrating safety and efficacy.”

Where does he stand on the Prescription Drug User Fee Act? In the past, he said he favored allowing drug companies to seek faster approvals under PDUFA’s rules.

What’s his position on adaptive trials? In his role as deputy FDA commissioner, Gottlieb favored allowing drug companies to adjust trials as they proceeded, making them larger or smaller as needed and changing how patients get assigned if necessary. Such approaches could shorten some trials, he said. During his confirmation hearings, he reconfirmed his support for such an approach, Science magazine reported.

Seema Verma Does Her Homework, Pushes for Beneficiaries To Have More on the Line

The new CMS administrator made her reputation in Indiana with a Medicaid program that she says has “strong personal responsibility mechanisms” built in, including monthly fees.

By Timothy Kelley
Senior Contributing Editor

In June’s waning days, when Senate Majority Leader Mitch McConnell was attempting to sell 51 of his fellow Republican Senators on the Better Care Reconciliation Act, a key person reportedly sat in on the face-to-face meetings: President Trump’s CMS administrator, Seema Verma. As CNN said, her job was to “soothe lawmakers’ nerves over changes to Medicaid.”

Big-time soothing was required. Although the act’s proposed changes wouldn’t take full effect for almost eight years, the legislation would have drastically cut federal funds for Medicaid and fundamentally alter the way the program is funded, changing it from a state–federal share to capped federal contributions on a per-capita or block-grant basis. Several GOP senators were said to be more than nervous. As we went to press, the fate of the bill—and the entire Republican effort to junk the ACA and swap in their own program—was in the fog of a political and policy war. But one thing was clear: The administration had deployed a persuader with potent policy-wonk credentials.

Verma, 46, is more than a saleswoman for the GOP health bill; she’s reported to be one of its chief architects too. The second-generation Indian-American is a University of Maryland graduate with a master’s in public health from Johns Hopkins. In 2001, she founded SVC Inc., a health policy consulting firm, which has advised several states on their Medicaid programs. (Upon taking the top post, Verma sold SVC to Health Management Associates in Lansing, Mich., where it became a subsidiary called HMA Medicaid Market Solutions.) Medicaid mavens and others took notice when Verma and her company helped former Indiana Gov. Mitch Daniels create a plan for low-income Hoosiers that took advantage of a Section 1115 waiver. She got some of the credit early in Daniels’ term for sharply reducing a 10% annual growth rate in Medicaid spending. Then came another Republican governor—current Veep Mike Pence—and a new incarnation called Healthy Indiana Plan 2.0, which, with certain special exemptions, doubled as Medicaid expansion. “If I had to describe her in one word it would be ‘innovative,’” says Susan Jo Thomas, executive director of Covering Kids and Families of Indiana, an advocacy organization. Thomas worked
with Verma on the Healthy Indiana Plan and, before SVC, on a program that applied good old-fashioned managed care methods to hospital charity care and that was “wildly successful” at saving money, Thomas says. Beneficiaries had an ongoing relationship with a PCP. That meant fewer trips to the emergency room, as well as gatekeeping by the PCP. At the same time, beneficiaries had broader access to health care; previously, eligibility rules pretty much limited adult Medicaid to pregnant women and people with disabilities.

Thomas isn’t privy to the conversations her former collaborator has had with GOP senators this summer, but she’s dead certain of this: Verma has done her homework.

“I’ve watched her negotiate,” says Thomas. “I was incredibly impressed with how prepared she was. She didn’t have knee-jerk reactions. She went out of her way to collect input from patient advocates on our HIP [Healthy Indiana Program] program, for example—including parts that may not have been popular with them.”

“She’s a policy wonk, but she’s far more than that,” says Mitch Roob, who worked with Verma when he headed Indiana’s Family and Social Services Administration, which administers the state’s Medicaid program. Roob, who is now president of a telehealth company called Healthcare Anywhere, says Verma has “practical, on-the-ground knowledge of the way public policy translates into the lives of the people who are receiving health care.” And he praises her work ethic; he recalls her working until 2 a.m. or 3 a.m. on drafts they were preparing for legislators.

Verma grew up in a Democratic household, but her 55–43 confirmation vote as CMS administrator in March drew only three Democratic votes. Indeed, her policy work has helped make Medicaid expansion palatable to conservatives who might otherwise look askance. HIP 2.0, for example, requires a small monthly payment from the beneficiaries, with a six-month lockout for those who don’t pay within a 60-day grace period. “It’s a strong personal responsibility mechanism,” Verma has said.

After being confirmed, she wrote the nation’s governors urging that Medicaid recipients be required to pay premiums, be charged for ER visits, and be encouraged to get jobs or job training. This “skin in the game” approach appeals to conservatives, though critics say it can depress participation among the poor.

“Back home in Indianapolis,” said CNBC in February, “Verma gets high marks for working across the aisle to help secure buy-in to the [state’s] plan from state legislators, the Obama administration, and local health care leaders.” But a 2014 Indianapolis Star article pointed to a possible conflict of interest, noting that Verma was both a consultant for Indiana and an employee of a Hewlett-Packard division that was one of the state’s major Medicaid vendors.

As for her current post at CMS, “I think she’ll do a great job,” says Thomas, “and for the most part not be partisan about it.”

“She’s very resourceful and intelligent,” Indiana Democratic State Rep. Charlie Brown told NPR on her appointment last November. “But the question now becomes, ‘What will be her marching orders as they relate to Medicare and Medicaid?’”
Bernard Tyson Preaches Gospel of Tech—and Change

The Kaiser CEO sees a future in which telehealth rules—and consumers know their bodies at least as well as they know their cars.

By Timothy Kelley
Senior Contributing Editor

At a Stanford Business School conference last year on “disruptive” new technology, Kaiser Permanente Chairman and CEO Bernard J. Tyson was happily explaining the “sea change” under way in his organization. Quipped one of the hosts: “So I don’t need to pitch you on digital, it seems.” Indeed not. Selling this health care leader on tech would be preaching to the choirmaster.

Arguably the two big changes under way in health care are the tech revolution and the realignment of incentives toward value. Kaiser has long been ahead of the game on the latter. Controlling “the entire dollar” as both insurer and provider, Kaiser has treated hospitals as cost rather than revenue centers for decades. As a consequence, it has done a far better job of integrating care than most providers. Because of this emphasis—and the organization’s size—any Kaiser CEO would be listened to nationally.

But Tyson has been an especially high-profile leader of Kaiser. *Time* magazine put him on its 2017 list of the 100 most influential people in the world. And he gets props for his eager embrace of technology.

“He is the most influential national leader for the development of patient-friendly technology,” says Mitchell Katz, MD, director of the Los Angeles County Health Agency. “He recognizes that only by embracing modern technologies—such as patient portals, text messaging, and electronic consultations—can we make health care both more effective and more affordable.”

Tyson has said that if he were redesigning Kaiser from the ground up, he would begin with a technology platform, not with hospitals, and that “telehealth is going to be our future.” Tyson told his Stanford audience that in 2015 Kaiser completed almost 30 million secure e-visits between members and their physicians and that the company is investing $300 million in...
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¹Staskon F, Fu C, Kirkham H. Multiple Sclerosis Medication Adherence within Walgreens Local Specialty Pharmacies is Significantly Higher Compared to Other Class of Trade Pharmacies. AMCP Managed Care & Specialty Pharmacy Annual Meeting. 27 Mar 2017.

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developing secure platforms for HIPAA-compliant telehealth communication. He envisions a day when Kaiser’s traditional prevention orientation is married to wearables and other innovations to bring health care to each patient’s home—and when consumers are as savvy about, say, the role of sugar in their body as they are about gasoline in their car.

But tech trapdoors remain—for example, deciding what information “should be in the cloud and what should be in our own data center,” and figuring out how to overlay new capabilities on “legacy” computer systems. “A new pharmacy system that we completed last year was supposed to cost $500 million,” said Tyson in 2016, in the mild, matter-of-fact way that others might say they’d paid a buck too much for a cup of coffee. “It cost a billion dollars because we had to plug it into our existing systems to create an integrated approach for our members.”

That demeanor is part of Tyson’s leadership style at the helm of Kaiser, an 11.8 million-member health plan that operates in eight states and Washington, D.C. Its operating revenues in 2016 were $64.6 billion, which is just slightly more than Aetna’s total revenues for that year. Earlier in 2017, Kaiser got even bigger when it completed its acquisition of like-minded Group Health Cooperative of Puget Sound, adding that plan’s 600,000 members and in the process promising both a $1 billion investment in Group Health’s Washington State staff, technology, research, and facilities, and $1.8 billion toward a new not-for-profit Group Health Community Foundation.

