HEART FAILURE SHATTERS MILLIONS OF LIVES

HEART FAILURE PATIENTS: "STABLE" OR SILENTLY PROGRESSING?
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>1 MILLION HEART FAILURE HOSPITALIZATIONS OCCUR EVERY YEAR and rehospitalization continues to be an issue.

>24% OF HEART FAILURE PATIENTS DIE WITHIN 1 YEAR OF DIAGNOSIS; this increases to ~50% within 5 years.

The neurohormonal imbalance associated with chronic heart failure is a major contributing factor to the progression of the disease. Sustained overactivation of the RAAS and SNS, with dysfunction of the normal counterregulatory effects of the NPS and other compensatory mediators, lead to impairment in heart function and cardiac remodeling.

LET’S WORK TOGETHER TO CHANGE THAT

*Additional counterregulatory mediators include adrenomedullin, prostaglandin E, bradykinin, etc.*

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NPS=natriuretic peptide system; RAAS=renin-angiotensin-aldosterone system; SNS=sympathetic nervous system.

References:
Payment Does Not Come Easily When Miracles Don’t Come Cheap

By Frank Diamond

At a price of $84,000 for a 12-week regimen, Sovaldi and its recently approved corporate relative, Harvoni (fixed-dose combination of sofosbuvir and ledipasvir), will tax the capabilities of health plans with that unending question: Who pays? Or, rather: How can it be covered?

Our cover package by Contributing Editor Joseph Burns starts on page 20 by asking how or whether health plans can get a reasonable return on investment for these and other miracle drugs. Ideas abound. Peter B. Bach, MD, an attending physician at the Memorial Sloan Kettering Cancer Center, thinks that it might be possible to set rates at the cost per year of life gained.

Benjamin Isgur, director of PwC’s Health Research Institute, says that huge upfront costs could be balanced by better outcomes down the road. The $1,000 pill a patient takes today might prevent the $580,000 liver transplant later. To which the health plan might ask: Will this patient still be in our plan? But HCV past or present, would any plan want such a member?

On page 24, Joe’s coverage shifts to the considerable problem of how to treat patients with these drugs without bankrupting them. Health plans might consider linking coinsurance levels to members’ ability to pay, says F. Randy Vogenberg, PhD, RPh, a member of Managed Care’s Editorial Advisory Board. “Maybe the employer could eliminate the medication coinsurance for the employee making $15,000, and maybe the one making $150,000 has some type of coinsurance indexed to salary,” Vogenberg suggests.

This is at a time when consumers are increasing their clout. A recent study in Health Affairs mentions the pressure to cover drugs for Gaucher’s and Fabry’s diseases. The study states, “Well-organized patient advocacy groups appropriately ensure that others hear the [patients’] message that receiving the medications is a matter of life or death. And payers have chosen to accept the usually high spending required for them.” For now, anyway.

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Insurers, patients, and physicians caught in the crossfire.

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Traditional cost-sharing makes some new therapies unaffordable for many beneficiaries.

**Q&A: Jeff Goldsmith, Big-Time ACO Skeptic**
“The idea that ACOs work and multiply and somehow evolve into capitation is just a mass hallucination. It isn’t going to happen.”

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Hospitals certainly have the organizational part of the accountable care organization (ACO) going for them: access to capital, all different kinds of infrastructure, advanced IT, and often ownership or strong relationships with physician practices and other sorts of providers.

Most physician groups can’t bring that kind of know-how and organizational bona fide to the ACO experiment. Moreover, roughly 1 in every 3 of the dollars spent on health care goes to inpatient care. A hospital has direct control over that spending, so in today’s quest for value-based health care, the hospital-led ACO would have a grip on a very important lever.

If a simple head count were the metric, then today’s hospital- and physician-led ACOs are basically in a tie. According to a tally kept by Leavitt Partners, a Salt Lake City health care consulting firm, there are 257 ACOs (49%) sponsored by hospitals and 272 (51%) sponsored by physician groups.

Results from the first two years of CMS’s elite Pioneer ACO program for large provider organizations with experience taking on risk confirm the conventional wisdom that the hospital-oriented ACO may have the edge. Six of the 19 (32%) ACOs with hospital involvement have dropped out of the Pioneer program, compared with 7 of the 13 ACOs (54%) in which a physician group is the main organization.

In some cases, the demarcation between the hospital ACO and the physician ACO gets a little fuzzy. For example, 1 of the 4 second-year dropouts, the Genesys Physician Hospital Organization, describes itself as a collaboration between Genesys Health System, anchored by the 410-bed Genesys Regional Medical Center, and Genesys Physicians Group Practice.

If you looked at earned savings over the first two years of the Pioneer program, the upper echelon is dominated by hospital-led ACOs, including Montefiore Medical Center in the Bronx and Banner Health Network in Phoenix. However, some physician ACOs have also done quite well during the first two years, including the Beth Israel Deaconess Physician Organization in eastern Massachusetts and Monarch Healthcare in Orange County, Calif.

The picture is a bit more mixed in the Medicare Shared Savings Program (MSSP). Seven of the top 10 shared savings earners for the first performance year are physician group ACOs, but the top earner, by a long shot, was a hospital-based ACO, the Memorial Hermann ACO in Houston.

What it means to be a hospital or hospital system is changing. Nimble organizations are

**Pioneer ACO top 10 shared savings earners**

<table>
<thead>
<tr>
<th>Name</th>
<th>Service area</th>
<th>Combined years 1 and 2 earned shared savings (in millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Montefiore Medical Center</td>
<td>The Bronx and lower Westchester County, N.Y.</td>
<td>$27.4</td>
</tr>
<tr>
<td>Banner Health Network</td>
<td>Phoenix metropolitan area</td>
<td>$22.6</td>
</tr>
<tr>
<td>Beth Israel Deaconess Physician Organization</td>
<td>Eastern Massachusetts</td>
<td>$18.4</td>
</tr>
<tr>
<td>Monarch Healthcare</td>
<td>Orange County, Calif</td>
<td>$14.7</td>
</tr>
<tr>
<td>Steward Health Care System</td>
<td>Eastern Massachusetts</td>
<td>$12.1</td>
</tr>
<tr>
<td>Michigan Pioneer ACO</td>
<td>Southeastern Michigan</td>
<td>$10.0</td>
</tr>
<tr>
<td>Brown and Toland Physicians</td>
<td>San Francisco Bay area</td>
<td>$7.8</td>
</tr>
<tr>
<td>Bellin ThedaCare Healthcare Partners</td>
<td>Northwestern Wisconsin</td>
<td>$7.6</td>
</tr>
<tr>
<td>Partners HealthCare</td>
<td>Eastern Massachusetts</td>
<td>$7.2</td>
</tr>
<tr>
<td>Mount Auburn Cambridge</td>
<td>Independent Practice Association</td>
<td>$4.3</td>
</tr>
</tbody>
</table>

Green = Physician group
*List does not include ACOs that deferred reconciliation until the end of performance year 3.
weaning themselves off of an overdependence on revenue from inpatient care. Readmission penalties are motivating hospitals to strengthen their relationships with post-acute care providers, including skilled nursing facilities, rehab centers, and home health agencies.

Still, the ACO model — and the bolus of value-based care that it is designed to inject into American health care — does run counter to the interests of inpatient hospitals as they have been traditionally run under fee-for-service payment. Hospitals have been rewarded for filling beds and adding services. If ACOs are to have their intended effect, episodes of expensive acute care should decrease so that fewer people will need to be hospitalized.

“It is a big shift if you have been operating an inpatient facility for a long time as a revenue center and suddenly it changes into a cost center,” says Joshua Seidman, PhD, a vice president of Avalere, a health care consulting firm. Today, many hospitals are torn between fee-for-service revenues and incentives and value-based payment that is supposed to steer health care away from acuity, says Seidman: “They have one foot on the dock and the other in a canoe that is sailing away. It is really hard to be in the in-between space.”

ACOs and value-based payment don’t undermine the economics of physician groups in the same way. The ACO and the emphasis on population health, medication adherence, and care management expand the physician’s portfolio. Sure, some of the hospital ACOs may enjoy early success, but the physician groups may win out in the long run.

“If I were betting, I would bet on the physician groups,” says David Muhlestein, PhD, JD, director of research at the consulting company Leavitt Partners.

With the $19.4 million in earned shared savings, the Palm Beach ACO was top performer among the MSSP ACOs. Dana Hart, the executive director, and the medical directors, Leonard Sukienik, DO, and Theresa Goebel, DO, say the ACO has been successful because it has focused on primary care physicians and getting them in sync with the ACO and its incentives rather than following the playbook that involves hiring case managers.

“It is supposed to be about the primary care physician,” says Sukienik. “It is not supposed to be about adding more people into the mix.”

Goebel says the ACO has worked with participating physicians on creating schedules that leave openings for same-day visits. Physicians have also been coached to schedule and use the correct billing codes for wellness visits and, after their patients have been discharged from a hospital or skilled nursing facility, for transition care management.

There’s probably plenty of room in the ACO-sphere for both hospitals and physician groups to prosper, especially with hospitals morphing (some would say mushrooming) into organizations that no longer live and die by the filled bed. But Sukienik sees physician groups as being the better vehicle for the ACO. “As a hospital, they can control admissions — who comes in and out — but after a year or two, those controls don’t work as well as letting physicians do their jobs.”

Peter Wehrwein is a freelance writer in Newton, Mass.

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<tr>
<th>Name</th>
<th>Location</th>
<th>Earned shared savings, year 1 (in millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Memorial Hermann ACO</td>
<td>Houston, Texas</td>
<td>$28.3</td>
</tr>
<tr>
<td>Palm Beach ACO</td>
<td>Palm Beach, Fla</td>
<td>$19.4</td>
</tr>
<tr>
<td>Catholic Medical Partners–Accountable Care IPA*</td>
<td>Buffalo, N.Y.</td>
<td>$13.7</td>
</tr>
<tr>
<td>SEMAC (Southeast Michigan Accountable Care)</td>
<td>Dearborn, Mich.</td>
<td>$12.1</td>
</tr>
<tr>
<td>RGV (Rio Grande Valley) Accountable Care Organization</td>
<td>Donna, Texas</td>
<td>$11.9</td>
</tr>
<tr>
<td>ProHealth Accountable Care Medical Group</td>
<td>Lake Success, New York</td>
<td>$10.7</td>
</tr>
<tr>
<td>Triad Healthcare Network</td>
<td>Greensboro, N.C.</td>
<td>$10.5</td>
</tr>
<tr>
<td>Wellstar Health Network</td>
<td>Marietta, Ga.</td>
<td>$9.7</td>
</tr>
<tr>
<td>MaineHealth Accountable Care Organization</td>
<td>Portland, Maine</td>
<td>$9.4</td>
</tr>
<tr>
<td>Accountable Care Coalition of Texas</td>
<td>Houston, Texas</td>
<td>$9.4</td>
</tr>
</tbody>
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Yellow = hospital
* Has hospital partners
† Includes Moses F. Cone Memorial Hospital Operating Corporation

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Medicare Shared Savings Program, top 10 shared savings earners*

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As Goes South Dakota So Goes the Country?

Voters overwhelmingly approved an any-willing-provider law, striking a blow against narrow networks

By Richard Mark Kirkner

You won’t hear too many health care policy wonks talk about South Dakota as a bellwether, but on election day a ballot question there that would require health plans to include any qualified provider willing to accept the plan’s payments and policies got the attention of advocates for health plans, including America’s Health Insurance Plans. AHIP released a white paper about five weeks before election day making the case that any-willing-provider (AWP) laws are counterintuitive to controlling health care costs.

AWP activity picks up

But if South Dakota voters are any measure of the rest of the country, the public really, really likes AWP laws when given the choice. South Dakotans passed the measure overwhelmingly, 62% to 28%, despite the opposition of two large health care organizations and at least one major newspaper in the state.

In the snail’s paced world of AWP laws, activity in state legislatures has picked up precipitously since passage of the Affordable Care Act. Today, 27 states have AWP laws; 13, including South Dakota, apply broadly to physicians, according to the National Conference of State Legislatures (NCSL). In the past two years, three states — Alabama, West Virginia, and Utah — have tweaked their AWP laws.

In Mississippi, AWP legislation died in committee this year. AWP laws have been proposed in Pennsylvania and New Hampshire; the latter would specifically require that any willing provider be allowed to participate in any plan sold on the state insurance exchange.

Richard Cauchi, who tracks health care for NCSL, does not consider this recent activity a groundswell, but he adds, “I do think people are keeping an eye on South Dakota, and there’s no question that state legislators and legislatures do keep a focus on what’s going on in other states.”

AWP laws have been around since the early days of managed care in the 1980s. “Most interest came during the 1980s and 1990s, when states in large numbers were trying to put in what they saw as laws to control and redirect how managed care companies were working,” Cauchi says. “The Affordable Care Act has certainly revived concerns and thinking in this area, although so far it is not a policy that has swept the states or gotten everyone’s attention to enact new or broader-based state law requirements.”

Before 2012, he notes, “there was relatively little change.”

The AHIP white paper notes an uptick in interest in AWP — mostly in response to a narrowing of provider networks in existing health insurance products, most notably Medicare Advantage plans, along with health plans creating new products for public and private exchanges that have provider networks that are much narrower, and with substantially lower premiums, than pre-exchange plans.

Cauchi pinpoints where the push for AWP laws has come from historically: “the providers affected.”

Paul Ginsburg, PhD, author of the AHIP white paper on AWP and senior fellow at the Schaeffer Center for Health Policy and Economics at the University of Southern California, affirms that the public rarely, if ever, clamors for AWP regulations.

Providers push

“Any-willing-provider laws really came about in the 1980s, and it was actually at the initiative of physicians, particularly prominent physicians who stayed out of managed care networks on their own initiative, but upon seeing the growth of managed care enrollments, became concerned that they might not be able to get back in,” Ginsburg says.

