By paying members to use lower-cost providers, plans hope to foster competition and reduce prices

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HEART FAILURE SHATTERS MILLIONS OF LIVES

HEART FAILURE PATIENTS: "STABLE" OR SILENTLY PROGRESSING?
Heart failure is a progressive disease that is characterized by frequent hospital admissions and high mortality rates:

>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.5-7

LET'S WORK TOGETHER TO CHANGE THAT

*Additional counterregulatory mediators include adrenomedullin, prostaglandin E2, bradykinin, etc.1

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

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References:
Focus Turns to Payment, Spending

By Peter Wehrwein

Whatever you might think of the ACA as a means, the end was admirable: extending health insurance coverage to millions more Americans through the exchanges and Medicaid expansion. The record is mixed, with beholden often seeing selectively and opining loudly, and the Damocles sword of court rulings still hanging over the five-year-old law’s head. Let’s just stipulate that the mechanics of American health insurance coverage creates a noisy, herky-jerky sort of contraption with many moving parts.

Hang on, it’s a bumpy—and increasingly high deductible—ride.

But now the focus is shifting from coverage to payment and spending. A few weeks ago, HHS Secretary Sylvia Mathews Burwell announced what some are calling health care reform 2.0. Surrounded by representatives of health care’s heavy hitters (Aetna, Anthem, Humana, AHIP, AARP, AHA, AMA), Burwell declared that 30% of Medicare payments will be funneled through ACOs and bundled payments by the end of 2016, and 50% two years later. The secretary said the goal was to have 90% of all Medicare payments tethered to quality metrics of some sort by 2018.

Talking will always be easier than doing. That is a comparison that cynics savor, skeptics attend to, and gullible souls ignore. But payment and spending changes are happening, folks.

In this issue of Managed Care, Senior Contributing Editor Michael D. Dalzell describes an intriguing CMS initiative for chronic care management that unhooks payment to providers from the patient visit. Certainly something fascinating is going on with the country’s health care spending habits. Just read Managing Editor Frank Diamond’s piece in this issue about national health expenditures and the smallest annual increase on record.

They say it’s a curse to live in interesting times. But as the new editor of Managed Care, I couldn’t be happier about covering, with the help of my colleagues, these most interesting times in American health care.
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Dangling Money in Front of Members
Some health plans are paying members to pick lower-cost hospitals, surgical and imaging centers, infusion sites, clinical laboratories, and other care providers. The more these insurers save, the greater the financial incentives they give out.

Welcome to the New Era of Health Care Spending
When the relentless climb crested in 2002, few predicted that we may have turned a corner. Take a good look. Not only are the increases in health care spending getting smaller, but we may eventually be talking about decreases. How will health plans help keep it going?

Another Step Away from Fee-for-Service
CMS is edging away from fee-for-service with chronic care management payments of about $40 per month. Electronic medical record requirements and out-of-pocket costs for beneficiaries may compromise the effectiveness of the well-intended effort.

Weapon for Opioid Overdose May Pay Off
Faster care provided by a new naloxone autoinjector could balance the costs for the devices, according to researchers. Evzio does not require medical training to use.

Editor’s Memo
Blessed to cover interesting times.

News & Commentary
A PCMH works, in a study.

Legislation & Regulation
Death by a thousand cuts for the ACA?

Medication Management
How pharmacy fits into CDHPs.

Biologics in Development
Help on way for Parkinson’s psychosis.

Medical Device Monitor
Two hot issues: registries and taxes.

Tomorrow’s Medicine
New hope for children with TIS.

Ad Index
Mobile devices not yet in doc black bag.

Outlook
Medicare spending slows.
PCMH Finds Success Within Narrow Limits

A patient-centered medical home (PCMH) geared toward children with chronic conditions won health care’s triple crown of improving care and outcomes while lowering costs.

The question: Can this success be broadly replicated? Researchers conceded that better outcomes and savings “seem likely to be achievable only in high-risk populations treated in major academic centers with the subspecialists, resources, and clinician commitment to provide such care.”

Michael Millenson, a quality improvement consultant and a member of Managed Care’s Editorial Advisory Board, points to the red flags about the widespread applicability of PCMHs.

He notes that while the concept has been promoted as an improvement in primary care, the researchers specifically acknowledge that the study’s findings may support the viewpoint of those who “reject the [PCMH] as a generic approach to health care delivery.”

Yet will better care coordination be better for patients than the alternative? Of course, says Millenson.

In the study, the PCMH reduced the number of youngsters with serious illness by 55%. It also reduced total hospital and clinic costs compared with children who received usual care (about $16,500 vs. $27,000 per child-year respectively).

Millenson notes that coordination comes with costs, and this study is an indication that the big-dollar savings from PCMHs may come from better care for the very sick, while most PCMH patients have run-of-the-mill maladies.

The study looked at 201 high-risk children treated at the University of Texas Medical School; 105 were enrolled in a PCMH, and 96 were given usual care. The study ran from March 2011 to February 2013.