Tyson, 57, is steeped in Kaiser culture. His 30 years with the company include service as a hospital administrator, a division president, and chief operating officer. In July 2013 he became CEO; half a year later, he added the chairman title.

Other influences go back further. He credits his father, who worked as a carpenter and minister, with instilling religious values in him early on and teaching him the importance of living by his word, keeping his commitments, and explaining forthrightly when for some reason one can’t be kept. And he holds undergraduate and business degrees from San Francisco’s Golden Gate University, a more-than-century-old institution that evolved out of YMCA night classes.

“I used to think that because I’m the kind of leader who thinks out loud, then everybody is supposed to think out loud,” Tyson told the New York Times in 2013. But he has learned to respect individuals’ different styles. He says he promotes a teamwork ethic at Kaiser rather than a “gotcha” mentality. But some things don’t fly even for the tolerant Tyson. In late June, for example, he withheld his approval from proposed Republican health care reform legislation. “It does not do enough to protect people in need of care,” he said.

Elisabeth Rosenthal, A Storyteller Who Hopes Her Telling Will Make a Difference

After penning a book that slams greed, waste, and confusion in health care, Elisabeth Rosenthal, MD, is in a position to push back as editor-in-chief of the increasingly influential Kaiser Health News.

By Timothy Kelley
Senior Contributing Editor

Elisabeth Rosenthal, MD, editor-in-chief of the not-for-profit news service Kaiser Health News, considers herself more storyteller than specialist. Yes, she was trained as a physician and once worked as an emergency room doctor. But she leaves the “MD” off her book-jacket byline on her new book, An American Sickness: How Healthcare Became Big Business and How You Can Take It Back, which calls out every sector of the health care industry as “rigged” against patients.

In 22 years as a reporter for the New York Times, Rosenthal wrote about topics like the global environ-
ment and events in Beijing, where she was based for six years. Even after her award-winning health care series “Pay Till It Hurts” led to a book contract for *An American Sickness*, she returned to the *Times’* projects unit and wrote up a proposal for a series on the nation’s infrastructure.

**Important, timely, and unresolved**

That’s when it hit her. “I thought, ‘I don’t want to write about infrastructure,’ she recalls. ‘I want to write about health care.’” She wasn’t done with journalism, but the topic she had embraced in her book was simply too important, timely, and unresolved to leave behind.

In her new role at the eight-year-old KHN (unconnected, she points out, with Kaiser Permanente health plans), this graduate of Stanford and Harvard Medical School is doing that. She leads a staff of 25 editors and reporters that includes two deep-digging data whizzes. Their work lands in places like the *New York Times*, the *Washington Post*, USA Today and, as she says, “some of our smaller local partners who can no longer afford to have their own health care reporters.

“I want us to help people understand how policy stuff in Washington is connected to their lives,” says Rosenthal. “It’s not something far away.” She points to a KHN series on how the Orphan Drug Act has been manipulated by pharmaceutical companies to cover “drugs that are not really ‘orphans’ in the classic definition.” The series, aired on National Public Radio, led to Senate Judiciary Committee hearings led by Republican Sen. Chuck Grassley of Iowa, who specifically credited it—along with public concern about drug prices—as his inspiration. Rosenthal sees drug prices as an area where journalism can have a discernible impact because “there’s been so much noise about it” from politicians of both parties. Asked how she’ll know in a few years if KHN’s efforts have succeeded, she looks for a “smarter debate” on health care in legislators’ town hall meetings.

KHN’s role in the landscape of health care journalism today inevitably suggests the old “best of times, worst of times” cliché. While newspaper staffs all over the country are shrinking—with health care coverage often a victim—reporting on health care topics by venues like KHN, the health news website *Stat*, the news site *Vox*, and the “nonprofit newsroom” *ProPublica* is arguably at least as probing and thorough as past coverage.

When Rosenthal’s book came out in April, it gave hints of the disruptive effect an ongoing journalistic conscience could have on the industry. Chapter by chapter, she takes down hospitals with needless showy luxuries and outlandish and confusing bills, doctors who profit from their own referrals, insurers who don’t question whopping prices so they can pay huge salaries and still boast of their medical-loss ratios, drugs that are repackaged in meaningless ways just to protract patent protection, and competition that inflates prices rather than controlling them.

The book’s publisher reports that it debuted in sixth place on the *New York Times* bestseller list and that both sales and reviews have been “terrific.” Still, those hoping Rosenthal’s volume will change the world might want to check in with Marcia Angell, MD, Maggie Mahar, David Goldhill, Steven Brill, T.R. Reid, Otis Brawley, MD, and others who have written similarly provocative, well-sourced indictments of the health care system—after which the waters failed to part.

Why might her book prove more influential? “I feel we’re at a tipping point in attention to health care,” she says. As costs rose in recent years, higher premiums, deductibles, and copays were supposed to make consumers more prudent purchasers of health care because they have “skin in the game,” she explains. “But the fact is, you can’t be a very good consumer in the current health care system because you don’t have the information you need. Patients are realizing this is not sustainable.”

Rosenthal’s book offers specific tips about things consumers can do to make their health care more accountable. But she shies away from endorsing any one overall solution.

“I can’t tell Congress what to do,” she says, “because then I’d be a pundit, and I’m not quite ready for that.”

Plans that would extend Medicare to younger people might work, she says (if Medicare is empowered to negotiate drug prices), but so could a private enterprise-based system like that in Switzerland. She believes, though, that piecemeal solutions won’t suffice: “I don’t see how we’re going to get there without some major systemic change.”

**No one-dimensional villains**

Perhaps one hopeful sign is that even as she criticizes the segments of the industry, she’s not in search of simple villains. “Everyone wants a bad guy, but there are good people in each part of the system,” she says. “It’s the way the system is designed and the way the parts interact that is the problem.” And she doesn’t let patients off the hook either.

“People I know will say, ‘I love that hospital because when you go in the door there’s a concierge who meets you and shows you to your room,’” she says—never mind that such marketing-oriented extras are helping to break the bank for all of us. “We say we want to choose who does our knee replacement, but then how do we choose? It’s ‘Oh, my husband plays golf with this orthopedic surgeon.’”
James Capretta, a Conservative Health Care Policy Expert, Is Suddenly a Hot Ticket

Conservative? Definitely. James Capretta is the first Milton Friedman Chair at the American Enterprise Institute. But he says partisanship makes health care unstable, politically and otherwise.

By Howard Wolinsky

In Jim Capretta’s view, the failure and lack of fix of the ACA can be traced back to the fact that it passed with the support of one party. Now, the conservative voice of reason on American health care policy and a fellow at the American Enterprise Institute thinks the same thing is about to happen as Congressional Republicans uproot Obamacare and replace it with legislation more to their liking.

“It would be far preferable for the country to reach some stability around health policy that both parties bought into,” says Capretta.

The partisanship of the ACA has led to both political and programmatic instability around the law, he notes. “I fear that the exercise the Republicans are engaged in right now is going to have the same result, just in a slightly different direction. So that it, too, is going to be subject to a lot of attack by opponents who are not invested in it. That means it could be subject to substantial revision at the next opportunity when the other party is in power. So you could have this swinging back and forth instead of some stability that might bring a little bit more coherence to the system.”

Partisanship may be bad for policy, but it can be a blessing for policy experts as journalists and the public try to figure out what lies behind all the maneuvering. And while they may have their misgivings about what the Republicans have cooked up, experts with conservative points of view are in demand right now, a group that includes Avik Roy, Joseph Antos (who like Capretta is at the American Enterprise Institute), and Michael Cannon. But Capretta has stood out as sensible and rational in a time of national division, so he is on the contact list of scores, if not hundreds, of journalists and politicians. And he is prolific. He has written for Health Affairs, where he is a member of the editorial board; the JAMA Forum, National Review, the Wall Street Journal, and the Weekly Standard. When health care is in the news, he is a familiar face on PBS NewsHour, Fox News, CNBC, and Bloomberg Television.

“Even if I don’t always agree with him, I find him very thoughtful and knowledgeable,” says Gail Wilensky, a Republican health care economist who served in the Bush 41 and Bush 43 administrations.

Capretta, 53, moved around the country as a child. He attended high school in Winston-Salem, N.C. “Part of our orientation was to be a Catholic Democratic family with Irish and Italian roots. So it was just sort of part of the blood to be a Democrat when you have that kind of an upbringing,” he says.