The South Dakota scenario is somewhat dif-
This more recent interest may be from the specific issues of physician-owned specialty hospitals, where insurers are often reluctant to include them in their networks,” Ginsburg says.

**Vital tool**

For payers and ACOs, the ability to select providers and create narrow networks goes well beyond controlling costs; it’s also a vital tool for improving outcomes across populations, as Ginsburg explains.

“Any-willing-provider laws might be more disruptive going forward because some of these narrow-network plans are involved in more than just looking for low prices,” he says. “Now that insurers have far more sophisticated data capabilities, they’re increasingly looking at providers’ overall cost rather than just their unit prices.”

He offers as an example a surgeon who admits patients to an expensive hospital and has higher-than-average readmission and complication rates. “That means the insurers really wouldn’t want to have that surgeon, even if the surgeon’s unit prices are low,” Ginsburg says. “So in a sense, whereas any-willing-provider does not come into play if the narrow networks are just built on low prices — because basically to get into a network you have to meet the insurer’s terms and conditions — it’s really about providers whose prices are low enough but the insurers don’t want them because of their overall practice records. It becomes a quality issue, a broader efficiency issue.”

Ginsburg’s white paper also makes the case that while the trend toward narrow networks has sounded an alarm for some physicians and hospitals on the outside looking in, it also creates the potential for AWP to be even more disruptive to approaches managed care has used to constrain health spending and promote quality. The paper argues that instead of protecting consumer choice, AWP laws interfere with meeting consumer and employer demand for lower-priced plans that have less choice of provider.

For insurers, including Medicare, opening their panels to entities like physician-owned specialty hospitals encourages cream-skimming, where healthier patients are directed to the specialty hospitals while the more complicated, and costly, cases go to the traditional settings, Ginsburg notes.

“This is hurting community hospitals that thus have a less attractive patient mix,” he says. “I’m also somewhat concerned about how powerful the incentives are on those physician owners to do more surgery.”

Ginsburg warns that AWP regulations could particularly disrupt an emerging trend to structure narrow networks around a large, prominent health system, not unlike the relationship Medica and Mayo Clinic Health System forged in the summer to offer group coverage through Medica’s private health exchange.

“The plan that has a Mayo Clinic network isn’t going to want to accept providers that are really not part of the Mayo Clinic and its affiliated providers,” Ginsburg says. “In a sense, that could disrupt what people think is a promising trend of narrow networks, the fact that here’s an opportunity for a prominent provider to have a branded insurance product built around it that’s going to be able to compete for more patients.”

New AWP regulations may only be of concern in states that have a health care landscape similar to South Dakota. “I think the main force is that physician-owned specialty hospitals are a very important factor in South Dakota, and I don’t think they are in California or New York,” Ginsburg says. “I think Texas is another place where there’s a lot of this specialty hospital activity.”

**AWP legislation in the hopper**

Pending AWP bills still had some life in November in two states, but their fates remain unclear. Will there be votes this year? Will they be taken up in 2015?

- **New Hampshire.** The House passed an AWP amendment in March, but no Senate vote has been scheduled. Both houses adjourned on October 30. HB 1294 would allow all qualified providers to participate in the health exchange.

- **Pennsylvania.** HB 1622 would require health care payers to contract with any provider who agrees to accept the payer’s standard payment levels and meets and agrees to adhere to the payer’s quality standards. No vote has been scheduled, although the House returned to session after election day.

**All eyes on Texas**

Texas has an AWP law, but it only applies to general hospitals in limited regions. Health plans may be hoping that AWP advocates won’t mess with Texas the way they did with South Dakota.
Specialty medications will continue to dominate the pharmacy benefits landscape next year. “Several new breakthrough drugs — incredible medications for patients — have received recent approval and more are anticipated in 2015,” says Sharon Frazee, vice president for research and analytics at Express Scripts. “But they are coming out at incredible prices: Some come out as orphan drugs and then they tack on additional indications but they never lose the premium price they set as an orphan drug.”

New specialty agents will fuel skyrocketing specialty expenditures that are expected to reach about 25% of total prescription medicine spending. IMS Health reports that 2013 prescription drug expenditures totaled $327 billion. Expenditures are increasing between 3% and 6%.

The year will also see increases in expenditures for traditional drugs. “We’re now on the other side of the trend curve in traditional pharmacy,” says David Lassen, PharmD, chief clinical officer at Prime Therapeutics. “The 2012 and 2013 patent expirations that either reduced the rate of expenditure increases or actually reduced expenditures are now giving way to generic drug price increases that can be as high as 10%.”

Experts at three national PBMs — Frazee, Lassen, and Brian Solow, MD, chief medical officer at OptumRx — have identified several recently approved or expected-to-be-approved medications that they say could significantly affect pharmacy expenditures in 2015.

Topping the list of potential specialty blockbusters are two cholesterol fighters that will re-ignite cost increases in the fight against lipedema. They are injectable monoclonal antibodies, expected to cost $1,000 a month as chronic therapy, a stark contrast to generic statins that come at pennies a pill.

The competing drugs are evolocumab, from Amgen, and alirocumab, which is codeveloped by Sanofi and Regeneron. Food and Drug Administration approval of both is expected to occur around next June, although alirocumab may be delayed by a patent-infringement suit against Sanofi and Regeneron by Amgen.

The two agents offer a new mechanism of action by targeting a gene called PCSK9, which prevents the liver from discharging cholesterol. “Nearly 71 million people have high cholesterol, and about 11 million of them are not well controlled with existing statins,” says Solow. Reports about the market for these new lipid agents say it may reach $10 billion. The initial FDA approval of these agents is likely to be for treatment of familial hypercholesterolemia, but experts expect their use to expand significantly.

In 2015, health plans and PBMs will try to use competition among hepatitis C (HCV) medications to control costs. In 2014, the cost of a course of therapy was as high as $160,000 for one regimen involving sofosbuvir (Sovaldi) plus a second agent.

In September, Harvoni, a new combination agent also from Gilead Sciences, was approved. It increases patient convenience by combining Sovaldi with ledipasvir in a single pill. Harvoni was initially priced at $1,125 per pill, thus reducing the cost of therapy slightly to $94,500 for a 12-week course. Approximately 45% of patients are eligible for an eight-week course of Harvoni costing $63,000.

New entries

Health plans and PBMs are anxiously awaiting the approval of another HCV drug, this one from Abbvie and still unnamed. This candidate is a combination of antiviral agents: ombitasvir, dasabuvir, ABT-450, and ritonavir. The three-pill regimen requires patients to take two in the morning and one in the evening. That is less convenient than the Harvoni regimen, but
health plans and PBMs are hoping to gain some leverage and the opportunity to negotiate prices and rebates for a lower total cost of treatment.

The FDA also has approved pembrolizumab (Keytruda) for melanoma as a breakthrough therapy and orphan drug. It is intended for use after treatment with ipilimumab (Yervoy), a type of immunotherapy, and a BRAF inhibitor if the patient is BRAF V600 mutation-positive.

Keytruda’s efficacy was established in an open-label, dose-comparative clinical trial with 173 patients with advanced melanoma whose disease progressed after earlier treatment. Of patients who received the recommended dose of 2 mg/kg, approximately 24% saw their tumors shrink; responses lasted 1.4 to 8.5 months. This therapy will cost about $12,500 a month for the average U.S. patient and is expected to generate $1.5 billion in sales in 2017.

In October, the FDA rushed approval of two novel products for idiopathic pulmonary fibrosis. Pirfenidone (Esbriet) from Intermune and nintedanib (Ofev) from Boehringer Ingelheim will each cost approximately $100,000 per patient per year (PPPY).

The FDA granted both agents fast-track priority review, orphan product, and breakthrough designations based on their ability to reduce the production of fibroblasts involved in the formation of hard fibrous tissue.

In October, the FDA announced a priority review for palbociclib as a first-line treatment for two types of cancer: estrogen receptor-positive (ER+) and human epidermal growth factor receptor 2-negative (HER2−) breast cancers. The experimental agent inhibits two signaling pathways that stimulate tumor growth. It is taken with letrozole (Femara).

One of the most expensive of the expected drugs targets cystic fibrosis (CF). Lumacaftor is a novel molecular corrector of the cystic fibrosis transmembrane conductance regulator (CFTR). In two global trials, lumacaftor, in combination with ivacaftor (Kalydeco), another Vertex drug, achieved statistically improved lung function. Lumacaftor may correct the underlying cause of disease for 50% of CF patients in the United States, but at a PPPY cost of more than $300,000.

Another highly anticipated drug is a monoclonal antibody for plaque psoriasis. Secukinumab by Novartis has a novel mechanism of action targeting the interleukin-17A messenger protein that is linked to the development of plaque psoriasis. It showed significant skin clearance at 12 weeks that lasted through 52 weeks with continued treatment. There are a number of anti-inflammatory agents for plaque psoriasis, yet there is still a market opportunity for new entrants in this class. The National Psoriasis Foundation reports that 52% of the 7.5 million psoriasis patients are dissatisfied with how their disease is being managed.

All three PBM experts say that in 2015, antidiabetic medications will continue to be the leading driver of cost increases in traditional pharmacy. New agents such as empagliflozin (Jardiance, a SGLT2 inhibitor from Boehringer Ingelheim), combination pills, and injection pens contribute to rising expenditures.

**Opportunities in diabetes**

The antidiabetic medications are the most expensive traditional therapy class. Express Scripts says that per-member expenditures in 2013 were $84. Utilization increased 2.4% and unit costs increased 11.6% — the largest increase for any therapy class. The total 2013 increase was 14%. Prime Therapeutics reported an 11% price increase for antidiabetic agents.

The pipeline continues to spit out antidiabetic drugs, but those generated so far have not added much clinical value. “Some of the existing classes, such as the GLP-1s, are evolving with additional medications, but in many instances those new medications are not correlating with better outcomes,” says Lassen.

The GLP-1s are evolving from twice-daily to once-daily and once-weekly formulations. Lassen says Prime Therapeutics is working with its owner, a group of Blue Cross/Blue Shield companies, to track the performance of the antidiabetic drugs and to review opportunities that may be available for formulary and benefit designs that might help to control costs without compromising patient convenience or clinical results.

“The next generation of basal insulins may offer improved clinical benefit over the current leading insulins,” says Express Scripts’ Frazee. “If late-stage trials confirm improved patient benefit, these products could become the standard of care.”
Variety of Cost-Cutting Tools Used for Specialty Medications

Location, location, location should be the mantra of those trying to figure out a way to lower the costs of specialty medications. A study in the October issue of Health Affairs says that a small group of specialty drugs could make up about half of total pharmacy spending by 2018.

“These medications are no longer only for patients with life-threatening conditions. Patients across the spectrum of disease severity are receiving specialty medications,” says the study, “Specialty Medications: Traditional and Novel Tools Can Address Rising Spending on These Costly Drugs.”

But there are plenty of obstacles to containing costs. For instance, “The economic incentive for physicians to administer more medications and select the higher cost option remains intact.”

In addition, generics have traditionally put a brake on the cost of medications. However, legislation allowing for generics “does not apply to biologics, which are the most costly subset of specialty pharmaceuticals.” Biosimilars are not generic versions of other biotech drugs.

So how to manage? “The fees paid to providers using the buy-and-bill method vary significantly by the site of care. In most instances, the highest-cost site of drug administration is the hospital outpatient center.”

Drugs administered there can cost up to 50% more than when administered in a doctor’s office or patient’s home.

“This discrepancy has led many payers and pharmacy benefit managers to develop programs that limit the use of hospital outpatient centers for infusions,” the study states. “However, hospitals’ acquisition of specialist physician practices has made it difficult for payers to transition patients to community providers.”

Pharmacy benefit managers and insurers focus more on patient self-injection and nurse-assisted home infusion “for a limited spectrum of clinically appropriate agents.”

There is no magic bullet, but help is on the way, say researchers. “The introduction of meaningful specialty generics and the subsequent introduction of the first biosimilars during the remainder of the 2010s should provide new opportunities for the application of traditional pharmacy tools such as tiered formularies and step therapy.”

Patients Value ACO Experience

Finally, some good news for accountable care organizations (ACOs). Medicare beneficiaries being served by the two government-sponsored ACO projects report having better access to care and their medical records, and they also feel that their care is being better coordinated, according to a study in the New England Journal of Medicine.

This comes as health plans abandon the Pioneer ACO program. There were 32 participating plans at the start; now there are 19. Using a sort of global capitation model, ACOs take on risk for managing the care of patients, but the question has always been whether provider organizations have the capability to do this.

“The ACO program is just too complex — there are too many quality metrics to track, and the incentives aren’t strong enough,” Chas Roades, chief research officer at the Advisory Board consulting company, tells the Wall Street Journal.

The Pioneer Program and the Medicare Shared Savings Program serve about 5.6 million beneficiaries.

The NEJM study compares about 32,000 fee-for-service Medicare beneficiaries served by ACOs with about 250,000 beneficiaries served by other providers.

“As compared with local control groups of patients served by non-ACO providers, patients served by ACOs reported improvements in domains more easily affected by organizations (access to care and care coordination) but not in domains in which changes in physicians’ interpersonal skills may be required to achieve gains (interactions with physicians and physician ratings),” the study states.

“In addition, medically complex patients, who were more likely to be the focus of ACO efforts to control utilization and enhance quality, reported significantly better overall care after the start of ACO contracts.”

There are some important implications here, say researchers. “Enhanced experiences by patients may encourage their loyalty to ACOs, potentially addressing some of the care fragmentation and instability in beneficiary assignment that diminish incentives and rewards for ACOs,” the study states. “Moreover, should preliminary evidence of savings generated by ACOs be confirmed, our findings would indicate that ACOs may be able to achieve savings in ways that do not adversely affect patients’ experiences.”