Patients were included if, in the previous year, they’d gone to the emergency department three or more times, had two or more hospitalizations, or had one or more admissions into a pediatric intensive care unit.

The PCMH included services from primary care clinicians and specialists...
NEWS & COMMENTARY

with multiple features to promote effective care, according to the study, which was published in the December 24/30 issue of JAMA. Usual care was provided in private offices or faculty-supervised clinics.

PCMHs have been overshadowed recently by ACOs, and there has been some question whether they can deliver on the dollar aspects of the triple aim.

The authors of the JAMA study mentioned that prior studies have found that PCMHs do not save money and that the payments needed to develop and sustain PCMHs may not be forthcoming unless they are shown to improve outcomes with minimal or no increase in costs. That kind of home improvement won't be easy.

Healthy Lifestyle Gets Another Nod

A healthy lifestyle started early can lead to hale and hearty old age for women—with an emphasis on the hearty part, according to a study that tracked nearly 90,000 nurses from 1991 until 2011.

Indiana University researchers looked at six factors known to affect health: smoking, diet, physical activity, television watching, BMI, and alcohol consumption. They found that adherence to a healthy lifestyle drastically lowers coronary heart disease (CHD) and the risk factors for cardiovascular disease. Their results were published in January in the Journal of the American College of Cardiology.

The nurses with the healthiest lifestyle were 90% less likely to experience heart disease than women with the least healthy lifestyles. Part of the reason the researchers conducted this study was that while overall mortality rates from CHD have declined in the last four decades, the drop among people ages 35 to 54 has been smaller. In fact, the researchers note that the mortality rate from heart disease among women ages 35 to 44 years increased an average of 1.3% per year between 1997 and 2002.

Jaundice Treatment Guidelines Reaffirmed

The risk of newborns with jaundice getting a rare form of cerebral palsy is virtually nil if guidelines developed by the American Academy of Pediatrics (AAP) are followed.

Yet the authors of a study in JAMA Pediatrics say the guidelines would benefit from some revision.

High levels of the yellowish pigment bilirubin cause jaundice, but the condition usually disappears without treatment.

If it doesn't, the first-line treatment is phototherapy. If that fails, there's exchange infusion, which involves replacing the infant's blood with donor blood, a procedure that comes with risks of blood clots, bleeding, and blood pressure instability.

Researchers at UCSF Benioff Children's Hospital in San Francisco were especially interested in kernicterus, a neurological disorder triggered by high levels of bilirubin that can cause a rare and life-threatening type of cerebral palsy.

The study involved two groups selected from over 520,000 babies born in 15 hospitals in the Kaiser Permanente Northern California region from 1995 through 2011.

One group included about 1,800 infants with levels of bilirubin above the AAP guidelines. The other included about 100,000 newborns with lower levels. The two groups were followed for seven and six years respectively.

Three newborns with the highest levels of bilirubin had kernicterus,
but they also had other risk factors, including hemolysis or sepsis.

Cerebral palsy caused by kernicterus did not occur in any newborn with high levels of bilirubin without other risk factors being present.

Yvonne W. Wu, MD, MPH, the study leader, said that the current guidelines for when to perform exchange transfusions has prevented kernicterus, but the study results suggest that the threshold for the blood exchange procedure could be higher for infants with high bilirubin levels who are otherwise healthy and who have no other risk factors for brain injury.

**Aetna Promises Pharm Flub Fixed**

Aetna found itself the focus of unwanted attention recently with reports that the health plan misidentified some pharmacies as belonging to its network. Some Aetna members couldn’t get their prescriptions filled.

The National Community Pharmacists Association brought the problem to the public’s attention in December. Aetna responded and corrected the problem soon after.

If the pharmacy was listed incorrectly, Aetna is watching for those claims to ensure that members pay in-network prices, says Cynthia Michener, an Aetna spokeswoman. The company is also contacting members to help them find pharmacies that are, in fact, in the plan’s network.

**Treating Headaches Becomes a Headache**

The use of CTs and MRIs in the workup for headaches more than doubled between 1999–2000 and 2009–2010, according to a study in the Journal of General Internal Medicine.

2009–2010, according to a study in the Journal of General Internal Medicine.

**Medicare Advantage Growth Is a Mix**

The growth in Medicare Advantage (MA) enrollment is coming both from people switching out of traditional Medicare and from beneficiaries new to Medicare, according to a study published in the January 2015 issue of Health Affairs.

In 2011, 52% of new MA enrollees switched out traditional Medicare to join the plans and 48% were newcomers to Medicare who went directly into an MA plan, according to Kaiser Family Foundation researchers.

In past years, the switchers accounted for a greater percentage of new MA enrollees, and the Kaiser researchers reported that the percentage of new Medicare beneficiaries going right into MA has been inching upward, from 15% in 2006 to 22% in 2011.

The researchers also examined the early effect of the ACA on MA. Many predicted that ACA-mandated payment reductions would make MA enrollment decline because the benefit packages would be less rich. The MA plans often include vision and dental benefits and even, for some, gym memberships. But in the early going, that decline didn’t happen.