That changed for Capretta when he went to Duke to get his master’s degree in public policy studies. “When I got to graduate school and then beyond, and started studying more economic matters, I started to take on the view that it was very important to have the incentives right for a strong and growing economy and that was not inconsistent with also having a safety net to serve people when they needed it,” says Capretta. “I believe in limited government.”

After grad school, Capretta started as a career civil servant in the Office of Management and Budget. In the ’90s, he took a position as a senior policy analyst at the Senate Budget Committee, where he was responsible for health care issues. He served as associate director in the White House’s Office of Management and Budget from 2001 to 2004 when George W. Bush was president, where he was responsible for all health care, Social Security, welfare, labor and education issues.

Five years ago, Capretta joined the American Enterprise Institute, which he described as “the premier think tank devoted to defending the principles of a
free society and free enterprise, as well the important role of the U.S. in world affairs.” He doesn’t like the common media characterization of AEI as right wing.

Last year, he was named the first Milton Friedman Chair at AEI. Friedman, the Nobel Prize–winning economist, is revered at AEI because of his strong belief in markets and enterprise. Not surprisingly, Capretta is a Friedman fan. But when it comes to health care economics and policy, he has been influenced by Alain Enthoven, a Stanford economist and leader of the managed competition school for health care reform, and Mark Pauly, a University of Pennsylvania economist who favors market-based reforms. “I would put myself in between [Enthoven and Pauly],” he says.

Capretta recently has made a couple policy proposals that would, if enacted, affect the managed care industry. “I really think it’s important to organize and clarify Medicare’s choices for the beneficiaries in a better fashion so that it will intensify competition amongst the options, cut costs, and make it easier for managed care companies to do well by cutting costs and increasing value,” he said.

He also favors amending health savings accounts so patients could buy directly from managed care entities without calling that purchase a premium. “So if somebody already has got a high-deductible plan, but they need to buy access to services with their balances in the HSA account, they should be able to do that directly with the managed care entity without it being called an insurance premium with all the regulations that come with that,” he said.

Howard Wolinsky is an independent health care journalist based in Chicago.

Paula Steiner Brings Her Blues Back Into the Black

The president and CEO of Chicago-based HCSC made tough decisions to raise premiums and narrow networks. But, at least for now, HCSC plans to stay in the ACA exchanges while other insurers are jumping ship.

By Joseph Burns
Contributing Editor

If the health insurance business is about managing risk, why would anyone make a bet on the individual markets this year? But that is exactly what Paula Steiner is doing.

While many of the biggest names in the business—Aetna, Anthem, UnitedHealthcare—are fleeing the individual markets, Steiner and Health Care Service Corp. are hanging tough and staying in them in five states, while keeping their options open and not making a final decision until the fall. By then, HCSC will know more about what it can charge in each state and about the biggest risk in health care insurance today—whether Senate and House Republicans and President Trump will be successful in repealing and replacing large parts of the ACA.

Even if she wasn’t going against the grain, Steiner, 60, would rank among the most important health care executives in the country. HCSC isn’t going to win awards for name recognition—Health Care Service Corp. could be almost any kind of health care company. The parent company for Blues plans in Illinois, Montana, New Mexico, Oklahoma, and Texas, HCSC is the country’s fourth-largest insurer by revenue (nearly $35 billion in 2016, the company says) and members (15 million), and the second-largest Blues plan after for-profit Anthem. The headquarters in downtown Chicago are in a gleaming, 57-story office building that the company owns.

What led to Steiner’s interest in health care was her rejection for a job as a lifeguard while she was in high school, according to a 1997 Crain’s Chicago Business profile. An avid swimmer, Steiner instead got a job that
Bob Kocher Believes (With Missionary Zeal) That Venture Capital Can Start To Cure What Ails American Health Care

Whatever happens to the ACA, says this upbeat doctor-policymaker-entrepreneur, it was only the beginning of health care’s transformation. But will this version of better health care mean pink slips?

By Timothy Kelley
Senior Contributing Editor

ew health care ventures to spend money on? That would seem the last thing the U.S. economy needs. We’re far and away the world’s champion health care spender already, burning up the green stuff to the tune of roughly $3.5 trillion a year, according to a Plunkett Research estimate. But to Bob Kocher, MD, that’s exactly why a venture capital firm is the place to be.

Trained as an internist, Kocher, 46, helped Obama’s team write the ACA and also worked on Michelle Obama’s “Let’s Move” childhood obesity initiative. Then he joined the Palo Alto venture capital firm Venrock as a partner to help nurture new businesses in health care information technology and services. Venrock began as a Rockefeller family operation, helping to finance Eastern Airlines and McDonnell Aircraft; after its formal launch in 1969, it hit a homer by funding a company called Intel.

“Bob is probably the most influential person in Silicon Valley when it comes to health care investments,” says Robert Wachter, MD, chair of the Department of Medicine at the University of California–San Francisco and author of the 2015 book The Digital Doctor. Conceding that “business-type thinking” in
health care can be “a double-edged sword,” Wachter adds: “You want the entities that are given capital to try to make health care better to be led by clinicians who understand the needs of patients and care deeply about patients. I think Bob does.”

Where some these days see a federal policy train wreck, Kocher sees opportunity. “Health care now costs $15,000 per year for a family,” he says. “People can’t afford it. And no amount of government subsidies can overcome that gap. That poses a great opportunity to redesign health care—and a great entrepreneurial challenge.”

If Kocher’s no Pollyanna (he did confess to an interviewer last fall his worry that the GOP would act too hastily, with unforeseen consequences), he’s no Cassandra either. He’s pleased, he says, that both parties endorse a shift from fee-for-service to value-based care, with providers rewarded for quality, not volume. He believes any successful Republican legislation will keep much of the ACA architecture in place—though he acknowledges that continuing uncertainty about the individual market may chill new investment in that area for a while.

If “venture capitalists are on a mission to heal the ailing U.S. health care system,” as the website TechCrunch has declared, Kocher has the appropriate missionary zeal. Venture capital investment “increases the speed of learning for everyone involved in health care,” he contends, “and when startups gain traction, they are emulated by incumbents and help health care get better faster.” For example, he says, the employee health benefits platform, Castlight Health, which Venrock has funded in part, has helped make cost and quality data more available; the telehealth vendor Teladoc has opened access to care without the hassle of an office visit; and Oscar Health, a tech-focused health-insurance startup in New York City has made payers care more about the member experience (Josh Kushner, Jared’s brother, is the cofounder of Oscar).

In addition to Castlight, recipients of Venrock funding in health care have included Doctor on Demand, which offers physician consults via video; Virta Health, which helps people with diabetes control their diet and weight; and the former Sirna Therapeutics, a biotech firm that according to the New York Times had market capitalization of $6 million when Venrock bought it in 2003—then, a little over three years later, was sold to Merck for $1.1 billion.

“Since the ACA, $10 billion of new money has gone into health care services,” says Kocher. “It’s created about 500 new companies. Sure, they’re not all going to work. But they wouldn’t have happened by themselves.”

In economics, of course, good news generally comes with a flip side: Hail low food prices and you know farmers somewhere are hurting. When Kocher and his ilk get through with health care, it may not be quite the job-creating machine many credit with having pulled the country out of the Great Recession.

“Yes, there are super-expensive drugs, but two thirds of that $3.5 trillion annual health care spending is wages,” says Kocher. He gives presentations explaining that a $50 Tylenol pill you get in the hospital isn’t making the hospital rich; $47 of it goes to salaries. He believes the industry is ripe for the kind of streamlining “disruption” other businesses—financial services, for example—underwent decades ago, in order to make it leaner and more cost-effective, safe, and satisfying to the consumer. Prognosis: pink slips.

Kocher, a graduate of the University of Washington and George Washington University’s medical school, recalls his residency at Harvard-affiliated Beth Israel Deaconess Medical Center in Boston and “how hard it was—even in a prestigious place—to have things organized so that the right thing happened naturally.” Kocher says that he still thinks about patients every day and that his current entrepreneur role—like his policy work under Obama—is just another way of trying to help them by organizing things.
ACOs Sit Like Gibraltar In Rough Seas of Change

They are expected to survive and possibly even thrive no matter what form the health system takes under the Trump administration.

By Robert Calandra

When the dust finally settles on congressional Republicans’ seven-year quest to repeal and replace the ACA, who knows which parts of the law will survive and which won’t?