Ports Might Help Reduce Infection

The costs of care for children battling cancer who get central line-associated bloodstream infections (CLABSiS) are growing fast, according to a study in the American Journal of Infection Control.
NEWS & COMMENTARY

Such infections can add about 21 days to a hospital stay and $70,000 in cost. Researchers examined about 1,560 inpatient admissions for 291 children with cancer between January 2008 and May 2011. They divided the children into two groups: those with CLABSIs and those without.

They note that “Very little has been written about the attributable cost of CLABSIs in pediatric patients with malignancies commonly seen in a hematology/oncology practice” and hope that the study’s findings “may inform decisions regarding the value of investing in efforts to prevent CLABSIs in this vulnerable population.”

The study states that patients who have a port installed stand a better chance of avoiding infection. “Patients receiving short-term therapy with a need for frequent central access will likely use [tunneled catheters], which are technically easier to place and do not require an additional trip to the operating room for removal,” the study states. “Those patients anticipated to require long-term therapy and/or infrequent need for central access will likely receive a port-type device because of decreased infection risk over time.”

Briefly noted
Former U.S. Rep. Pete Stark, whose Stark Law tried to keep doctors from profiting from referrals, tells the Wall Street Journal that his law has been watered down with amendments in the two decades since it passed. “Pretty soon, the law got to be as thick as a phone book for all the exemptions for this, that, and the other thing.” Other than that, he says he’s enjoying his retirement. ... Physicians seem to be less wary of electronic health record systems, according to a survey by Medical Economics. The survey finds that 55% of doctors are very satisfied with their EHR systems and 54% think that the technology helps them save money. ... Can employers force workers to get biometric testing as part of a wellness program? The Equal Employment Opportunity Commission says that Honeywell is violating the Americans with Disabilities Act and the Genetic Information Non-Discrimination Act by doing so. EEOC says the Honeywell wellness program’s provisions are not related to jobs. Honeywell won the first court skirmish. — Frank Diamond

Preparing for the good and bad of ICD-10

The coming of ICD-10 stirs up both hope and wariness among the medical industry’s stakeholders, according to a survey by the health information company Edifecs. Implementation is scheduled to take place next year. But even if it’s delayed again, it can’t be delayed forever. This is a crucial event for providers, who are struggling to switch over to the new payment system, and for health insurers, who depend on the codes to guide billing. The number of diagnostic codes will jump from 13,000 to 68,000, while the number of inpatient procedure codes will grow from 11,000 to 87,000. Edifecs asked 349 respondents, including payers, vendors, physician practices, and hospitals, how they plan to use the data and what tasks they think ICD-10 might make more difficult to perform.

How organizations plan to use ICD-10 data

<table>
<thead>
<tr>
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<td>Detection of fraud and abuse</td>
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These activities will be harder to do once ICD-10 compliance begins

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<tr>
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</tr>
<tr>
<td>Manage risk</td>
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</table>

Source: Edifecs
The number of deaths caused by cervical cancer remained stubbornly stable from 2007 to 2011. Millions of women do not use simple screening procedures, according to the Centers for Disease Control and Prevention. About 8 million women between 21 and 65 in 2012 hadn’t had a Pap smear in five years, and only 1 in 3 girls and 1 in 7 boys get the three-dose HPV vaccine for children ages 11–12. Current guidelines say that women over 21 should get a Pap smear every three years. More than 12,000 American women get cervical cancer each year, and about 4,000 die from the disease. “Up to 93% of cervical cancers are preventable,” the CDC says in its report, “Vital Signs” (http://tinyurl.com/CDC-cervical).

The percentage of women screened decreased slightly from 2008 and 2010, and the percentage of women not being screened is higher for those without a health care provider and insurance, but that’s not the total problem. “About 7 in 10 women who have not been screened in the last five years have a regular doctor and had health insurance,” according to the report. About 50% of all new cervical cancers are found in women who have not been screened in the previous five years.

**The Affordable Care Act (ACA):**
- Ensures that most health plans cover cervical cancer screening at no cost to the patient
- Ensures that most health plans cover HPV vaccination at no cost to patients who are in recommended age groups

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**LETTER TO THE EDITOR**

The American Academy of Urgent Care Medicine read with interest the article “Urgent Care Finds Its Place In the Age of ACOs” [November]. While we agree that urgent care centers provide care in “the most appropriate and lowest-cost setting,” we are concerned about the statement “Urgent care is essentially a doc-in-a-box concept.” The term “doc in a box” was initially used when urgent care centers first entered the health care market and consumers were unfamiliar with this new concept of care. However, the urgent care community has striven to leave the term in the past as it has a negative connotation, implying that the care provided at an urgent care center is substandard and inferior to that provided in the emergency department or by a family practitioner. The public has learned that urgent care is a good choice for quality care and patients are increasingly utilizing urgent care clinics for their immediate health care needs. To continue to educate the public that urgent care is a safe, economical source for first-rate health care, we must leave the term “doc in a box” in the past. — Franz Ritucci, President, American Academy of Urgent Care Medicine

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**SNAPSHOT**

**Decline in cervical cancer death rate ends**

The American Academy of Urgent Care Medicine read with interest the article “Urgent Care Finds Its Place In the Age of ACOs” [November]. While we agree that urgent care centers provide care in “the most appropriate and lowest-cost setting,” we are concerned about the statement “Urgent care is essentially a doc-in-a-box concept.” The term “doc in a box” was initially used when urgent care centers first entered the health care market and consumers were unfamiliar with this new concept of care. However, the urgent care community has striven to leave the term in the past as it has a negative connotation, implying that the care provided at an urgent care center is substandard and inferior to that provided in the emergency department or by a family practitioner. The public has learned that urgent care is a good choice for quality care and patients are increasingly utilizing urgent care clinics for their immediate health care needs. To continue to educate the public that urgent care is a safe, economical source for first-rate health care, we must leave the term “doc in a box” in the past. — Franz Ritucci, President, American Academy of Urgent Care Medicine

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**Death rate today is 40% of rate in 1975**

Source: National Cancer Institute, 2014
Here’s a question it seems everyone wants to answer: Will high-cost medications bust the budget or provide a return on investment?

On one side, we have the conventional wisdom among most health plans and their lobbying group saying that the price of some medications is astronomical and unsustainable and will certainly push health plan budgets into the red well before payers realize any return on their investment in these medications.

On the other side, we have the potential for substantial long-term savings from at least one high-cost medication, Sovaldi, according to a report earlier this year from the Health Research Institute at the consulting firm PricewaterhouseCoopers.

Indeed, it’s a difficult and pressing question, because spending on specialty medications is expected to rise from $87 billion in 2012 to $402 billion in 2020, according to a report in June from PwC, “Medical Cost Trend: Behind the Numbers 2015.” The numbers were based on an analysis of data from CVS Caremark.

In part because Sovaldi has a 90% rate for curing the liver virus that causes hepatitis C, the report says that Sovaldi (sofosbuvir) has a strong potential to deliver long-term savings.

But for health plans, the $84,000 cost of this antiviral (at $1,000 per day for 12 weeks) is astronomical and unsustainable, according to the lobbying group America’s Health Insurance Plans (http://bit.ly/1yrBabI).

Another factor driving up costs is inappropriate use of drugs for hepatitis C, says Brenda Motheral, RPh, MBA, PhD, president of Artemetrx, a specialty drug management consultant. “Our research of nearly 1,000 Sovaldi users found significant off-label use, overuse, and premature discontinuation of the drug or drug regimen, and an average waste of $33,000 per patient treated with Sovaldi,” she adds.

Express Scripts estimated, in a report on specialty medication in July, that states could spend $55 billion on Sovaldi if they treat the estimated 750,000 Medicaid patients and state prisoners who

### Sovaldi tier placement

Percent of plans. In categories with coverage, some plans may employ prior authorization and/or step therapy.

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Source: Managed Markets Insight & Technology, LLC database as of November 2014.
have hepatitis C. The pharmacy benefit manager expects U.S. health care purchasers to spend 18 times as much on hepatitis C medications in 2016 as they did in 2013, according to the company’s 2013 Drug Trend Report. “No major therapy class has experienced this high of a spending increase in the 21 years we’ve measured drug trend data,” the report said.

Next generation

In October, Gilead announced that Harvoni (ledipasvir and sofosbuvir), its next-generation treatment for hepatitis C, would cost $94,500 for a 12-week course. The cost of medications for cancer patients also has risen sharply, according to the global oncology trend report “Innovation in Cancer Care and Implications for Health Systems” from the IMS Institute for Healthcare Informatics.

When costs rise, health insurers react as consumers do: They begin asking what they’re getting for their money. As if to answer this question, PwC’s researchers suggested that while new high-cost therapies are driving up spending, it’s important to look at the potential to produce long-term savings. “Compare the average $84,000 for a course of the new therapy to medical costs for treating those with varying severity of liver disease,” the researchers wrote. “For instance, patients with no scarring of the liver can incur average annual costs of $17,000. Patients with compensated cirrhosis, a scarred but functional liver, can incur $270,000 in treatment over a decade. At the most severe side of the spectrum, patients who require a liver transplant could expect to be billed an average of $580,000.” PwC did the report independently and not at Gilead’s request, PwC said.

The researchers did not state that Sovaldi would provide an actual return on an insurer’s investment, but they did clearly suggest that the potential exists. It’s important to note that the cost of Sovaldi will be high in the next few years, says HRI Director Benjamin Isgur. “But our analysis also shows that while there are a lot of costs on the front end, the spending curve declines for high-cost medications because of their potency, says Benjamin Isgur, left, and Jim Prutow of PwC. As people are cured, fewer patients need to be on the therapy.

Rosy future for hepatitis C patients — and for payers

The use of new hepatitis C therapies will increase rapidly, but the greatest financial effect is likely to be in the early years. The highest cumulative effect on benefit costs for employer plans is 2015–2016. The trend quickly turns downward as patients are cured. Percentage change in employers’ costs:
those costs decline over the outer years as these treatments get into the population.”

Jim Prutow, a principal in PwC who contributed to the Sovaldi analysis, adds that “When you do the cost-benefit analysis, you can look at it as a profit-and-loss issue since you are making an investment in a therapeutic. Also, you can produce a cure, which means you will be preventing costs that result from an acute episode or a liver transplant. That’s why the spending curve declines. As you cure people, you have fewer patients who need to be on this therapy and you may have fewer new infections too.”

The PwC analysis was based on the 78,000 to 82,000 patients with hepatitis C who have employer-sponsored health insurance. An analysis of the unemployed, Medicaid patients, or those in prison might show a much different cost curve, Isgur and Prutow add.

Medicaid Health Plans of America (MHPA), an association representing these insurers, says that while the minimum treatment time for Sovaldi is 12 weeks, it could be 24 or even 48 weeks, depending on a patient’s viral load and treatment response. Also, the $84,000 figure is only part of the total treatment costs because Sovaldi is taken with other drugs for hepatitis C. For state Medicaid directors, Sovaldi complicates their spending plans because the FDA approved the medication in December 2013, after states set their capitated Medicaid budgets for this year, MHPA said.

“This unanticipated cost could put health plans at severe financial risk, since their capitated rates would not be actuarially sound as is required by federal law. This will potentially compromise the ability of health plans to provide access to other life-saving services and medications for Medicaid enrollees suffering from other diseases,” MHPA says. Health plans and state Medicaid programs will face a significant challenge in trying to manage the cost of Sovaldi and other high-cost medications, the association adds.

**Putting a price on quality of life**

While ROI is one way to evaluate a medication’s performance, another way is to analyze its effect on quality of life. For an analysis published in *Health Affairs* in October, researchers at Tufts University’s Center for the Evaluation of Value and Risk in Health (CEVR) calculated the quality-adjusted life-years (QALYs) that patients could expect from specialty drugs. To estimate the value of specialty drugs versus traditional medications, they reviewed published estimates of QALY’s for 58 specialty drugs and 44 traditional drugs the FDA approved from 1999 through 2011. Specialty drugs and traditional drugs were associated with median additional costs of $12,238 and $784, respectively, and mean incremental costs of $72,917 and $3,237, respectively, they reported in an article, “Despite High Costs, Specialty Drugs May Offer Value for Money Comparable to That of Traditional Drugs.” But also they found improvements in quality-adjusted life years as well: 0.183 QALYs for specialty medications in the first group compared with 0.002 QALYs for the group of traditional drugs.

“Our study suggests that although specialty drugs often have higher costs than traditional drugs, they...
also tend to confer greater benefits and hence may still offer reasonable value for money,” the CEVR researchers wrote. CEVR does custom research for government agencies, private foundations, and industry groups and says it maintains research independence and freedom to publish.

Peter B. Bach, MD, an oncologist, has suggested a similar approach to pricing cancer medications. An attending physician at the Memorial Sloan Kettering Cancer Center and director of its Center for Health Policy and Outcomes, Bach wrote an article, “Indication-Specific Pricing for Cancer Drugs,” published in the Oct. 22/29 issue of the Journal of the American Medical Association. In it, he said that drug prices are not usually linked to value.

Last year, the FDA approved eight new cancer medications, and the per-month cost of these medications for Medicare and Medicaid patients was $7,000 to $32,000, he wrote. While some of these drugs helped extend patients’ lives by six months, others extended lives not at all.

**Linking price to indication**

It might be possible to set payment rates at the cost per year of life gained, he suggested. A number of organizations are working to link price to benefits, an effort Bach says will be challenging.

In September, Bach’s colleague, Leonard Saltz, MD, chief of Memorial Sloan Kettering’s gastrointestinal oncology service and head of its colorectal oncology section, was featured on the CBS news program 60 Minutes explaining the cancer center’s approach to evaluating the cost and benefit of medications.

For now there is no easy answer to the question of whether specialty medications provide a return on investment. Instead, health systems and health insurers will be evaluating the costs and benefits over time while trying to avoid what MHPA calls the severe financial risk of paying for a rising number of high-cost drugs.

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- Injectafer® (ferric carboxymaltose injection)
- INVOKAMET™ (canagliflozin and metformin HCl tablets)
- INVOKANA™ (canagliflozin)
- JAKAFI® (ruxolitinib)
- PLEGRIDY™ (peginterferon beta-1a)
- Quillivant XR™ (methylphenidate HCl) for extended-release oral suspension, CII
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Health Plans, Patients Struggle To Pay for High-Cost Drugs

Beneficiaries and physicians can be surprised and dismayed to find that in some drug classes in some plans, there is no preferred agent at all.

By Joseph Burns
Contributing Editor

Health plans appear to be using 20th century strategies to solve a 21st century problem. Faced with rising costs from specialty medications, health plans are using the same model of payment that pharmacy benefit management companies developed in the late 1980s and early 1990s, says F. Randy Vogenberg, PhD, RPh, co-leader of the National Employer Initiative on Biologic & Specialty Drugs, a partner in Access Market Intelligence, and principal in the Institute for Integrated Healthcare.

This outdated method of pricing and evaluation is inefficient in a market where spending on specialty medications is rising faster than spending on traditional therapies, he adds. Specialty drugs accounted for 25% of all pharmacy spending this year and will account for more than half of all costs by 2019, said Express Scripts in a report, “A Shifted National Focus Toward Specialty Meds.”

By staying with many of the same cost-sharing mechanisms they used 30 years ago, health plans and PBMs have shifted more costs to patients, causing some patients to stop taking their medications because they’re too costly, Vogenberg says. What’s more, health plans and PBMs use the same strategies for all medications — whether they are high-priced specialty medications or lower-cost generics, he adds. Those strategies include shifting costs to patients and placing medications on tiers designed to limit the use of the most expensive medications.

The problem with this approach is that by adding more tiers health plans have confused employees and made some medications more expensive — the antithesis of a value-based strategy. They also have retained cost-sharing mechanisms that make high-priced drugs unaffordable for many patients, Vogenberg says. A 25% copayment on a drug priced at $1,000 a day costs a patient $1,750 each week or more than $7,000 per month. Many patients simply cannot afford their medications, even though commercial plan members often use copayment assistance programs from pharmaceutical manufacturers and can avoid such high cost-sharing amounts, says Brenda Motheral, RPh, MBA, PhD, president of Artemetrx, a specialty drug management consultant.

The Center for Value-Based Insurance Design (VBID) at the University of Michigan reports that until 2002, most people with employer-sponsored insurance that included prescription drug coverage were in plans with one or two formulary tiers. As of last year, nearly 25% of insured people were in plans with four or five tiers, and the highest two tiers typically were devoted to specialty medications.

Antiquated benefit design

Increasing the number of tiers is one of the few changes that PBMs have made since the 1980s and 1990s, Vogenberg says. “When health plans started managing pharmacy costs, they had a simple tiering system — one for generics and another for brand-name drugs,” he notes. “That went on for years until just recently, when health plans went to three, four, five, and even six tiers, with little consideration for why we need so many tiers. We never progressed, even though we’ve added more bells and whistles.

“What are PBMs trying to accomplish with so many tiers?” he asks. “Placing higher-cost medications on higher tiers does not accomplish what health plans intend, which is to have consumers consider the cost of medications before buying them. Instead, if consumers find high costs to be unaffordable, they may discontinue taking their medications.
Do plans discriminate against high-cost patients?

 inexplicably, some health plans have structured their pharmacy cost-sharing arrangements to discourage patients from getting the medications they need, according to a September 17 article in the New York Times, “How Insurers Are Finding Ways to Shift Costs to the Sick.” Some consumer advocates suggest that these cost-sharing arrangements are so onerous that they may be discriminating against patients with certain chronic conditions, the article said.

In an article on the same topic in the American Journal of Managed Care, A. Mark Fendrick, MD, director of the Center for Value-Based Insurance Design at the University of Michigan, and Gerry Oster, PhD, a health care consultant in Boston, reported that some health plans are instituting high copayments for generic drugs and designating some generics as nonpreferred — even medications that insurers want physicians to prescribe as the preferred medication under evidence-based guidelines.

“Nonpreferred disease”

“For some diseases, in fact, many insurers have no preferred generic medicines, effectively rendering the diseases themselves ‘nonpreferred,’” Fendrick and Oster wrote. “Designation of clinically important generic medicines as ‘nonpreferred’ without ensuring that patients have access to therapeutically equivalent ‘preferred’ drugs runs counter to established principles of formulary design, may increase other health care costs, and ultimately may undermine emerging payment reform initiatives.”

Consider how such a designation would affect metformin, a first-line therapy on every guideline internationally for diabetes, Fendrick says. “Even though it’s recommended, some plans do not include it as a preferred drug,” Fendrick told Managed Care. “Instead, some health plans put it on the high-cost generic tier.

“Or look at what some plans do with medications for patients with HIV. Some plans have no preferred drugs for HIV, which leads some people to raise the specter of discrimination,” he says.

“Before doing this research, I didn’t know that a nonpreferred tier existed while at the same time there was nothing in the preferred branded tier for some patients,” Fendrick says. “By creating preferred and not-preferred generic tiers, insurers are putting lower-priced drugs in the lower tiers, and expensive generics in the expensive tiers, but with no thought about how preferred drugs are prescribed based on evidence or guidelines for certain conditions.”

It’s likely that health plans are doing so simply to reduce the use of high-cost generic medications, he adds. “Whatever the reason, it clearly flies in the face of the idea of moving to a quality-based health care system,” Fendrick says.

As a practicing physician, Fendrick is asked to ensure that he prescribes recommended medications for patients with certain chronic conditions and to ensure that his patients take these medications, he notes. Those directives come from the medical directors of the health plans that pay him to care for their patients, he adds. Yet the pharmacy directors of these same health plans are establishing cost-sharing mechanisms that conflict with what medical directors do, he says.

“Clinicians in medical homes or accountable care organizations are being benchmarked on the quality of care we provide to patients with chronic conditions.”

Placing financial barriers of any significance in front of consumers with those same conditions flies directly in the face of our movement from volume to value. In other words, doctors should be really upset when they see that a health plan is actually working in the exact opposite direction of this multi-billion-dollar move to make them accountable for what they do,” he says.

Patient advocacy groups have filed a complaint with the Office of Civil Rights of the federal Department of Health and Human Services, claiming that health plans sold in Florida discriminated against HIV patients, the New York Times reported. The complaint alleged that the plans put generic and other medications for HIV patients on the highest tier, which requires a 40% copayment.

“With truly high-cost drugs, which are the biologics and specialty products, the multiple-tier approaches don’t work,” he asserts. “As consumers become more sensitive to rising costs, they are beginning to question the value of paying much more for needed medications. And health plans and PBMs don’t have an answer because they haven’t done anything to address the problem of copayments that many consumers can’t afford.

“What choices do consumers have?” Vogenberg
asks. "They can choose not to take the drugs prescribed for them, and increasingly they are doing so."

Nonadherence already is a significant problem throughout the health care system and is counter to the goals health plans set for patients, Vogenberg says.

An analysis of health insurers’ formularies in 123 health plans offered on the federal marketplaces by the consulting firm Avalere found that many of the plans required copayments of 10% to 40% for 19 classes of medications for patients with chronic conditions. More than 60% of silver plans put all covered medications for patients with multiple sclerosis, rheumatoid arthritis, Crohn’s disease, and certain cancers in the highest formulary tier.

For patients with HIV/AIDS, 25% to 35% of plans put all covered medications on the highest tier. One in five silver plans required copayments or deductibles of 40% or more for drugs in 7 of the 19 classes, Avalere reports. For 10 of the 19 classes, 1 in 5 silver plans required coinsurance of 30% or more.

In addition to what members pay for coinsurance for pharmacy benefits, they might also have to pay higher amounts than they paid in the past because they have high-deductible health plans, Vogenberg points out. “Some health plans include pharmacy benefits, but some don’t. If they don’t, those members might have two different copayments and deductibles to meet each year, which could greatly increase their out-of-pocket costs,” he says.

Indexing copayments to income

Perhaps it’s time to eliminate coinsurance, as Pitney Bowes did years ago, on copayments for certain medications to ensure that patients, particularly those with chronic conditions, can afford the drugs they need, Vogenberg suggests. Health plans also might link coinsurance levels to members’ ability to pay, he says.

“If an employer has an employee making $15,000 a year and one making $150,000 a year, the ability to afford prescription medications is completely different. So maybe the employer could eliminate the medication coinsurance for the employee making $15,000, and maybe the one making $150,000 has some type of coinsurance indexed to salary,” he says.

Vogenberg is not alone in suggesting that copayments and deductibles should be much lower or eliminated for patients who need medications for chronic and costly conditions. Reducing coinsurance for some medications is a hallmark of VBID, which A. Mark Fendrick, MD, the director of the Center for VBID has advocated for more than 10 years.

The average coinsurance for specialty medications is 30%, and some health plans set it as high as 50%, according to “Supporting Consumer Access to Specialty Medications Through Value-Based Insurance Design,” by the Center for VBID and the National Pharmaceutical Council. “Increased consumer cost-sharing may trigger cost-related nonadherence ... leading to more complicated and expensive medical interventions and correspondingly adverse results for payers,” the report says.

The report describes specialty pharmaceuticals as medications that consist of complex molecules, have qualities that result in costly delivery, or carry high costs, such as $600 or more per month.

Fendrick recommends that insurers designate guideline-recommended therapies as nonpreferred only when the formulary also lists preferred and therapeutically equivalent medications. Preferred medications should be priced lower or should have no copayment, while copayments for nonpreferred medications should be set higher, he adds.

Motheral suggests health plans coordinate the management of pharmacy and medical benefits instead of managing each one separately. “Some strategies might be similar to traditional drug management while others might require new ways of thinking and greater understanding of the medical benefit,” she adds.

Also, pharmacy benefit managers should accept some of the risk of keeping patients healthy, says Vogenberg. "What is the value proposition of PBMs?" he asks. "It has to go well beyond distributing drugs and processing claims, because today everything relates to reducing population health risk. PBMs are not at risk for keeping patients healthy because they’re basically being paid under a fee-for-service model. That’s contrary to where the market is moving. So PBMs will have to change and their value proposition will need to change as well."
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Health care reform and a long list of surprising market shifts have created clear opportunities for health plans to improve their bottom lines. Increases in Medicare Advantage enrollment, evolving physician networks, providers’ willingness to negotiate discounts, and a growing individual market are just some of the places to look, says Jeff Goldsmith, PhD, president of Health Futures, a consulting firm, and associate professor of public health sciences at the University of Virginia.

But the insurers that ultimately come out on top will be the ones that figure out how to take better care of members, finding new and more sophisticated ways to define and address risks, he says. “The highest and best use of managed care is what you do inside populations with large amounts of avoidable illness represented.”

Goldsmith has been studying the health care market and identifying trends for 40 years. He has been national adviser for health care at Ernst & Young, director of planning and government affairs at the University of Chicago Medical Center, and a fiscal and policy analyst for the governor of Illinois.

Goldsmith is the author of four books and many articles. He lectures on a range of health care topics at the Wharton School of Finance and the University of Virginia. He is frequently quoted in the press and serves on the editorial boards of Health Affairs and Managed Care. Goldsmith earned a bachelor’s degree from Reed College and a doctorate in sociology at the University of Chicago. He spoke recently with Managed Care Editor John Marcille.

**Managed Care:** What will the new composition of Congress mean for the Affordable Care Act?

**Jeff Goldsmith, PhD:** For all of the huffing and puffing, the ACA is going to remain largely intact, and that isn’t just because the Republicans don’t have enough votes to kill ACA. Plus it would be suicidal politics to take coverage away from 10 million people. But Republicans could certainly do a lot of damage to the law. The Independent Payment Advisory Board and the Patient-Centered Outcomes Research Institute are unloved and imperiled pieces of the ACA. The medical device excise tax and the Prevention and Public Health Fund are also vulnerable, as is the CMS Innovation Center. The Supreme Court is actually a much bigger threat than a Republican Congress.

**MC:** It’s not a popular law overall.

**Goldsmith:** My daughter Amelia is an ACA navigator in Virginia and has spent the last 15 months signing people up for health insurance. She says everyone has a strong opinion about the law but almost no one knows what’s actually in it for them. The administration committed so much political capital to making the ACA happen that when they finally got the bill signed, they basically said,
“We’ve got to pivot to the economy right now and didn’t bother to explain to people what was in their own bill. They permitted the opponents of this law to define it.” Even people who are massively helped by the ACA have a negative opinion of it.

**MC:** How did insurers make out under reform? Was it net positive?

**Goldsmith:** This is turning out a lot better than many people expected. For the previous decade, fully insured lives for our commercial insurance sector were going down by 1 million a year. Anything that produced new commercial customers for these companies had to be positive. However, other public policy changes have helped the industry as much as the ACA has. The significant growth in Medicaid managed care and in Medicare Advantage has made a more significant contribution dollarwise.

**MC:** And that is in spite of the ACA rate controls and MA cuts?

**Goldsmith:** The Congressional Budget Office forecast that the changes in Medicare Advantage rates embodied in the ACA were going to take Medicare Advantage enrollment down as low as 6 million. It is now 16 million, 30% of the program. MA is the future of Medicare.

**MC:** And Medicaid enrollment has grown.

**Goldsmith:** The sharp lurch of Medicaid enrollment toward private health plans is something that was going on before the ACA was enacted. It was a response to governors around the country needing to do something about their Medicaid spending even before the recession. But the increased involvement of private insurers in these two public programs markedly increases the cyclical risk to the industry. In other words, when we have another recession, the capitation rates that states are paying to health plans to manage Medicaid lives are going to be reduced. It’s inevitable.