But the ACO, a creature of the ACA that often gets confused with its progenitor, seems like it will survive—and maybe even thrive—in whatever health-scape emerges from the Republican anti-ACA push. Just how the Trump administration and Congress might unwind the law remains to be seen. What will happen to all the various forms of the ACO—the Medicare Shared Savings Program (MSSP), Next Generation, and commercial ACOs?

“I honestly don’t think that if the ACA repeal were to happen, it will have any impact whatsoever on the future of ACOs, and when I say ACOs I mean both MSSPs and commercial,” says Matthew Amodeo, a partner in the health care group of Drinker, Biddle, & Reath in Albany, N.Y. “The train has left the station.”

Amodeo represents and provides legal advice to ACOs.

HHS Secretary Tom Price, who was an orthopedic surgeon before he went into politics, has made his objections to mandatory value-based programs clear. As a congressman, Price opposed mandatory value-based health care payment models like the Comprehensive Care for Joint Replacement (CJR) model. So it was no surprise when Price announced in March that the expansion of that payment model—and another for cardiac care—would be delayed until October. And no one would be shocked if that delay became permanent.

Still, Amodeo believes that Price is generally in favor of value-based reimbursement programs, just as long as they are voluntary.

David Muhlestein, chief research officer at Leavitt Partners, the Salt Lake City health care consulting company, says the fact that CJR has only been delayed and not made nonmandatory underscores that while Price may have some problems with the way value-based programs were implemented during the Obama administration, he is not against them altogether.

Price “has always expressed his support for these different payment models in general,” says Muhlestein. “What he doesn’t like is mandating ones that haven’t been proven. That’s a philosophical approach which I think a lot of people could agree with.”

Price has railed against the administrative burden on providers, so it seems likely that he will look for ways to reduce reporting requirements and other aspects of ACOs that impinge on providers.

Will CMMI survive?

But Price’s interest in making programs voluntary means that many of CMS’s ACOs might flourish with Price in charge. It may also mean that another ACA creation, CMS’s Center for Medicare and Medicaid Innovation (CMMI),

You can’t look at ACOs in a vacuum,” says Matthew Amodeo of Drinker, Biddle, & Reath. You have to keep MACRA in mind.

Growth in the number of ACOs over time

Source: Muhlestein et al., Health Affairs blog, June 28, 2017
might survive the long knives of congressional Republicans. CMMI is the petri dish from which the Next Generation ACOs and other value-based experimental reimbursement programs have sprung.

Paul Ryan’s A Better Way plan called for eliminating CMMI in 2020. But Muhlestein says some in the GOP now see CMMI as a useful haven for some trial and error. “As soon as they realized what it was, some recognized the potential power it offered them to experiment with things.”

Of course, ACOs, CMMI, or any other experimental form of alternative reimbursement could go the way of the law that spawned them if they weren’t producing results or the marketplace rejected them. But they are, and it hasn’t. Commercial insurers have jumped on the ACO bandwagon in a major way.

Health care insurers see ACOs as the wave of the future, says Robert Ramsey, who has practiced health care law for 30 years with Buchanan, Ingersoll, & Rooney in Pittsburgh and represents and counsels ACOs. “You can bet, he says, insurers are telling Congress that no matter what replaces the ACA, it had better include ACOs.

“Commercial payers are already embracing various forms of the payment models,” Ramsey says. “All you have to do is look at what some of the big insurance companies are doing. They are tying payment to quality. They are tying payment to risk. So you have a tremendous amount of momentum that will continue this in some form.”

That momentum is evident in the number of insurers adopting ACO programs. Two years ago, Leavitt Partners and the Blue Cross Blue Shield Association prepared a report on insurers and ACOs. It found that 136 unique payers had entered into ACO contracts. Of those, 117 were commercial payers and 19 were government payers. (CMS is the main government payer, but state-run Medicaid programs are also busy signing ACO contracts.) In an article posted in June on the Health Affairs blog, Muhlestein and two colleagues at the Duke-Margolis Health Policy Center reported that as of the first quarter of 2017 there are 923 active public and private ACOs that cover more than 32 million lives, or roughly 10% of the country’s population. There’s some churn: 138 new ACOs began operation since the first quarter of 2016, according to the numbers reported by Muhlestein and company, but 46 entities shed their ACO status, so the net gain was 92.

One area of confusion in ACO scorekeeping is whether you are counting ACOs or ACO contracts because one organization may, of course, have multiple ACO contracts or arrangements. So, in the Health Affairs piece, while the total number of ACOs was 923, the total number of ACO contracts was 1,366. Counting contracts puts a lie to the notion that ACOs are mainly a CMS creation, although there’s no question that the CMS programs have been instrumental. Just over half (715 of 1,366, or 52%) of the ACO contracts are with commercial insurers and they tend to cover more lives than Medicare contracts (26,700 per contract vs. 16,800). All of this argues for ACOs having some staying power and momentum beyond what federal and state health officials are doing to promote the payment model.

“What you are seeing is actual ACO adoption, ACO growth,” says Joe Paduda, a managed care consultant and author of the well-regarded Managed Care Matters blog. “That’s because the ones that are succeeding are having a significant impact on improving patient outcomes and reducing costs.”

Paduda points to Anthem. “They own 13 Blues plans and have 15 to 20 ACOs running, and almost half of their spend right now is going through some sort of value-based bonus payment. The company has saved about $70 million because of the ACOs.”

“The market for health insurance is extremely price sensitive,” Paduda says. “Price is driven by claims experience, and because ACOs and patient-centered medical homes reduce costs, those are going to win. So whatever pronouncements come out of HHS, the market is going to do what makes the most sense. What makes the most sense is delivering care at a lower cost.”
A boost from MACRA
ACOs may get a boost from the MACRA legislation. Under MACRA, physicians and other eligible providers have a choice between the MIPS or APM tracks, and participation in some types of ACOs (Next Generation and Tracks 1+, 2, and 3 of MSSP ACOs) will entitle them to incentive payments under the APM track.

“You can’t look at ACOs in a vacuum,” Amodeo says. “You have to consider them in the context of MACRA and the significant payment changes in the way physicians are reimbursed that touches on the value-based concept, quality and costs, and patient satisfaction.”

The overwhelming support for MACRA in Congress was, if not a watershed moment, at the very least a validation of the ACO concept. But Ramsey says CMS was looking for an ACO-type solution long before the ACA. To quell health care’s rising economic and market pressures, CMS started experimenting with a variety of reimbursement options that tied quality to reimbursement payments.

“If you look at those programs, you will sort of see why so many people believe that ACOs are here to stay,” Ramsey says. “You have a tremendous amount of momentum that will continue this in some form.”

But what form?
The Republicans went all-in politically with pulling the plug on the ACA. Now that they are in power, some of them may have some remorse about the anti-ACA stance, given all the difficulties of legislating a replacement. But ACOs and value-based care really don’t have much in the way of politics attached to them.

They are inside baseball, known only to health policy experts, health care executives, and consultants.

Politics will almost certainly play a lesser role in the continuing development of ACOs and other reimbursement programs than in most policies. Muhlestein and others believe Price will listen to and work with the nonpartisan career staff at CMS.

Disappearing ACOs
Muhlestein sees a future of different payment models for different types of providers.

The population-based model requires a primary care focus, Muhlestein says. Surgeons, for instance, don’t really fit within the population-based model. They perform procedures and don’t really manage ongoing care. And they aren’t the only providers that will probably be just a piece of the payment puzzle that the ACO will put together.

“There will be an increasing number of different payment models that can be rolled up to an ACO,” Muhlestein says.

While he believes ACOs are here to stay, Amodeo says they are really just a means to an end, a laboratory for weaning physicians off straight fee for service to value-based payments and ultimately full risk—in other words, capitation.

“This is just kind of an interim step in the process,” he says. “Ultimately, we won’t be calling them ACOs any more.

“I would say that 10 years from now, you will be looking at a more risk-based reimbursement model. ACO will just kind of be a term of art that will eventually disappear.”

Robert Calandra, a regular contributor to Managed Care, is an independent journalist in Philadelphia with more than 20 years’ experience writing about health care.
Navigating the Changing Tides of Health Care: 5 Areas for Leaders To Watch

By Zachary Hafner
Advisory Board

It’s hard to imagine an industry more embroiled in change than American health care today. Somewhere among changing payment models, big data, evolving customer expectations, and incredible uncertainty, today’s health care leaders are navigating uncharted waters.

Questions abound. Which trends will take hold—and which will fizzle? What will market conditions be like six, 12, or 18 months from now? Are there moves to make without compromising what you’ve worked so hard to achieve?