**MC:** How will that affect beneficiaries? Is quality of care going to decline?

**Goldsmith:** The rate reductions will pinch, but quality has been rising. Anything that can be done to better organize how care is provided to these two large government-funded populations can only help beneficiaries. The only way you are going to be able to sustain Medicare and Medicaid long term is to identify the pockets of health risk within those populations and to do something proactively to address them, and to control episode costs better when people do get sick.

**MC:** Are you seeing evidence of that?

**Goldsmith:** It is why I thought decisions like WellPoint’s to acquire CareMore or DaVita to acquire HealthCare Partners were important. These were incredibly sophisticated managed care organizations that focused a lot of energy on sick populations and that also had significant public enrollment. The intellectual property in organizations like that is going to be incredibly valuable long term, even if there are challenges in scaling the organizations up.

In the last five to seven years, you’ve seen the executives of large health care enterprises vault over the surgeons and radiologists in the food chain.

**MC:** You mentioned targeting pockets of these populations.

**Goldsmith:** I am in a narrow-network MA plan, and I have had a couple of conversations with my carrier about them sending a nurse to my house to examine me and talk about my health. I declined. I am really healthy. I will probably have a different answer for the person calling to send the nurse to my house in 10 years. Right now, I don’t need the nurse or a medical home. But a lot of people my age are already in serious health trouble. The real art form here is realizing that the risk is lumpy and in fitting the care model to the specific constellation of the patient’s risk. Figuring out how to segment the risk and building the care models that fit that risk most closely is really going to be the secret. One size, one scheme, does not fit everyone.

**MC:** With so much change and uncertainty in the market, where else should insurers be focusing on in terms of business strategy?

**Goldsmith:** Nearly everybody in Washington underestimated the rate of growth of the individual insurance market — and they still are. CBO said it would rise to 29 million as a result of ACA. I think it will be more like 40 million. The small group market is rapidly collapsing into the individual market via the exchanges. A lot of the large group market will also individualize through private exchanges as big employers attempt to create an off ramp as they approach the Cadillac tax in 2018. So I think 40 million is an intermediate stopping point.
The idea that ACOs work and multiply and somehow evolve into capitation is just a mass hallucination. It isn’t going to happen.

In areas such as preventive care.

Goldsmith: Some have, but we are just not there yet. Why don’t we start paying people to show up for all their prenatal visits? Why don’t we give people cash incentives to renew their prescriptions, or to find a cheaper place to have their hips done, not just by making the copayments go away but by writing them a check? If consumers are reducing the downstream risk of a serious medical event or saving the insurer money, we ought to give them a piece of the saving. Send them positive signals about what you wanted them to do. My MA carrier sent me a $50 voucher recently, but for the life of me, I couldn’t figure out what I did to get it or how to get another one — and I am not unacquainted with our health system. Maybe that nurse would have told me. Clearly people are beginning to grope toward this idea that simply having a $5,000 fence between me and the medical care system probably isn’t a good benefit design. But they haven’t yet sent me a clear set of economic signals about what they want me to do. That’s the heart of it.

MC: The plan could be providing something you value?

Goldsmith: I shop at Walmart. I like the idea of saving $2,500 a year on things that are essentially commodity items that Walmart can buy cheaper than anyone else. Health insurers that win are going to be the ones that can create demonstrable reductions in out-of-pocket outlays for their subscribers — to do the equivalent of what Walmart is doing for me. If my health insurer can figure out a way for me to avoid spending $2,500 I would rather not spend on medical care, I am going to re-enroll.

MC: We keep hearing about lifestyle changes and decisions.

Goldsmith: Some illness is our fault; most of it isn’t. The real waste in our health care system is what happens after people do get sick and require acute intervention. That intervention is poorly scripted and poorly managed and there are still incentives operating within the provider community that are inducing care that probably isn’t producing value for society. It is our response to the illness that isn’t our fault where many billions of dollars are wasted.

MC: Cost increases have been low for a while. You have a talk entitled “Is the Health Cost Dragon Dead or Sleeping?” Which is it?

Goldsmith: The pause in cost increases is durable. The dragon might be on extended holiday in the Seychelles. We are going to be in mid-single digits for a very long time. This has been a remarkable last six years, and unlike the CMS actuaries, I don’t think it’s over. They forecast that 2014 would be a 50 percent acceleration in cost growth. I don’t see it. We have had four-and-a-half years of boomer enrollment in Medicare, and yet Medicare costs are barely growing at all per beneficiary. I don’t see technologies out there that are sufficiently power-
furl to break it loose. I don’t see anything except Sovaldi, the hepatitis C drug, that is breaking out on the up side.

MC: And Sovaldi, even at $84,000 for a course of treatment, is going to reduce costs in the future.

Goldsmith: It certainly is, at a very steep price. People don’t think about all of the liver disease that we have avoided. We cured a horrible disease that affects 3.2 million people, and every one of those folks was eventually going to lose their liver unless something else killed them first. We actually need to start curing diseases. Alzheimer’s disease would be my next candidate. Let’s get busy. Let’s cure Alzheimer’s and then we can complain about the cost.

MC: I’m with you. And speaking about complaining, are salaries in health care appropriate?

Goldsmith: In the last five to seven years, you’ve seen the executives of large health care enterprises vault over the surgeons and radiologists in the food chain. A lot of physicians are rejoining the middle class in terms of income levels. What’s happening to advanced practice nurses vs. primary care physicians is really interesting. Certified registered nurse anesthetists and masters level ICU and surgical nurses are making north of $200,000 in some markets. Market forces are adjusting what people are getting paid to their value. On the issue of executive salaries, some of these big health systems are $10 billion to 15 billion operations — and they are a lot more complicated than a typical $10 billion corporation. So is paying those guys $5 million a year paying them too much? They don’t get stock options. Some of the big insurers are $60 billion to $80 billion companies. There’s a lot of capital at risk and a lot of investor equity at risk in how those organizations perform. The argument that executive compensation is out of line because these organizations have scaled up to the size they are is a little bit hard to swallow. Compensation is not where the waste is. The waste is in all the layers and the unnecessary bureaucracy and the wasted time and motion in medicine.

MC: Are hospitals going to keep buying physician practices?

Goldsmith: There has been roughly a 50 percent increase in the number of physicians employed by hospitals in a decade. It has been an economic disaster for the hospitals. According to the MGMA, in 2013 the average hospital-employed doctor lost the hospital $206,000. Physician economic risk is surging into hospitals. There’s a lot of soul searching going on right now about how many of these contracts hospitals can afford to renew and at what price. A lot of the big losses were due to the collapse of private cardiology that took place in the wake of the Deficit Reduction Act cuts in high-tech imaging. All of the sudden, the practices that were dependent on imaging were no longer viable and they were all for sale. For a hospital, it really wasn’t a negotiation. If your leading cardiology group comes to you and says, “We really can’t remain private any longer and we would love to come work with you if we can work out a really good long-term salary guarantee. Would you like all of our procedures or none of them?” That happened all over the country. Hospitals ended up with guns to their heads making these terrible contracts — with cardiologists, oncologists, and orthopedists — the imaging-dependent specialties. It wasn’t just primary care physicians that couldn’t find a place to go. Reducing those physician practice losses may be the single most important thing that hospital executives are trying to do in an environment where their top line isn’t growing.

MC: What’s the answer?

Goldsmith: One big question people are going to be asking is, “Do I need to employ them or can I contract with large groups to provide my physician services?” For a significant chunk of the so-called hospital based physicians, there are alternatives available in the form of national groups, and in some cases regional groups. Another piece is, “If I am in managed care contracts, where there is some risk to me, do I really want to pay my physicians on the basis of relative value units — RVUs? Would that encourage them to order more tests or to hospitalize patients? It may damage my ability to be eligible for performance bonuses or to make money under a cappedit contract.” There is going to be tremendous pressure on hospitals to rethink the compensation model.

MC: What will the new models look like?

Goldsmith: The footprint of physician employment is probably going to shrink somewhat. So
what structures are going to emerge in the physician community to absorb some of the docs who don’t want to be employed by the hospitals? That’s where a lot of the uncertainty is. I think you are going to see a lot of large regional physician groups emerge. In Florida and a lot of other places, 10- and 20-person groups are merging into 100-person groups. You get up to 100 people, and you really do have the administrative support and scheduling flexibility to begin taking on younger physicians who don’t want to work 100 hours a week.

**MC:** Are super-large groups going to have increased bargaining power with the payers?

**Goldsmith:** Payers are going to welcome an alternative to having the hospitals control all of the doctors. It is powerfully in the insurers’ interest to support those independent physician groups because they are probably going to have lower overhead and lower per-capita medical costs.

**MC:** And less propensity to refer to hospitals and hospital-based services.

**Goldsmith:** Correct. It’s going to be a challenge because there has been a lot of mistrust between physicians and insurers historically. But the idea that payers could be completely dependent on hospitals for hospital and physician services really narrowed their bargaining power.

**MC:** So this improves the insurers’ position?

**Goldsmith:** There’s a lot of potential leverage available to insurers for having some diversity in that physician base, particularly if bundled payment emerges as a viable concept. It would be a disaster if the only potential receptors/managers of the bundles were hospitals. Physician groups are fully capable of organizing physician-centric care models that manage patients for oncology, for joint replacement, and for some of the complex episodic care that best fits the bundling model. And insurers have a tremendous opportunity to foster multiple choices for their patients if they are willing to share some of the savings with them. They have to make sure that physicians are at the table and that they have an opportunity to participate in the new care models.

**MC:** You like bundled payment?

**Goldsmith:** I am really bullish on bundling, in major part because of the Geisinger and CalPERS experiences. I think we are going to see a diversity of payment models. But one trend I am not buying is the move to population health payments.

When I go to health care meetings right now, it’s almost unanimous that we are going to move from fee-for-service to population health, which to me means capitation. I don’t see capitation growing at anywhere near the rate that it would need to grow to be even a tiny fraction of the total provider payment in the country anytime soon. Most of the commercial ACO deals that are happening — the non-Medicare ACO deals — aren’t capitation. There aren’t a lot of these deals and nearly all of them are one-sided risk with fee-for-service playing loudly in the background. There’s a discount on the front end and an opportunity for the provider to earn back some of the discount by checking the right boxes. But the idea that ACOs work and multiply and somehow evolve into capitation is just a mass hallucination. It isn’t going to happen. The vast majority of providers are not now and never will be risk-bearing enterprises.

**MC:** What is affecting contracting talks right now?

**Goldsmith:** From an insurer’s standpoint, it is difficult to find a more favorable contracting environment than the one we are in. Remember back to the birth of the PPO, when there was a tremendous amount of anticipatory discounting by providers. They were willing to give discounts because they were worried they were going to be locked out of narrow networks or were greedy and wanted to grow at their neighbor’s expense. Well, of course, almost none of them were locked out of those networks; they just gave up huge chunks of their previous rate structure. I think that’s happening again except that some providers are getting locked out this time. Insurers are trying to lower their per-unit cost of procuring hospital and physician services. There’s a lot of panic pricing going on in the hospital world right now, because many hospital executives really believe that if they give a huge discount, they will be rewarded with increased volume. Hospitals are giving up discounts far in excess of potential rewards that are going to accrue from new volume coming in. I think that is one of the things that will help health plan earnings and keep the cost trend from rising.

**MC:** Thank you. **MC**
Programs for High-Need Patients
What Makes the Good Ones Good?

They’re customized to local caseloads and conditions, they coordinate with primary care practices, and they focus on building trust with patients.

By Michael Levin-Epstein

A busy primary care physician and a major insurance company in a health care system in the Northeast were becoming frustrated trying to manage the seemingly out-of-control HbA1c and dangerously high blood pressure of a diabetic patient. Sound familiar?

It turned out that behind this clear-cut medical problem lay a much simpler but equally vexing problem: the patient wasn’t showing up for his regular appointments. The reason was simple: He lived with his son, who took the family car to work. The remedy was equally simple, according to a consultant advising the health care system: Arrange through a care manager for transportation. Not surprisingly, once that was taken care of, the patient’s health improved dramatically.

Indeed, according to a major new study on complex care management (CCM), health care providers and payers can improve patient outcomes by intervening with high-need, high-cost patients — like the diabetic patient with transportation problems — by using a customized, non–cookie-cutter approach.

Health insurers should look critically at how to adapt these programs to meet the needs of their patients, the study concludes.

Published in August by the Commonwealth Fund, the study looks at the operational approaches of 18 successful CCM programs (page 35) and offers practical guidance to providers, payers, and policymakers on best practices. The study focuses on programs in which specially trained teams coordinate closely with primary care teams to meet the needs of patients with more than one chronic condition or with advanced illness. Many face social or economic barriers to obtaining services.

The study, “Caring for High-Need, High-Cost Patients: What Makes for a Successful Care Management Program?” was written by Clemens S. Hong, MD, MPH; Allison L. Siegel, MPH; and Timothy G. Ferris, MD, MPH.

Hong is a physician researcher in the general medicine division at Massachusetts General Hospital in Boston. Siegel is a consultant at Slalom Consulting in Seattle. Ferris is medical director of the Massachusetts General Physicians Organization and vice president for population health management of Partners HealthCare, which is based in Boston.

“The science of complex care management is still in its infancy,” the researchers caution.

While the evolving nature of CCM made identifying best practices difficult, they found distinct similarities in design and operations in the diverse group of successful programs. The most important similarity: belief by program administrators that there were still opportunities to improve care and reduce cost for these complex patients.

Role of chronic conditions
How much do chronic diseases affect our health care system? Check out these statistics from the Centers for Disease Control and Prevention:

- As of 2012, about half of all U.S. adults (117 million people) had one or more chronic health conditions, and 1 in 4 adults had 2 or more.
- In 2010, 7 of the top 10 causes of death were from chronic diseases.
- In 2006, 84% of all health care spending was for the 50% of the population that has 1 or more chronic medical conditions.