I don’t have all the answers, but here is my Top 5 edition of issues that health care leaders should be paying close attention to and key implications for planning going forward:

1) **The consumer revolution.** The buzz surrounding the consumer-driven health care market is everywhere, but is there really a consumer revolution underway? Clearly, consumer financial exposure to health care cost is on the rise and transparency is improving on a daily basis—but how quickly and comprehensively this will translate to a full-blown retail marketplace has significant ramifications for localized strategy.

**Implication:** Be intimately familiar with the pace of change in your market and prioritize “no-regret” moves that enhance your relationship with your customers under any set of circumstances.

2) **Care management.** The promise of population health management is directly tied to longitudinal care management that spans multiple care settings and participants. In today’s regulatory environment, however, not all of the information necessary for effective care management can be shared across independent entities. With so much in health care in flux, it is difficult to know what will be permissible and to invest accordingly.

**Implication:** Continue to ensure that patients do not fall through the cracks and leverage the structures that enjoy broad-based support, such as clinically integrated networks and ACOs for broader reach.

3) **Merger mania.** Every day seems to bring a new headline about yet another health care consolidation. But how much of this M&A activity is delivering near- or even long-term value? Consolidation has reached fever pitch, making it hard to watch from the sidelines without getting queasy with FOMO and worrying that your ship has sailed. But mergers of desperation rarely yield the intended benefits.

**Implication:** Consolidation may or may not be a right answer for your organization. Either way, it must be evaluated thoughtfully. Make sure you have a solid strategic rationale with a roadmap for realizing the value potential.

4) **Medicare Advantage.** Industry interest in Medicare Advantage has spiked in recent years as providers and insurers alike are recognizing the financial arbitrage opportunity associated with improving outcomes and managing chronic disease for “top of the pyramid” patients (i.e., the top 5% who account for about 50% of the total spend within a Medicare population). In reality, succeeding in Medicare Advantage is a complex and risky endeavor that requires nuanced skills drawn from both payer and provider areas of expertise.

**Implication:** Ensuring the proper set of integrated skills is make-or-break for Medicare Advantage. In many cases, strategic partnerships may yield better results than going it alone.

5) **Medicaid.** While a variety of approaches to Medicaid are under consideration as part of the Republican health care revision, most call for reducing the number of covered lives and the total amount of benefit dollars. This has many stakeholders concerned that uncompensated care will explode and with it, commercial insurance cross-subsidization.

**Implication:** Predicting exactly how this will play out is impossible, but broader access to lower-cost care settings with a variety of payment options will be needed to prevent a backslide to broken health system economics and unsustainable cost shifting.

With so many unknowns blurring line-of-sight to the future, it may be tempting to sit back and take a wait-and-see approach. But by keeping an eye on these Top 5 issues and implications, leaders will have an edge in charting a successful course.

Zachary Hafner leads the Advisory Board’s strategy consulting practice.
If your company is feeling pinched by health care costs, there is good reason. U.S. employers spend three times more on health care for their employees than many wealthy countries spend for their residents. It’s a growing expense that reduces your company’s ability to repurchase shares (if you’re publicly held), fund capital expenditures, invest in R&D, and pursue mergers, acquisitions, and strategic partnerships.

Perhaps nowhere is frustration greater than in Alaska. The state’s costs are rising faster than those of any other, and Alaska spends more on health care per person than any state except for Massachusetts. Making matters worse, Alaska ranks nearly last in the nation in the number of physicians and facilities that serve its citizens.

**Alaska Teamster**

Alaska’s motto is “North to the Future,” but the Alaska Teamster–Employer Welfare Trust looks south to rein in the cost of care to the organization and its 2,230 union members. Its members travel to the lower 48 states for knee replacements and other orthopedic, spine, women’s health, bariatric, cardiac, and neurological procedures under a domestic medical travel benefit program from my company, BridgeHealth. From 2013 to 2016, the program saved the trust more than $1.2 million on surgeries.

BridgeHealth identified top-quartile hospitals and surgical centers based on nationally recognized quality ratings. The firm then negotiated with these high-performing surgical teams for episode-of-care case rates, bundling the various charges for each surgery into a single discounted price. We brought these discounted case rates to Alaska Teamster, and the union encouraged eligible members to use the medical travel program by waiving deductibles and coinsurance. The union also picked up the tab for airfare, hotel accommodations, meals, and incidentals. As the plan sponsor, the union spearheaded communications that educated members about the program. BridgeHealth handled eligibility confirmation, precertification, and benefits coordination with Alaska Teamster’s PPO plan administrator. Alaska Teamster paid a nominal per-employee, per-month fee for administration of the program, plus a service and access fee for each surgery performed. Every year, this innovative solution has delivered an ROI ranging from 1.9 to 5.88.

Companies outside of Alaska are also benefiting from medical travel. At one organization, hip replacement surgery performed at a facility in another part of the country cost the company $18,000 less than if the surgery had been performed in a local hospital. Patients paid no out-of-pocket costs through BridgeHealth vs. paying $2,500 if they obtained the surgery locally. For a variety of bundled surgeries, another employer saved $1.1 million over three years. ROI has ranged from 2:1 to 16:1, depending on the level of engagement plan sponsors choose.

**Ask questions**

Not all medical travel programs are created equal, so employers should shop with a discerning eye. Most programs use a “proprietary” method to evaluate and select high-quality providers for their networks. It is important to ask questions. What exactly is their selection process? Are their provider selections based on clinical, independent evaluations or are they based on the self-interest of the medical travel firm? On what basis does a medical travel firm determine that its providers are top performers? What are the rates of readmission and postoperative complications in a medical travel firm’s network? What provisions are there for patients who must delay their return home due to surgical complications? Must families foot the bill to travel with patients to provide support and encouragement?

The best medical travel programs address these and other questions and concerns to the satisfaction of customers.

Medical travel programs can work to the benefit of everyone involved. Employees and dependents win because they become more informed, engaged consumers of medical care, and pay little or nothing for high-quality surgeries. Financial hardship no longer is a reason to delay necessary care.

The employer wins because it enjoys deep savings on the best surgical treatment for its employees, which helps to attract top talent and free up dollars to invest in growing the business.

*Mark Stadler is CEO of BridgeHealth, a surgical-cost containment company in Denver.*
One of the most fundamental changes in the health care industry today is the transition away from fee for service in favor of value-based payment models. The goal of these value-based models is to promote good outcomes, increased quality, and cost efficiency.

Large payers continue moving toward value-based payment. The Arizona Health Care Cost Containment System, the state’s Medicaid agency, is requiring that a majority of covered lives be under value-based contracts by the end of 2018. Many of the nation’s health insurance leaders predict that by 2020, as much as 75% of the business will be in value-based arrangements.

But, in my view, value-based contracting is just one piece of a puzzle of health care reform.

At Phoenix Children’s Hospital, we are developing one of the nation’s leading pediatric, clinically integrated organizations. Phoenix Children’s Care Network (PCCN), established in 2013, is redefining the approach to pediatric medical management in our marketplace. This new path includes a more integrated approach to patient access, quality improvement, collaboration across care providers, and systemwide data analytics.

PCCN offers patients access to more than 1,000 providers, representing 65% of all general pediatricians across metro Phoenix, as well as 85% of pediatric subspecialists including all of Phoenix Children’s Hospital’s sites of service. The strength of PCCN is founded in the strong partnerships with its more than 100 independent community-based physician practices, as well as with Phoenix Children’s Hospital.

Some tips
From a value-based perspective, constructing the architecture of PCCN incorporates several key initiatives, which may provide a blueprint for other health systems developing clinically integrated organizations.

- **Care model.** Provide a centralized care-management model for defined populations across all aspects of the care continuum.
- **Data platform.** Create a robust data analytics-and-reporting platform that aggregates data from payers, electronic medical records, claim files, labs, pharmacy, and other relevant data sources to enable successful management of segmented populations.
- **Point-of-care interventions.** Deploy point-of-care toolsets to providers that enable proactive management of defined populations, as opposed to reactive medicine.
- **Adult system partnerships.** For pediatric clinically integrated organizations, develop partnerships with adult care systems to provide management of pediatric populations for relevant insurance products.
- **Payer contracts.** Leverage resources for the health system to thrive in any contract environment from fee for service to a full-risk paradigm.