According to the study, primary care-integrated
CCM programs are the right approach to deal with these chronic conditions because their structure enables providers and payers to identify and engage patients at high risk for poor outcomes and unnecessary utilization, conduct comprehensive health assessments to identify problems that can be addressed through effective intervention, and respond rapidly and effectively to changes in patients’ conditions to avoid unnecessary services, especially emergency department visits and hospitalizations.

What separates these 18 programs from the pack? First, the study notes, they focus on building trust with patients and primary care providers. Then the programs use a combination of qualitative and quantitative methods to identify patients and customize their approach to local contexts and caseloads. And finally, the initiatives offer specialized training for team members, using cutting-edge technology to bolster program efforts.

**Customization is a must**

Even with these features, customization — tailoring programs to account for particular context, such as practice size, location, program sponsorship, and governance — is essential, the researchers say.

For example, small, independent practices, which are less likely to have enough complex patients to justify investment in a CCM team, need to share CCM resources with each other, the researchers say.

In contrast, they note, regional care management entities that serve multiple practices are “particularly well suited for areas where smaller practices predominate,” such as in rural locales.

CCM programs in rural settings require greater team resources or smaller caseloads “to offset the increased travel time and relative scarcity of community resources,” whereas larger practices with sufficient numbers of complex patients should have “embedded care managers at primary care practices and other key sites.” The researchers say, “Some CCM team members can be shared across practices.”

Also critical for success is buy-in from providers. “Primary care teams familiar with the principles of team-based care and quality improvement processes are likely to be supportive of CCM programs, while CCM team members may facilitate practice change at primary care sites,” they write.

Massachusetts General’s Hong cautions that CCM treatment is complex. “We can’t say, ‘Do this and it will be perfect.’” He believes a good starting point is to look at the examples used to illuminate best practices (see “Recipe for success” above). And the study has two clear-cut lessons, Hong suggests: Pay attention to psychosocial factors and coordinate all services involving patients, providers, HMOs, and other managed care plans.

In addition, patients often have more than one condition requiring coordinated treatment. This implies that a health plan or integrated health system can reduce cost and improve quality if it works closely with providers to develop complex care management programs that are embedded in primary care practices.

These practices will need data, financial support (including incentives to adopt CCM programs and seed funding to get going), and technical assistance on model design and implementation to be successful. And the approach will be different in settings with numerous small practices versus what it is in a large health care system.

For example Health Quality Partners, in Doylestown, Pa., supports many small and medium-sized practices in rural Pennsylvania that would otherwise not have the capacity or capital to develop their own programs.

Health Quality Partners receives a monthly care management fee to serve higher-risk Medicare beneficiaries in collaboration with primary care physicians in more than 100 practices in seven

### Recipe for success with complex care?

A study by the Commonwealth Fund looked at 18 organizations’ complex care management (CCM) programs to determine what makes them successful. The report says the good ones:

- Customize their approach to local contexts and caseloads
- Identify patients via both qualitative and quantitative methods
- Consider care coordination one of their key roles
- Focus on building trust with patients and with primary care providers
- Match team composition and interventions to patients’ needs
- Provide specialized training for team members
- Bolster their efforts with technology

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MANAGED CARE / DECEMBER 2014
counties. This approach allows many practices to benefit from the program without each one having to hire, train, and manage highly specialized nurse case managers.

In contrast, large health care systems like Partners Health Care may have the capacity and capital to develop their own CCM infrastructure and might focus on ensuring that incentives are aligned through full or partial risk contracts or at-risk care management fees.

It takes at least two years for programs to begin to achieve sufficient efficiency to generate savings. So in either case, health plans should account for this in their contracting.

“Treating people from a whole-person perspective became even more critical when distinguishing the best care management programs,” says Slalom Consulting’s Siegel, expanding on the notion of managing multiple diseases. “The best care management programs used a team approach to care for patients.”

The approach wasn’t as simple as having a care coordinator, a primary care provider, or a disease manager in charge of dealing with a patient, which might seem like old-school care management.

Instead, Siegel says, the idea was to create a multidisciplinary team that “always included the primary care provider, the care manager, and the patient, and often included a social worker, a pharmacist, and other support personnel — for example, behavioral health, community support organizations, and specialists.”

Geriatricians and nutritionists, for example, might be included.

“They invested in caring for people, not diseases,” says Siegel.

That means taking care of non-medical issues as well as medical ones, she stresses. The most successful high-risk care management programs took time to engage patients in key issues affecting their health, medical or not, as in the case of the diabetic patient without transportation.

This kind of approach requires trained health professionals who can engage in effective motivational interviewing.

For example, Care Management Plus, a cooperative project between Oregon Health & Science University and the John A. Hartford Foundation, surveys care managers after every training.

It consistently hears that the motivational interviewing skills it teaches are the best part of the training because they help managers interact with patients daily and engage patients in self-management, according to Siegel.

The Commonwealth Fund’s 18 successful CCM programs

These organizations have achieved success in targeting high-need, high-cost patients with complex care management (CCM) programs, says the Commonwealth Fund, and their experience may provide lessons for other provider organizations and health plans:

1. Aetna’s Medicare Advantage Provider Collaboration Program (national)
2. AtlantiCare Special Care Center (New Jersey)
3. Camden Coalition of Healthcare Providers (New Jersey)
4. Care Management Plus (Oregon/national)
5. CareOregon Health Resilience Program (working on behalf of Health Share of Oregon)
6. Community Care of North Carolina (Community Care of the Sandhills)
7. The Everett Clinic (Washington State)
8. Fletcher Allen Health Care–Vermont Blueprint Community Health Team (Vermont)
9. Geisinger ProvenHealth Navigator (Pennsylvania)
10. Genesys HealthWorks Health Navigator (Michigan)
11. Geriatric Resources for Assessment and Care of Elders (GRACE) (Indiana)
12. Guided Care (Maryland)
13. Health Quality Partners (Pennsylvania)
14. King County Care Partners (Washington State)
15. Massachusetts General Hospital Care Management Program (Massachusetts)
16. New York City Health and Hospitals Chronic Illness Demonstration Project: Hospital 2 Home (New York)
17. Oklahoma SoonerCare Health Management Program (Oklahoma)
18. Sutter Care Coordination Program (California)
A case study in complex care management

Health Quality Partners (HQP), headquartered in Doylestown, Pa., is a not-for-profit health care management organization serving high-risk patients in rural and suburban southeast Pennsylvania since 2000.

Under its complex care management (CCM) program, HQP accepts Medicare patients who have at least one chronic illness and who have had a hospitalization in the past year. HQP assigns a trained nurse to visit the patient with a frequency that typically ranges from monthly to weekly (but can be greater) to assess the patient’s health and to arrange treatment if it is needed.

By combining this approach with applied research and development techniques, HQP has been able to reduce hospitalizations by 39% and Medicare costs by 28% for high-risk Medicare beneficiaries, according to a report drafted by Mathematica Policy Research in 2011.

Kenneth Coburn, MD, MPH, HQP's cofounder, chief executive officer, and medical director, stresses that taking a long-term, evidence-based approach can yield better results than employing only short-term measures. Coburn said he was delighted that the Commonwealth Fund report rated the quality of evidence associated with each program, calling that action rare.

This program reports 25% fewer deaths in the chronically ill Medicare population compared with usual care.

For Coburn, CCM success is all about an evidence-based approach that includes thorough monitoring of data on patient outcomes and using the data to improve treatment.

To back up his assertion, Coburn cites his own research, published in July 2012 in the online open-access journal PLoS Medicine, which looked at a community-based nursing intervention developed by HQP that became one of 15 models of care coordination tested in randomized controlled trials in the Medicare Coordinated Care Demonstration. The study, evaluating the effect of the HQP program on survival versus the effect of usual care up to five years post-enrollment, concluded that compared with conventional care, the HQP management model reduced deaths of chronically ill older adults by 25%.

“And unlike many drug and device interventions, this result was achieved with no known adverse effects,” says Coburn. Rather, the outcomes were the result of a carefully designed and managed nursing intervention provided in collaboration with primary care physicians and other key assets of the health system.

A burger said it all

Providers and health plans can improve outcomes in CCM just by communicating better, Siegel insists. “There is terrible continuity of care for all of our patients because providers don’t or can’t share information about patients across offices,” she says. “This is a big problem between systems, but frequently it’s a problem within a single system, too, especially for pharmaceutical or behavioral health management.”

Siegel offers a way for health care systems to improve communication: Invest in building multidisciplinary teams embedded in primary care, and set care managers up to succeed with balanced caseloads and the right tools to efficiently track and manage ongoing communication.

A good care manager will coordinate with the primary care doctor and other providers to avoid costly hospitalizations and complications. But often, she says, organizational change is needed — and that’s not a quick fix.

The bottom line, according to Siegel, is that CCM program operators need to build trust with patients in managed care plans.

“‘My favorite story,’ she says, ‘was from a nurse-social worker team who told us that the way they gained the trust of one patient was to buy her a Big Mac. Not exactly what you’d expect from a health care provider, but it opened the door for this patient to allow the team to help her.’

Many of the successful CCM programs point to reducing costs as the rationale behind their initiatives. Della Gregg, health manager for Oklahoma’s SoonerCare Health Management Program, says that the program was implemented as a direct response to legislative changes to reform Medicaid.

The initiative included researching alternatives to traditional disease management strategies and focusing on SoonerCare members with chronic diseases.

The program identified more than 100,000 patients, and the top 5% in utilization were targeted — including face-to-face contact for the
top 1%, according to Gregg. “To run an effective program that improves quality while reducing costs, there needs to be a team-based approach in which the right members are identified and the entire multidisciplinary team is engaged.”

**When health plans lead**

Sometimes, it’s the health plan or health system itself that takes the lead in CCM. For example, says Randall Krakauer, MD, Aetna’s national Medicare medical director, the health plan or insurer may believe that patient-centered collaborative ventures can serve as stepping stones to aligning financial incentives with higher-quality and more efficient care.

Aetna’s national Medicare Advantage Provider Collaboration Program includes the use of an Aetna nurse case manager, embedded with the medical group whenever possible, who helps coordinate care for Aetna Medicare Advantage members and works face to face with the medical group clinical staff to coordinate the care that plan members receive from the medical group physicians.

There are now more than 150 physician provider groups with collaborative arrangements with Aetna for Medicare that include clinical outcomes goals, data sharing, and clinical collaboration and support.

Under the program, Aetna nurse case managers also use advanced technology to monitor Aetna Medicare Advantage member care and health progress, supported by the ActiveHealth CareEngine System, which monitors all available information on patients, comparing it to current medical evidence and identifying and alerting members and doctors to possible urgent situations and opportunities to improve care.

The data can include an alert when a patient isn’t taking a prescribed medication, suggest potential therapies that might be recommended for a diagnosis, or even propose tests that may not have been ordered for certain diagnoses.

The seven-year-old program grew out of Aetna’s effort to build an aggressive case management system for Medicare patients. Aetna decided to work with providers to focus on outcomes rather than costs.

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**Taking ‘the 7-day pledge’**

The Camden Coalition of Health-care Providers (CCHP) began as a small group of Camden primary care providers meeting over breakfast at the town’s Rutgers University campus to discuss problems they faced practicing in the city. Its members have become “community organizers of the Camden health provider arena,” says Jeffrey Brenner, MD, a family physician, and the group’s executive director since 2003.

“Frequently in large, urban environments across the country, health care delivery is fragmented, episodic, uncoordinated, and extremely inefficient,” says Brenner — and that’s what CCHP aims to fix. Getting hospitals and health systems to share data from patient claims, the group discovered patterns of hospital and emergency department use. In Camden, it found, 80% of the costs went to the care of 13% of the patients, and 90% of the costs went to 20% of the patients. The total price tag for hospital and emergency department care over five years was $650 million — mostly public funds.

In 2007, the coalition began implementing a citywide care management project to intervene and direct appropriate outreach attention to the most frequent users of the services. “We refer to our intervention in three different stages: the push, the carry, and the catch,” Brenner says.

“In the first stage, we want to push the patient out of the hospital and back into the community. The carry piece involves our care teams working with the patients in their homes, helping them to navigate the health care system and re-engage with providers. The catch refers to having them engaged or re-engaged in a relationship with a primary care office.”

Brenner says CCHP has “many examples of our cost savings successes” — but he’s not yet able to share the data publicly. Meanwhile, he can share one key recommendation to improve treatment outcomes: Make sure patients see their primary care provider within seven days of hospital discharge to reduce readmissions. CCHP has launched a citywide campaign called the “7-day pledge” to encourage discharged patients to follow up with their providers.
than volume of service, Krakauer says. That was possible thanks to Aetna’s ability to exchange information with providers, he adds.

Krakauer says that the collaboration also emphasizes getting “as close to the action as possible” in treating patients, which is leading Aetna to continue to move case management out of call centers and embed it in the community and with providers.

In addition to these newer CCM initiatives, health plans, integrated health systems, and insurers are relying on more traditional care management techniques, such as embedding personnel.

In California, for example, the Sutter Care Coordination Program (SCCP) uses embedded personnel to detect and monitor people with chronic diseases or conditions.

Michael Avriette, Sutter Health’s vice president for care coordination, says the program began approximately 18 years ago and has continued to be updated in response to the results that are obtained.

It combines chronic care and disease management to address the medical and psychosocial needs of people with more than one chronic condition, Avriette says.

According to the Agency for Healthcare Research and Quality (AHRQ), the program reduced patient visits to specialists by 24%, emergency department visits by 13%, and hospitalizations by 39%.

“Because the program’s sponsor, Sutter Health Sacramento Sierra Region, serves many patients on a capitation basis, much of the savings achieved through avoided medical costs are shared by its physician organizations and hospitals,” AHRQ says.

AHRQ also notes that the program was the first of its kind to receive disease-specific certification from the Joint Commission. SCCP is specifically designed to make it easy for patients to take good care of their health and to use Sutter services and community resources, according to Avriette. That means giving attention to all aspects of personal well-being, including physical, mental, emotional, educational, and social support, he says.