Some trap doors
Clinical integration has great potential, but it’s relatively new. With newness, come some challenges:

- lack of leadership and support from health system executives
- resistance, active and passive, to integration of hospital and employed medical group operations
- immature enterprise IT/data and analytic systems
- payer engagement
- high cost of development and economic sustainability
- inexperienced staff required to build new and innovative operational models.

Value-based payment is gaining traction and proving to be a major factor in health care reform. But the success of those value-based models will depend on true clinical integration of providers—not just lip service to coordination.

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Chad Johnson is senior vice president of Phoenix Children’s Care Network. Johnson formerly served as CEO of the Children’s Health Network in Minneapolis.
Management of a Rare Disease Population: A Model for Identifying a Patient Population With Tuberous Sclerosis Complex

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INTRODUCTION
To reduce long-term health care costs, health plans are pursuing various strategies to improve patient health, including disease management programs. Although common conditions such as asthma and diabetes are typical targets for these programs, rare diseases, which collectively affect more than 25 million patients in the United States each year (HHS 2010), represent potential targets for disease management programs.

Health plans and payers with access to large volumes of patient population data are in a unique position to provide key insights into improving identification and treatment of patients with rare diseases. The diagnosis of rare diseases, in comparison with common diseases, typically takes longer, requires more hospital visits, involves multiple primary care providers and specialists, and entails an assortment of diagnostic tests and procedures (Schieppati 2008, de Vrueh 2013). Moreover, rare diseases, particularly for disorders with variable severity and appearance of associated manifestations, require a high frequency of health care resource utilization, with uncertainty about which procedures are necessary for either diagnosis or treatment (Schieppati 2008, de Vrueh 2013). One such disorder is tuberous sclerosis complex (TSC), a rare genetic disorder characterized by cognitive deficits; behavioral disorders; a high rate of intractable seizures; and benign tumors in the brain, kidneys, heart, eyes, lungs, and skin (Curatolo 2008, Crino 2006). The incidence of TSC is 1 in 6,000 live births, and between 25,000 and 50,000 people in the United States and 1 to 2 million worldwide live with the disease (NIH).

Diagnosis and management of TSC is challenging because TSC affects every patient differently (Wataya-

Glossary
Angiomyolipomas  
benign renal tumors
Subependymal giant cell astrocytomas (SEGAs)  
benign tumor in the ventricles of the brain
Cortical tubers  
malformed tissue in the gray/white matter interface
Subependymal nodules  
small lesions found in the lining of the brain ventricles

ABSTRACT
Purpose: Rare diseases are potential targets for disease management programs because of the expense and difficulties in their diagnosis and treatment. Tuberous sclerosis complex (TSC) is a rare genetic disorder affecting the brain and other vital organs with varying symptoms and severity among patients. This study developed and validated a risk model to identify patients with TSC using large databases of medical and pharmacy claims.

Design: This retrospective, case-controlled study investigated patient and treatment factors present in health care-related claims associated with TSC.

Methodology: Patients were identified from Jan. 1, 2000, to Dec. 31, 2011, for study inclusion from the Optum Research database (ORD) and the Impact National Benchmark database (Impact), which contain medical and pharmacy claims from U.S. health plan members. We developed a logistic model to score patients’ likelihood of having a TSC diagnosis and evaluated it for both internal validation with the ORD sample and external validation using the Impact sample.

Results: A total of 7,360 patients (TSC, n=1,472; control, n=5,888) were obtained from the ORD. In the logistic regression model, the top covariates for patients with TSC were the presence of an evaluation and management procedure code (odds ratio=11.4; P<.001), seizure disorders (odds ratio=5.9; P<.001), and angiomyolipomas (odds ratio=5.8; P<.001). The area under the receiver operating characteristic curve, a measurement of predictive probability, was 0.77 and 0.75 for the ORD and Impact validation sample sets, respectively.

Conclusion: We generated a validated risk model that could be a useful tool for assisting health plans involved in the care and management of TSC.

Key words: Tuberous sclerosis complex, rare diseases, risk model, payer
Tubercous sclerosis complex (TSC) is a genetic disorder that affects multiple organ systems but with diverse and variable manifestations and severity across pediatric and adult patients (Krueger 2013b). Virtually all patients with TSC have skin abnormalities that vary with age and appearance between individuals (Northrup 1999). TSC-associated neuropsychiatric disorders include autism spectrum disorder (Spurling Jeste 2014, Kaneda 2013), attention-deficit/hyperactivity disorder (de Vries 2007, de Vries 2007), and mild to profound intellectual disability (Joinson 2003). An additional common condition associated with TSC in female patients is the formation of cysts in lymphatic vessels in the lungs and abdomen (lymphangioleiomyomatosis) (Crino 2006).

None of the aforementioned clinical features in TSC are pathognomonic. Current diagnostic criteria for TSC (Table 1) require the presence of any of two major features or identification of pathogenic mutations in TSC1 or TSC2 as sufficient for TSC diagnosis (Northrup 2013). Alternatively, the presence of one major feature plus two minor features is also sufficient for diagnosis. Once diagnosed with TSC, consensus recommendations call for abdominal imaging, annual assessment of kidney function (Krueger 2013b, Rouviere 2013), and evaluation for neuropsychiatric disorders (Krueger 2013b). Brain magnetic resonance imaging is recommended every 1 to 3 years to assess SEGa development (Krueger 2013a).

With such an assortment of potential disease manifestations requiring assessment, treatment, and monitoring, care of TSC patients is associated with high health care resource utilization, resulting in substantial economic costs (Lenert 2013, Rentz 2015). Surgical resection of SEGAs and angiomyolipomas, in particular, are associated with significant direct medical costs and high utilization of medical resources (Vekeman 2015, Sun 2015). Additionally, disease burden for individuals with TSC affects their health-related quality of life, particularly around the mental health domain, with TSC patients reporting a significantly greater mental health burden than cancer patients and more depressive symptoms compared with nonpsychiatric community controls (Rentz 2015).

The growing availability of disease- and treatment-related patient data is a resource that health plans can leverage to improve understanding and management of rare diseases. Rare disease surveillance can be difficult and expensive. Population surveys often lack a sufficient number of observations, patient registries can lack generalizability to the overall population, and active surveillance requires medical chart review, which is time consuming and costly.

In contrast, passive surveillance through claims data offers several benefits. Claims data are inexpensive, readily available, and provide insight into mortality rates, comorbidities, access to health care services, and costs of care. At a population level, these data can be used to guide the provision of health services and evaluate the cost-effectiveness of medical care and interventions.

Using patient health care claims data from large digital databases, this retrospective case-controlled study sought to identify key patient and treatment factors associated with TSC. Identifying patients with TSC at an early stage has important clinical implications for prevention of further complications and receipt of appropriate clinical care.

TABLE 1
Diagnostic criteria for tuberous sclerosis complex

<table>
<thead>
<tr>
<th>Main features</th>
<th>Minor features</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angiofibromas</td>
<td>Confetti skin lesions</td>
</tr>
<tr>
<td>Cardiac rhabomyomas</td>
<td>Dental enamel pits</td>
</tr>
<tr>
<td>Cortical dysplasia</td>
<td>Intraoral fibromas</td>
</tr>
<tr>
<td>Hypomelanotic macules</td>
<td>Multiple renal cysts</td>
</tr>
<tr>
<td>Lymphangioleiomyomatosis*</td>
<td>Nonrenal hamartomas</td>
</tr>
<tr>
<td>Multiple retinal nodular hamartomas</td>
<td>Retinal achronic patch</td>
</tr>
<tr>
<td>Renal angiomyolipomas*</td>
<td></td>
</tr>
<tr>
<td>Shagreen patch</td>
<td></td>
</tr>
<tr>
<td>Subependymal giant cell astrocytoma</td>
<td></td>
</tr>
<tr>
<td>Subependymal nodules</td>
<td></td>
</tr>
<tr>
<td>Ungual fibromas</td>
<td></td>
</tr>
</tbody>
</table>

*Combination of renal angiomyolipomas and lymphangioleiomyomatosis with no other features does not meet the criteria for a definite diagnosis.
Management of Tuberous Sclerosis Complex

METHODS
Study design
Patients were identified for inclusion in the study during the identification period from Jan. 1, 2000, through Dec. 31, 2011. Of the more than 75 million commercial and Medicare Advantage enrollees in the Optum Research Database (ORD) and the Impact National Benchmark database (Impact) during the study period, 5,525 were identified with at least one medical claim of a TSC diagnosis (International Classification of Disease, 9th revision diagnosis code 759.5x). Inclusion criteria for the TSC sample consisted of TSC diagnosis occurring from January 2000 to December 2011, with the first claim with a TSC diagnosis considered the index date. Patients had to have 12 months of continuous enrollment with medical and pharmacy benefits prior to the index date (baseline period). The inclusion criteria for control patients were medical coverage during this same period and no diagnosis of TSC. The index date was randomly assigned for the control group during the enrollment period. Patients were excluded if they had a TSC diagnosis during the baseline period.