SCCP team members include registered nurse case managers, medical social workers, and health care coordinators who help patients to understand their health conditions and to obtain services they need. The program also provides periodic monitoring to ensure that patients are following their doctors’ instructions on taking medication.

**Rx: sodium chloride, 1 grain**

The Commonwealth Fund reports urges regulators and policymakers to encourage adoption of CCM programs.

“Both the emergence of key operational characteristics of successful programs and the apparent opportunity for continued improvement of these programs should spur policymakers to reduce barriers to more widespread adoption of primary care–integrated complex care management programs,” the paper concludes.

But some experts warn against putting too much trust in CCM. The Commonwealth Fund study’s findings “should be taken with a grain of salt, and eyes wide open, by any health delivery system, especially a managed care plan,” says Brent Williams, MD, MPH, medical director at the University of Michigan Complex Care Management Program.

The programs in that study showed that they were effective in improving results for patients and lowering costs, but other studies have shown that CCM was not effective, Williams says, noting that the Commonwealth Fund report was based primarily on observational rather than randomized studies.

Another problem with the study, according to Williams: There are “many subpopulations” of high-utilizing patients who may come under the CCM mantle — they may include people approaching the end of life, people with behavioral problems, and patients with chronic conditions, catastrophic diseases, or limited resources.

In other words, he says, not every patient can easily be placed into a cost-effective CCM program if quality of life or social circumstances are particularly complicated. The effectiveness of CCM depends on carefully selecting patients, tailoring treatment, and continuing treatment.

But Williams, like the Commonwealth Fund researchers, stresses that CCMs work best when embedded in or tightly integrated with primary care practices.
Personalized medicine is caught in gridlock. Just as having too many cars in Manhattan creates rush-hour headaches, having too much information about genetic variants is overwhelming the process of identifying variants that are significant and useful in clinical practice.

The gridlock is the result of two closely related problems. First, more efficient and powerful genetic tests include multiple genes. With these tests, next-generation sequencing is finding new associations between variants and diseases. Second, and perhaps more important, the infrastructure for personalized medicine is ill-equipped to handle the information that is coming from these powerful tests. There are no proven mechanisms in use to convert new information into knowledge that can be used in clinical practice. In fact, there is a long list of deficiencies in the standards, procedures, and resources that make up the personalized medicine infrastructure.

Then, there’s the issue of perspective. To some extent, the excessive claims of finding new pathogenic variants may be rooted in irrational exuberance over the role that genetic testing will play in the health care system.

A place in the toolbox

“I have seen a lot of medical technologies come onto the scene — MRI and CT scanning, robotic surgery, and biologic drugs,” says David Finley, MD, a Cigna national medical director. “Often, the initial reaction is, ‘This will change everything,’ but as technologies unfold they find their place in the toolbox. To a certain extent, that will probably be true for genetic testing. There will be a period of intense interest and increased utilization of genetic testing and looking at the data showing where genetic information changes outcomes. Eventually, its usefulness will be established in certain areas and it will be shown to have limited benefit in other areas.”

We’re not there yet. As a starting point, there is no central database for cataloging variants that can be shared by researchers trying to verify information about the significance of a variant. Commercial genetic labs often have their own proprietary databases; groups of academic and research labs have banded together to form their own separate biobanks; and the federal government has only recently issued grants to develop a well run centralized repository.

Another problem is that the quality of information on genes and variants in the existing databases varies widely, with more recent reports generally containing better information than early test results. The inconsistency in information is compounded by the fact that there are no standards for reporting test results and there is no universal classification system for labeling variants as pathogenic, probably pathogenic, benign, and so on.

Problems in the classification of variants are fueled by venture capital-funded commercial labs and starry eyed researchers trying to make a name for themselves by claiming to identify new pathogenic variants that miraculously explain the root
cause of illnesses. For example, the Institute of Medicine report “Assessing Genomic Sequencing Information for Health Care Decision Making: Workshop Summary” describes a situation in a federally funded project where a rigorous review of pathogenic variants subsequently excluded 97% of them, reclassifying them as benign or inconclusively pathogenic.

Complicated picture

The problems with the genetic infrastructure are becoming more complex as testing moves from genetics (testing individual genes) to genomics (testing of gene panels, exomes, or an individual’s entire genome). Next-generation sequencing and other powerful assay technologies have stepped up the pace for identifying new genes and new variants that are associated with illnesses.

The Cystic Fibrosis Foundation says 1,800 variants have been identified in the CFTR gene, but the screening guideline from the American College of Medical Genetics and Genomics lists only 23 that have been adequately evaluated. Very few of the 1,800 will prove to be significant, but the noise created by the worthless variants is overwhelming the process for identifying the variants that cause illnesses, variants that signal the risk of an inherited disease, or variants that will aid in the selection of pharmacotherapy.

“The challenging thing in genomics is that stakeholders cannot agree on the level of evidence necessary to determine if a variant is clinically significant,” says David Veenstra, PharmD, PhD, a researcher at the University of Washington who was cochairman of the workshop that produced the IOM report. “The key challenge over the next five years is to develop the framework for gathering and evaluating evidence about genetic variants for clinical decision making.” He adds: “Then it will take another five years to generate that evidence.”

Despite the lack of a solid foundation for determining the clinical significance of genetic variants, personalized medicine is marching on.

In September and October, the National Comprehensive Cancer Network (NCCN) released two new guidelines on genetic risk assessment
in colorectal cancer and breast/ovarian cancer. The guideline for colorectal cancer includes elaborate multigene testing strategies for Lynch syndrome and polyposis syndromes. The breast/ovarian cancer guideline “Genetic/Familiar High-Risk Assessment: Breast and Ovarian” covers testing for BRCA1/2, PTEN, and TP53 genes, which are well documented in breast cancer. It also provides detailed information on multigene testing for additional genes that have been linked to breast cancer.

The breast/ovarian cancer guideline explains how genetic testing is changing. “The introduction of multigene testing for hereditary forms of cancer has rapidly altered the clinical approach to testing at-risk patients and their families. Based on next-generation sequencing technology, these tests simultaneously analyze a set of genes that are associated with a specific family cancer phenotype or multiple phenotypes.”

**Medicare’s draft coverage**

In a separate development, Medicare has issued a draft coverage decision for a multigene test named Polaris that predicts progression in prostate cancer. The test is from Myriad, the company that gained fame for its efforts to patent the BRCA1 and BRCA2 breast cancer genes.

Polaris is a 46-gene RNA expression test that measures tumor growth characteristics for stratifying the risk of disease progression in prostate cancer. The company says it has been proven in 11 clinical trials with more than 6,000 patients to predict prostate cancer progression. Medicare’s draft designation status reflects a mandatory 45-day comment period before permanent coverage is awarded.

Polaris and another multigene test, the Oncotype DX GPS, are discussed in the NCCN’s latest prostate cancer guideline. The NCCN says that these gene panel tests, which target genetic markers for disease progression, may play a role in risk stratification for disease progression in men with localized prostate cancer.

The NCCN’s new guideline for multigene testing and Medicare’s approval of the Polaris gene panel test further emphasize the need to develop an infrastructure for genetic testing. “The ability of DNA sequencing to look at multiple genes has outpaced the ability of physicians and health plans to tell from studies just what clinical use the testing has and whether it improves health outcomes,” says Cigna’s Finley.

The lack of standards and evidence for genetic variants is a challenge for health plans that have been backed into a corner and forced to decide which variants and related tests warrant coverage. In many cases, health plans serve as arbiter of the value of genetic and genomic tests and are forced to make decisions with imperfect information.

In some diseases, coverage is increasing for variants that are documented in published studies or included in guidelines. However, almost all health plans consider next-generation sequencing of gene panels, exomes, and genomes to be investigational.

Clinical utility is the standard that health plans rely on for their coverage of genetic tests. A product or service has clinical utility when there is evidence that it improves patient management or outcomes. “We have a process for evaluating all new technology whether it’s a new device, a surgical procedure, or a diagnostic test,” says Finley.

He continues: “The key is that the service requested has been proven to produce a beneficial health outcome for the member. A beneficial health outcome is something that improves longevity or quality of life. It is not something that will shrink tumor size on an MRI.”

**Genetic counselors**

Developing a solid foundation for personalized medicine will take years but an important interim solution is emerging. The NCCN guidelines repeatedly refer to the role that genetic counselors can play in determining the best use of genetic testing and the best application of genetic test results. Cigna has taken a similar step in increasing the role of genetic counselors.

“In terms of providing appropriate access to genetic testing, my hope is that clinical genetics will grow as a specialty with a larger role for medical geneticists and genetic counselors, and I hope that the specialty will be more fully recognized,” says Finley.
Regeneron’s aflibercept (Eylea) injection in patients with diabetic macular edema demonstrated greater improvement in visual acuity than either of two Genentech biologics, bevacizumab (Avastin) and ranibizumab (Lucentis). In the National Institutes of Health-sponsored Diabetic Retinopathy Clinical Research Network comparative effectiveness study, the median number of aflibercept injections was one fewer than either of the comparative products.

Genentech counters that findings of a single trial at one year must be viewed in context of the totality of the evidence establishing the efficacy and safety of ranibizumab. NIH sponsored a comparative study of bevacizumab and ranibizumab several years ago, finding both equally effective in treating age-related macular degeneration.

Immune disorder studies

Amifampridine phosphate (Firdapse) tablets for the treatment of Lambert-Eaton myasthenic syndrome were superior to placebo in a double-blind, randomized withdrawal study. Both primary endpoints — changes in quantitative myasthenia gravis score and subject global impression — were met. Adalimumab (Humira) reduces abscesses and inflammatory nodules in moderate-to-severe hidradenitis suppurativa (HS), also called acne inversa, according to PIONEER II study data. At 12 weeks, patients with moderate-to-severe HS treated with adalimumab achieved a statistically significant greater response than those given placebo. No approved treatment for HS exists.

Novartis’s secukinumab improved signs and symptoms of adult psoriatic arthritis, compared with placebo, in the FUTURE 1 and FUTURE 2 studies. Secukinumab also improved physical function and quality of life vs. placebo in patients with ankylosing spondylitis, according to the MEASURE 1 and MEASURE 2 studies. The drug stops the action of interleukin-17A, a protein central to inflammation. Regulatory filings are intended for 2015.

Eli Lilly plans to scrap development of tabalumab after the anti–B-cell activating factor monoclonal antibody failed to achieve significant improvement on SRI-5, a measurement of lupus disease activity and response, compared with standard-of-care therapy in the ILLUMINATE-1 trial.

On the cancer front

Patients with Hodgkin’s lymphoma (HL) lived significantly longer without disease progression when given brentuximab vedotin (Adcetris) immediately after an autologous stem cell transplant versus those given placebo, according to results of the randomized AETHERA trial. Adcetris is an antibody-drug conjugate (ADC) directed to CD30, an overall survival analysis will not be available until 2016, though Takeda plans to file for marketing approval in 2015.

Nivolumab (Opdivo), when combined with platinum-based doublet chemotherapy, showed clinical efficacy similar to nivolumab monotherapy in patients with advanced refractory non–small-cell lung cancer (NSCLC), according to data from the Checkmate-012 study,
although researchers cautioned that more study is needed. The FDA has granted breakthrough status to the Bristol-Myers Squibb drug and aims to review its biologics license application by the end of next March.

Patients with epidermal growth factor receptor (EGFR) mutation-positive NSCLC who continue therapy with gefitinib (Iressa) after acquiring resistance to the tyrosine kinase inhibitor receive no further clinical benefit, according to results from the IMPRESS trial. IMPRESS included 265 patients with locally advanced or metastatic NSCLC with an activating EGFR mutation and prior progression on first-line gefitinib.

Amgen's trebananib with paclitaxel failed to demonstrate a statistically significant improvement in overall survival vs. paclitaxel with placebo in a trial involving women with recurrent platinum-resistant ovarian cancer. Median OS in the TRINOVA-1 study was 19.3 months in the trebananib arm, compared with 18.3 months in the control arm.

Have you heard?
The American Society of Clinical Oncology has endorsed a practice guideline garnered from several professional associations to guide physician decisions on when to offer molecular testing for EGFR and anaplastic lymphoma kinase mutations in patients with NSCLC.

A research team at Harvard Medical School found that only 14% of patients with newly diagnosed lung or colorectal cancer have discussed clinical trial participation with their physicians, and even fewer participate. Among patients treated with chemotherapy for advanced cancer, the discussion rate was only 25.7%. Younger age, higher education and income levels, and advanced disease were associated with a higher likelihood of having discussed clinical trial participation.

Another study, from researchers at the University of Michigan Comprehensive Cancer Center, found that nearly two thirds of colorectal cancer patients report a financial burden stemming from their treatment. Burden was greatest among patients who received chemotherapy and young patients who work in low-paying jobs.

— Katherine T. Adams

All clinical studies mentioned in this article are phase 3 unless otherwise stated.

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Beneficiaries pay more despite decreased utilization

A common payer strategy is to increase cost-sharing to induce the patient to use drugs prudently. According to the Health Care Costs and Utilization Report, published by the Health Care Cost Institute (HCCI) in October, beneficiaries continue to respond as planned — yet spending has risen.

Beneficiaries have cut back the most on branded drugs, although that’s also the segment in which their spending rose most. The result is a chain of events in which beneficiaries blame payers for higher cost-sharing as payers in turn blame drug companies for hiking prices. But do we have to play the blame game? Is there constructive action to be taken, or should we look forward to an end of pharmacy payers as we know them because they can’t keep beneficiary costs down? The optimist in me sees constructive action.

Increasingly, formulary decision makers are adopting quality measures to keep costs down. They can go a step further and react to newly published guidelines, where quality measures originate. There is roughly a 16-month lag between release of a guideline and release of updated quality measures. That’s more than an entire fiscal year of lost opportunity.