After application of the above inclusion criteria to the initial 5,525 patients with TSC identified in the databases, a total of 2,498 patients were retained in the final TSC cohort. Of these, the subset of 1,685 patients identified in the ORD was used for model development. The control cohort was paired with the patients with TSC on length of enrollment post index (±90 days) and year of index date (±2 years). The match yielded 1,472 patients with TSC and four controls per patient with TSC, which resulted in the retention of 5,888 patients in the control cohort. TSC and control patients were observed 12 months prior to the date of diagnosis of TSC and for varying lengths of time following the date of diagnosis. Patients with TSC and matched control patients from Impact were used to assess the applicability of the model developed in the ORD to an independent claims database.

Data sources
ORD and Impact contain medical and pharmacy claims linked to enrollment information from health plans serving members across the United States. The medical claims capture diagnoses and procedures from International Classification of Disease, 9th revision, Clinical Modification codes; Healthcare Common Procedure Coding System procedure codes; and Current Procedural Technology procedure codes. Pharmacy claims include National Drug Code, quantity dispensed, drug strength, and days’ supply. No identifiable protected health information was extracted or accessed during the course of the study.

Pursuant to the Health Insurance Portability and Accountability Act, the use of de-identified data does not require institutional review board approval or waiver of authorization.

Model development
The full ORD sample was randomly split in half to create development and validation samples (TSC, n=736; control, n=2,944, for each sample). Logistic regression coefficients were calculated from the development sample, and the validation sample was held out to test internal validation of the model. The dependent variable for this analysis was TSC diagnosis (yes=1, no=0). The analysis evaluated 600 potential independent variables for inclusion in the model. The first stage of model development included univariate assessment of dichotomous variables and graphical assessment of continuous variables to determine the most appropriate functional form of each measure. Continuous variables

TABLE 2
Patient demographics (ORD sample)

<table>
<thead>
<tr>
<th>Demographics</th>
<th>TSC (n=1,472)</th>
<th>Control (n=5,888)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD), years</td>
<td>35.98 (21.00)</td>
<td>36.74 (20.38)</td>
<td>.204</td>
</tr>
<tr>
<td>Age categories, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0–2 years</td>
<td>46 (3.13)</td>
<td>134 (2.28)</td>
<td>.06</td>
</tr>
<tr>
<td>3–19 years</td>
<td>351 (23.85)</td>
<td>1,283 (21.79)</td>
<td>.09</td>
</tr>
<tr>
<td>20–29 years</td>
<td>164 (11.14)</td>
<td>770 (13.08)</td>
<td>.046</td>
</tr>
<tr>
<td>29–39 years</td>
<td>269 (18.27)</td>
<td>941 (15.98)</td>
<td>.03</td>
</tr>
<tr>
<td>40+ years</td>
<td>642 (43.61)</td>
<td>2,760 (46.88)</td>
<td>.02</td>
</tr>
<tr>
<td>Gender, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>673 (45.72)</td>
<td>2,849 (48.39)</td>
<td>.07</td>
</tr>
<tr>
<td>Female</td>
<td>799 (54.28)</td>
<td>3,039 (51.61)</td>
<td>.07</td>
</tr>
<tr>
<td>Insurance type, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Commercial</td>
<td>1,393 (94.63)</td>
<td>5,570 (94.60)</td>
<td>.96</td>
</tr>
<tr>
<td>Medicare Advantage</td>
<td>79 (5.37)</td>
<td>318 (5.40)</td>
<td>.96</td>
</tr>
<tr>
<td>Health plan region, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Northeast</td>
<td>209 (14.20)</td>
<td>596 (10.12)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Midwest</td>
<td>449 (30.50)</td>
<td>1,759 (29.87)</td>
<td>.64</td>
</tr>
<tr>
<td>South</td>
<td>607 (41.24)</td>
<td>2,702 (45.89)</td>
<td>.001</td>
</tr>
<tr>
<td>West</td>
<td>205 (13.93)</td>
<td>829 (14.08)</td>
<td>.88</td>
</tr>
<tr>
<td>Other</td>
<td>2 (0.14)</td>
<td>2 (0.03)</td>
<td>.13</td>
</tr>
</tbody>
</table>

ORD=Optum Research database, TSC=tuberous sclerosis complex.
were capped at the 99th percentile to reduce skewing from outliers. Examples of these include visit counts, length of inpatient hospitalization, and health care-related costs.

The next stage of model development involved grouping similar types of variables into blocks, such as demographic characteristics, general comorbidity indexes, health care utilization and costs, diagnoses (e.g., seizures, cognitive disorder, angionyolipomas), procedures (e.g., imaging, genetic testing, electrocardiogram), and medications. Blocks were manually added to or removed from the model in a stepwise fashion based on Wald chi-square values while maximizing the probability of concordance between predicted and actual outcomes. At each step, variables within each block were added to the existing model one at a time; highly correlated variables were removed to preserve interpretability, and variables that did not improve predictability were dropped. Only the most predictive variables among partially redundant variables in a block were retained. While building the model, predictability and goodness of fit were assessed with c-statistics, and comparisons between models were made using likelihood ratio tests for nested models and Akaike information criterion for non-nested models (measure of the relative quality of statistical models). Each factor received a numeric value based on its relative strength of association with TSC diagnosis (i.e., odds ratio). These factors collectively equate to a predictive value (i.e., probability) that can be calculated based on the characteristics of a patient. To examine the sensitivity and specificity of the model, a receiver operating characteristic (ROC) curve was generated based on applying the model to the patient data in the internal validation sample. The area under the ROC curve (AUC) is a measure of test accuracy, where a value of 1 indicates that the model perfectly discriminates between a patient with TSC and one without and a value of 0.5 indicates a model that performs no better than chance (Agresti 2002). After deciding which covariates to include in the model, the patients in the Impact sample were scored using the estimates from the ORD development sample. This final test was to measure the external validity of the model and determine whether the model was biased toward the ORD database used in development.


RESULTS
Data acquisition and study sample description
Data from 7,360 patients (TSC, n=1,472; control, n=5,888) were accessed from the ORD. Each cohort had similar mean age (36 years for TSC and 37 years for control) and gender proportions (Table 2). Within the ORD sample, we analyzed 600 potential factors that were recorded in the year prior to and for varying periods following diagnosis of TSC. These factors were categorized and included demographics (age, gender, and region), general comorbidity indices, health care utilization and costs, diagnoses, procedures, and medications. Patient demographics and results of key descriptive factors are listed in Table 2.

The most frequent diagnoses in the TSC group identified in the ORD sample and control group, respectively, were skin disorders (41.6% and 17.9%; P<.001), kidney and urinary system disorders (21.4% and 12.3%; P<.001), depression (17.3% and 10.7%; P<.001), seizure disorders (16.8% and 1.7%; P<.001), nausea and vomiting (15.9% and 8.7%; P<.001), anxiety (14.4% and 9.9%; P<.001), sleep disturbances (13.7% and 9.2%; P<.001), and cardiac dysrhythmias and rhabdomyomas (12.2% and 6.2%; P<.001) (Figure 1).

TSC risk model performance
In the logistic regression model using the development sample, the top covariate for patients with TSC was
the presence of an evaluation and management procedure code (odds ratio=11.4; \( P<.001 \)) (Table 3). Compared with control patients, seizure disorders (odds ratio=5.9; \( P<.001 \) and angiomylipomas (odds ratio=5.8; \( P<.001 \) were the conditions most strongly associated with patients with TSC, followed by skin disorders (odds ratio=3.0; \( P<.001 \)), renal failure (odds ratio=1.6; \( P=.03 \)), and cognitive disorders (odds ratio=1.6; \( P=.02 \)) (Table 3).

To assess the performance of the model, an ROC was constructed to test the model against the internal validation sample data (TSC, \( n=736 \); control, \( n=2,944 \)). This test resulted in an AUC of 0.77 (Figure 2). Classifying patients with a predicted probability of greater than or equal to 80% yielded a sensitivity of 8.8% and a specificity of 99.4%, while classifying patients with a predicted probability of 34% yielded a sensitivity of 39.4% and a specificity of 91.9% (these are further explained in the Discussion section). The model was externally validated with Impact, which resulted in an AUC of 0.75, signifying that this model performed similarly in an insured population not used in model development.

**DISCUSSION**

This study sought to identify patient and treatment factors surrounding the TSC diagnosis that could be informative for health plans managing patients with this disease. Analysis of 600 potential predictors of TSC created from information included in health insurance claims revealed significant associations between TSC diagnosis and benign neoplasms of

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**TABLE 3**

**Patient and treatment factors associated with TSC (ORD)**

<table>
<thead>
<tr>
<th>Independent variables</th>
<th>Estimate</th>
<th>Odds ratio</th>
<th>( P ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intercept</td>
<td>-4.903</td>
<td>–</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Age categories (reference: 40+)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0–2 years</td>
<td>0.5118</td>
<td>1.668</td>
<td>.11</td>
</tr>
<tr>
<td>3–18 years</td>
<td>0.7644</td>
<td>2.148</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>19–29 years</td>
<td>0.3083</td>
<td>1.361</td>
<td>.07</td>
</tr>
<tr>
<td>30–39 years</td>
<td>0.4761</td>
<td>1.610</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Number of days post index</td>
<td>-0.00041</td>
<td>1.000</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Diagnoses</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Angiomyolipomas</td>
<td>1.7548</td>
<td>5.782</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Cognitive disorders</td>
<td>0.4453</td>
<td>1.561</td>
<td>.02</td>
</tr>
<tr>
<td>Other connective tissue disease</td>
<td>0.4154</td>
<td>1.515</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Renal failure</td>
<td>0.4748</td>
<td>1.608</td>
<td>.03</td>
</tr>
<tr>
<td>Seizure disorders</td>
<td>1.7812</td>
<td>5.937</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Skin</td>
<td>1.1079</td>
<td>3.028</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Procedures</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brain–CT scan, MRI, MRA, ultrasound</td>
<td>0.3055</td>
<td>1.357</td>
<td>.03</td>
</tr>
<tr>
<td>Cardiac: radiograph, CT scan, MRI, ultrasound, ECHO, EKG</td>
<td>0.7097</td>
<td>2.033</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Electrocardiogram, complete</td>
<td>-0.5553</td>
<td>0.574</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Influenza vaccine, ≥3 years, intramuscular</td>
<td>-0.5036</td>
<td>0.604</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Office/outpatient visit, estimated</td>
<td>0.3838</td>
<td>1.468</td>
<td>.01</td>
</tr>
<tr>
<td>Ophthalmology</td>
<td>-0.3349</td>
<td>0.715</td>
<td>.004</td>
</tr>
<tr>
<td>Utilization</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥6 ambulatory visits PPPY</td>
<td>0.3818</td>
<td>1.465</td>
<td>.002</td>
</tr>
<tr>
<td>Evaluation and management</td>
<td>2.4372</td>
<td>11.441</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Neurologist visit</td>
<td>0.4516</td>
<td>1.571</td>
<td>.002</td>
</tr>
<tr>
<td>Number of specialist visits PPPY</td>
<td>0.00801</td>
<td>1.008</td>
<td>.18</td>
</tr>
</tbody>
</table>

CT=computed axial tomography, ECHO=echocardiogram, EKG=electrocardiogram, MRA=magnetic resonance angiogram, MRI=magnetic resonance imaging, ORD=Optum Research database, PPPY=per patient per year, TSC=tuberous sclerosis complex
Management of Tuberous Sclerosis Complex

the skin, kidney and urinary system disorders, depression, seizure disorders, nausea and vomiting, anxiety, sleep disturbances, and cardiac dysrhythmias. Seizures and angiomylipomas were the clinical findings most strongly associated with patients with TSC. The strongest covariate was the presence of a code indicative of an office visit. Among TSC patients, 100% had a visit compared with 90% of the control patients (with visits defined based on codes for evaluation and management). Overall, these results are consistent with clinical diagnosis criteria (Northrup 1999, Northrup 2013) and match historical data (Wataya-Kaneda 2013).

Several measures of model performance are reported: predictive probability (AUC), sensitivity, and specificity. The AUC, a measure of the overall performance of the measure, obtained in this study was similar to values obtained for other risk–score models commonly used in practice in other diseases. Notably, the Framingham (cardiovascular) risk score and several related cardiovascular risk scores have reported external validation AUCs, ranging from 0.61 to 0.88 (Bitton 2010). By comparison, the TSC model AUCs of 0.77 (internal) and 0.75 (external) fall in the same range of these scores.

The sensitivity of the model, with a chosen threshold, estimates the proportion of true positive diagnoses to all patients with TSC within the sample population. As an example, at a threshold of 80%, the validation sample produced a sensitivity value of 8.8%, indicating that the model is expected to correctly identify 8.8% of patients with TSC in this sample at this cutpoint. The specificity measure gives the proportion of true negative patients relative to all patients without TSC. This model has a specificity value of 99.4% when a threshold of 80% is used, indicating it correctly specified 99.4% of control patients as not at risk for TSC. Selecting a lower threshold value results in a higher sensitivity at the cost of a lower specificity. At a threshold level of 20%, the TSC model has sensitivity of 64.8% and specificity of 77.1%, results that are similar to the performance of the Framingham risk score at the same threshold (74.3% sensitivity and 59.4% specificity) (Brindle 2005).

We present classification statistics using a threshold of 80% to indicate that anyone with a predicted probability of 80% or greater is at higher risk of having the disease. However, owing to very low prevalence of TSC, this calculation is more complicated and requires prevalence adjustment. For example, if we apply it to a population of 100,000 people, where the prevalence of TSC is about 0.2%, this model would identify 1,893 patients as high risk; only 27 of those would be true cases (1.4%). Because this condition is so rare, adjustments required to account for the low prevalence result in small numbers of patients identified within an overall population of enrollees. It is important to note that this model is not designed to have definitive predictive value; instead, it is intended to provide a relative TSC risk score that may enable health plans to further investigate TSC as a potential diagnosis or target patients for further management. This may enable a health plan to target a set of patients with complex and expensive medical care needs for improved health care management.

Study limitations

The conclusions drawn during development and the practical utility of the model are limited by the nature and quality of the patient data. Interpretation of descriptiv results, especially regarding binary events, should be made with caution because of the varying length of postdiagnosis
Management of Tuberous Sclerosis Complex

follow-up for each patient. This study used data from ORD from patient medical claims during a specific period of time, which may or may not accurately or completely reflect the true status or symptoms of the patient. The data are also limited by the resources available to the treating physician as well as the completeness of data, which were provided on claims for billing purposes rather than clinical use.

Potential applications and value

The model developed here could potentially serve as a quality of care tool for health plan managers and accountable care organizations. Population segmentation based on health indicators can enable the arrangement of commonly needed supports and services to meet their expected needs (Lynn 2007).

With the TSC model described here, three potential segments are patients diagnosed with TSC, patients with a high risk of TSC, and patients with a low risk of TSC. These segments could be targeted for population screening initiatives that seek to keep healthy patients healthy, reduce health risk, and ensure appropriate care for the patients with TSC (Meiris 2012). Information exchange and health coaching facilitated by accountable care organizations are prime examples of how the data developed here could be applied to improving health care. An example of information exchange in TSC care is the TSC-associated neuropsychiatric disorder checklist, which is a screening questionnaire completed by the clinician in collaboration with the patient or caregiver to address the often unmet need of psychiatric care in this population (Leclezio 2015).

In general, medical care is delivered and managed acutely in-house based on physician discretion and medical guidelines. This approach is limited by the resources available to the physician or hospital and may be subject to observational bias or based on outdated information (Feuerstein 2014).

The availability of large amounts of digital patient data is a growing resource that can be used to develop disease risk models that can support health plans to improve identification of patients with diseases and to implement data-driven population management plans.

Analysis of large patient-data sets helps to develop a more comprehensive understanding of symptoms, treatments, and procedures associated with disease management. Where disease progression leads to worse outcomes, early and accurate diagnosis is crucial for optimizing patient health. Improved understanding of risk factors and treatment options for patients with TSC (or potential patients with TSC) will support health plans in improving the health of their covered populations. Once implemented, this approach and data analysis could support improved patient outcomes and quality of life and reduce patient economic burden.

More generally, this data-driven approach provides a case example of how to use available patient data to improve the ability of health insurers and others that manage care at a population level to identify patient populations that may benefit from targeted interventions.

REFERENCES


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