For example, new lipid guidelines say that lower LDL-C is better, but quality measures reflecting this will not be released until 2015. The CDC has new recommendations on pneumococcal vaccination, based on results of a head-to-head trial. Quality measures reflecting these recommendations will be released in 2016, but plans can change formularies now to reflect the latest evidence and to lower hospitalization rates for pneumonia.


### Rising beneficiary expenditure despite decreased utilization (2012–2013)

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Disruptive change is under way in the medical device industry and its future will change dramatically, according to “Medical Devices: Equipped for the Future?”, a report from A.T. Kearney. The changes could cost medical device companies $34 billion in potential revenue by 2020, forcing device manufacturers to look at new segments, products, and services that address value, customer productivity, and total disease management, according to the report.

Based on interviews with 30 medical device industry executives, the study identifies five disruptive forces that will affect the industry:

- **New health care delivery models**, such as pathways and the shift from inpatient to outpatient care
- **A power shift** that places payers and providers together in the position of evaluating evidence-based treatments and value
- **Stagnant innovation**, referring to low R&D investments in new technologies relative to improvements on existing products
- **Greater Food and Drug Administration regulation** and more regulatory scrutiny in the form of audits
- **The need to serve lower socioeconomic classes** as market opportunities are shifting to the developing world

The full report is available at www.atkearney.com.

**Cost-effectiveness study a plus for CTDR device**

The incremental cost-effectiveness ratio of cervical total disc replacement (CTDR) using the two-level Mobi-C Cervical Disc, compared with anterior cervical disectomy and fusion surgery, is $24,594 per quality-adjusted life year, according to a study published in *JAMA Surgery*. The results, say the authors, suggest that CTDR is a “highly cost-effective option” and that, from a societal perspective, CTDR imparts greater quality of life at lower cost over four years.

The full cost-effectiveness study was published online on October 8. Mobi-C’s maker, LDR Holding Corp., specializes in developing technology for spinal procedures.

**New heart valves coming?**

Medtronic has initiated the global PERIGON (PERIcardial SurGical AOrtic Valve ReplacemeNt) trial to evaluate an investigational surgical aortic heart valve made from cow heart tissue that could replace a diseased or malfunctioning native or prosthetic aortic valve. The valve has been implanted in the first U.S. patient at ProMedica Toledo Hospital in Ohio and is available only for investigational use. The trial will study up to 650 patients at up to 40 sites in the United States, Canada, and Europe.

**FDA OKs urinary valve pump**

VisiFlo got FDA approval to market its InFlow Intraurethral Valve-Pump, a replaceable urinary prosthesis for adult women who cannot push urine out of the bladder. The condition, impaired detrusor contractility (IDC), is typically managed with various types of catheters, including clean intermittent catheterization (CIC). The FDA reviewed data for InFlow through the *de novo* classification process, a regulatory pathway for some low-to-moderate-risk medical devices that are not substantially equivalent to a legally marketed device. Approval was based on a clinical trial involving 273 women using CIC. Half of the women in the trial stopped using inFlow because of discomfort or urine leakage, but in the 115 women who continued to use the device, 98% had a comparable amount of urine left in the bladder after voiding as those using CIC.

**Available in Europe**

Novo Nordisk has launched NovoRapid PumpCart, the first prefilled pump cartridge with an insulin analogue specifically designed for insulin pumps. The device, which contains NovoRapid (insulin aspart), is designed to make insulin pump therapy more convenient for people with diabetes and their caregivers. The 1.6 ml cartridge was developed in partnership with Roche Diabetes Care and is compatible with Roche’s Accu-Chek Insight insulin pump therapy system.

The device is being launched in the United Kingdom, Sweden, and Austria, and is expected to be rolled out in more countries in 2015.
Boston Scientific has European “CE mark” approval for the Accolade pacemaker family and for the Visionist and Valitude cardiac resynchronization therapy (CRT) pacemakers with quadripolar pacing technology. These systems offer options to reach and pace a target location in the left heart ventricle, improving patient response to CRT therapy. CE Mark, or conformité Européenne, is mandatory for certain products sold within the European Economic Area and is similar to the Federal Communications Commission’s Declaration of Conformity used on certain electronic devices sold in the United States.

Research happenings

A team of Harvard scientists and engineers has developed a surface coating for medical devices that could prevent blood clotting and bacterial infection. The coating, using FDA-approved materials, repels blood from more than 20 medically relevant substrates, including plastic, glass, and metal, and also suppresses biofilm formation, a common issue with medical devices used in hospitals. Details were reported in *Nature Biotechnology*. The first tear-duct implant to treat inflammation and pain following cataract surgery is a reliable alternative to medicated eye drops, according to findings presented at the American Academy of Ophthalmology 2014 annual meeting. Known as a punctum plug, the device delivers postoperative medication to reduce ocular inflammation. Use of the device may address adherence problems with eye drops. In a phase 2 study, researchers found that the plug reduced inflammation and pain, versus placebo, for up to one month after cataract surgery. A phase 3 trial is planned.

Computer-aided nodule assessment and risk yield, a software tool developed at the Mayo Clinic, can characterize pulmonary adenocarcinoma using high-resolution computed tomography images and stratify non–small-cell lung cancer patients into risk groups with different probable outcomes. Results were published in the *Journal of Thoracic Oncology*. Pressure ulcers, or bedsores, could be prevented easily by a wearable patient sensor, says Leaf Healthcare, the maker. Results of a three-month study were presented at the American Nurses Credentialing Center National Magnet Conference, held in Dallas in October. The clinical trial evaluated the technology to improve patient-turning compliance. Bedsores are one of the most common and costly medical errors, costing more than $11 billion a year, according to the U.S. Agency for Healthcare Research and Quality. A Dartmouth study suggests it may be possible to use Diffuse Optical Spectroscopic Tomographic (DOST) imaging to provide biomarkers to help physicians predict which patients will respond best to chemotherapy for breast cancer. DOST imaging is used to measure tumor tissue for hemoglobin and oxygen-saturation levels.

—Katherine T. Adams
idiopathic pulmonary fibrosis (IPF) is the most common of 200 unique diseases included in a grouping called interstitial lung disease (ILD). All affect the area of the lung that surrounds the air sacks. Although some of the individual diseases included in the grouping ILD have known causes, the exact cause of IPF is unknown.

In the past, it was thought that exposure to cigarette smoke, coal, silica, stone, wood and metal dust, and livestock might have caused it. But these pneumoconioses are now thought to be different diseases entirely.

Incidentally, since the diseases in this category overlap in their clinical and radiographic characteristics, many were misdiagnosed in the past. Therefore, historic comparisons are virtually useless. In fact, until recently, few large, placebo-controlled clinical trials had been conducted. Early studies of IPF enrolled a heterogeneous population of patients with ILD.

It was not until 2000 that the American Thoracic Society outlined criteria to distinguish IPF from other ILDs. Also, meaningful endpoints are still undergoing refinement.

Symptoms
IPF usually develops in people between ages 50 and 70. It is estimated that there are currently between 50,000 to 70,000 people in the United States with IPF, and another 15,000 to 20,000 are diagnosed each year. The clinical presentation of IPF is a dry, nonproductive cough associated with progressive shortness of breath, impaired pulmonary function, and a sound not unlike the sound of Velcro being pulled apart when a physician listens to a patient’s chest with a stethoscope.

The diagnosis depends on excluding other causes of ILD. Although surgical biopsy has traditionally been used to make the diagnosis, high-resolution computerized tomography (HRCT) has eliminated the need for surgery in some cases. When a battery of diagnostic studies does not support a “confident” diagnosis of IPF, however, a lung biopsy is needed.

Prognosis is poor, with a median survival of two to five years and a five-year survival of 20%–40% once the diagnosis is made. For comparison, this is a worse outcome than either colon cancer or multiple myeloma. Death occurs from respiratory failure and cardiac failure — the patient suffocates.

In the past, because it was thought that this was an immune or inflammatory disease, a number of nonspecific, non-FDA-approved therapies were attempted. These included interferon gamma, anticoagulants, anti-inflammatories, and antirejection drugs, such as corticosteroids and the immunosuppressive agents azathioprine and cyclophosphamide. Another drug, N-acetylcysteine, an antioxidant, was also tried. None of these were ultimately found to be effective.

Rare occurrence
That all changed recently when, in a rather rare occurrence, the FDA approved two very different therapies on the same day. The now-competing therapies are pirfenidone, to be sold under the brand name Esbriet (developed by InterMune, a wholly owned subsidiary of Roche), and nintedanib, to be sold under the brand name Ofev (developed by Boehringer Ingelheim).

Esbriet will cost about $94,000 per year. Ofev will cost $98,000.

Because these two drugs were approved based
on placebo-controlled trials and were not compared with one another, and because there were significant differences in the enrollment criteria of the various clinical trials that led to their approvals, comparison of endpoints is not possible. Pirfenidone's mechanism of action is unknown, but is speculated to interfere with the production of transforming growth factor beta and tumor necrosis factor–α, two proteins involved in how cells grow as well as in inflammation. All told, more than 1,400 subjects have used pirfenidone. Also, more than 170 subjects have been exposed to the drug for more than five years.

Pirfenidone was studied in three clinical trials, including ASCEND, the pivotal trial. The placebo-controlled randomized clinical study leading to approval compared 801 mg (three tablets of 267 mg each) of pirfenidone given orally three times per day with placebo in 555 patients. ASCEND investigators enrolled patients in nine countries and 127 centers.

**Forced vital capacity**

The primary endpoint was a change (at least 10%) in forced vital capacity (FVC). At week 52, 17% of patients receiving pirfenidone showed a 10% or greater decline in predicted FVC, compared with 32% of patients receiving placebo. In addition, nearly a quarter (23%) demonstrated no decline in FVC at week 52, compared with only 10% of those receiving placebo. Survival was evaluated in all three studies. The product’s prescribing information states, “All-cause mortality did not show a statistically significant difference.”

Adverse events that included elevated liver function tests, photosensitivity, and gastrointestinal and skin-related problems were generally mild to moderate in severity, self-limited, and without clinically significant consequence. Of note is that the drug must be titrated upward over 14 days to reach full dosage. Also, if a patient misses more than 14 days of treatment, the patient must retitrate.

The second drug, nintedanib, was studied in 1,231 patients in one phase 2 study and two phase 3 studies. All studies were randomized, double-blind, placebo-controlled trials comparing oral nintedanib 150 mg bid against placebo for 52 weeks. The primary endpoint was the annual rate of decline in FVC.

A statistically significant reduction in the annual rate of decline of FVC was demonstrated in patients receiving nintedanib based on a random coefficient regression model. In the three trials, decline in the nintedanib groups ranged from minus 60 mL to minus 115 mL. In the placebo-treated group, the declines were minus 191 to minus 240, a clinically meaningful difference.

A secondary endpoint, acute IPF exacerbation, defined as worsening or onset of dyspnea, new chest X-ray findings, and/or new HRCT abnormalities, was noted to be significantly reduced in two of the studies but not in the third. All-cause mortality was also assessed but did not show a statistically significant difference.

Safety warnings include elevated liver enzymes and elevation of bilirubin. In addition, gastrointestinal effects were more common in the treated group.

During the past half-century, tremendous knowledge has been gained about the family of lung diseases to which IPF belongs. Neither pirfenidone nor nintedanib has demonstrated survival benefit. Both have demonstrated clinically significant improvement in lung function in this rapidly fatal disease. These changes again provide hope for even more developments in Tomorrow’s Medicine.

Disclosure: Dr. Morrow was employed by Genentech (a wholly owned subsidiary of Roche) from 2006 until May 2014. He was not involved in the clinical trials for Esbriet. InterMune was purchased by Roche in August 2014, after Dr. Morrow departed. He was unaware of any of the negotiations concerning this purchase. He does have Roche stock in his financial portfolio.
Smaller cost increases for states expanding Medicaid under ACA

One place the Affordable Care Act (ACA) is being keenly felt is in Medicaid, where delivery-system improvements occur as enrollment grows, according to a study (http://tinyurl.com/Medicaid-2015) by the Kaiser Commission on Medicaid and the Uninsured (KCMU). Under the ACA, 27 states and the District of Columbia have expanded Medicaid, and it seems to be making fiscal sense.

Even the 23 states not signed up with Medicaid expansion under the ACA are implementing ACA-related changes that require states to “streamline Medicaid enrollment and renewal processes, transition to a uniform income eligibility standard, and coordinate with new ACA insurance marketplaces,” the study says. “State Medicaid officials reported continued growth in managed care initiatives and other delivery-system reforms, including the implementation or expansion of Medicaid health homes, patient-centered medical homes, and initiatives to integrate care and financing for the dual-eligible beneficiaries.”

As the report was released, Diane Rowland, KCMU’s executive director, observed, “Whether a state elected to expand or not, Medicaid programs across the nation are being transformed with new enrollment procedures and outreach efforts combined with increased emphasis on delivery-system reforms.”

Medicaid programs focus on delivery-system reforms

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<tr>
<th>Number of states expanding programs, by fiscal year</th>
<th>2014</th>
<th>2015</th>
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<tbody>
<tr>
<td>Managed care expansions</td>
<td>22</td>
<td>23</td>
</tr>
<tr>
<td>Other delivery-system expansions</td>
<td>30</td>
<td>40</td>
</tr>
<tr>
<td>Home and community-based service expansions</td>
<td>42</td>
<td>47</td>
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The 28 states participating in Medicaid expansion will see increases of 18% in enrollment and 18.3% in total Medicaid spending in fiscal 2015, which for most states ends in July. “The spending growth is mostly driven by the boost in new enrollment that is financed by 100% federal funds,” says the study. The states will spend only about 4.4% more of their own money.

Meanwhile, the 23 states that are not implementing Medicaid expansion can expect state spending to rise 6.8%.

Expansion states to see higher enrollments

Source: Kaiser Family Foundation Commission on Medicaid and the Uninsured, October 2014