Some experts argue that the full sting of payment reductions has yet to be felt, thanks to a quality-based demonstration project that ended last year. The project blunted the effects of the payment reductions by increasing the size of bonus payments and extending bonuses to plans rated as average or better, according to the Kaiser researchers.

Despite all the switching into MA, the researchers note that most enrollees have a tendency to stick with their original choice. Gretchen Jacobson, associate director of the Program on Medicare Policy at the Kaiser Family Foundation and lead author of the study, realizes that sounds like a contradiction.

“Only about 5% of people, on average, in traditional Medicare switch to Medicare Advantage. The vast majority of people in traditional Medicare do not make a change,” she tells Managed Care. “However, that 5% is a larger number of people than the number of beneficiaries new to Medicare who enroll directly into Medicare Advantage each year.”

The appeal of MA might be convenience and extra benefits. The appeal of traditional Medicare has been the freedom to choose providers without having to worry about a network.

“For all beneficiaries, the burden of researching new coverage options and making a change, coupled with the fear and uncertainty about the effects of making a change, may be major deterrents to switching,” says the study.

— Frank Diamond

FEEDBACK PLEASE! Send your letters and comments to editors@managedcaremag.com
Introducing the first and FDA-approved treatment for patients with polycythemia vera who have had an inadequate response to or are intolerant of hydroxyurea.

Indications and Usage
Jakafi® (ruxolitinib) is indicated for treatment of patients with polycythemia vera who have had an inadequate response to or are intolerant of hydroxyurea.

Important Safety Information
- Treatment with Jakafi can cause thrombocytopenia, anemia and neutropenia, which are each dose-related effects. Perform a pre-treatment complete blood count (CBC) and monitor CBCs every 2 to 4 weeks until doses are stabilized, and then as clinically indicated.
- Manage thrombocytopenia by reducing the dose or temporarily interrupting Jakafi. Platelet transfusions may be necessary.
- Patients developing anemia may require blood transfusions and/or dose modifications of Jakafi.
- Severe neutropenia (ANC <0.5 X 10^9/L) was generally reversible by withholding Jakafi until recovery.
- Serious bacterial, mycobacterial, fungal and viral infections have occurred. Delay starting Jakafi until active serious infections have resolved. Observe patients receiving Jakafi for signs and symptoms of infection and manage promptly.
- Tuberculosis (TB) infection has been reported. Observe patients taking Jakafi for signs and symptoms of active TB and manage promptly. Prior to initiating Jakafi, evaluate patients for TB risk factors and test those at higher risk for latent infection. Consult a physician with expertise in the treatment of TB before starting Jakafi in patients with evidence of active or latent TB. Continuation of Jakafi during treatment of active TB should be based on the overall risk-benefit determination.
- Progressive multifocal leukoencephalopathy (PML) has occurred with ruxolitinib treatment for myelofibrosis. If PML is suspected, stop Jakafi and evaluate.
- Advise patients about early signs and symptoms of herpes zoster and to seek early treatment.
- When discontinuing Jakafi, myeloproliferative neoplasm-related symptoms may recur within one week. After discontinuation, some patients with myelofibrosis have experienced fever, respiratory distress, hypotension, DIC, or multi-organ failure. If any of these occur after discontinuation or while tapering Jakafi, evaluate and treat any intercurrent...
In a phase 3 trial of Jakafi® (ruxolitinib) vs best available therapy:

21% of patients receiving Jakafi achieved the primary composite end point of hematocrit (Hct) control and spleen volume reduction compared with <1% of patients on best available therapy at week 32 (*P* < 0.0001).

Jakafi is a registered trademark of Incyte Corporation.

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Visit www.jakafi.com/HCP to see Full Prescribing Information and learn more about Jakafi for use in PV illness and consider restarting or increasing the dose of Jakafi. Instruct patients not to interrupt or discontinue Jakafi without consulting their physician. When discontinuing or interrupting Jakafi for reasons other than thrombocytopenia or neutropenia, consider gradual tapering rather than abrupt discontinuation.

- Non-melanoma skin cancers including basal cell, squamous cell, and Merkel cell carcinoma have occurred. Perform periodic skin examinations.
- The three most frequent non-hematologic adverse reactions (incidence >10%) were bruising, dizziness and headache.
- A dose modification is recommended when administering Jakafi with strong CYP3A4 inhibitors or fluconazole or in patients with renal or hepatic impairment. Patients should be closely monitored and the dose titrated based on safety and efficacy.
- Use of Jakafi during pregnancy is not recommended and should only be used if the potential benefit justifies the potential risk to the fetus. Women taking Jakafi should not breast-feed.

* A randomized, open-label, active-controlled phase 3 trial comparing Jakafi with best available therapy in 222 patients. Best available therapy included hydroxyurea (60%), interferon/pegylated interferon (12%), anagrelide (7%), pipobroman (2%), lenalidomide/thalidomide (5%), and observation (15%). The primary end point was the proportion of subjects achieving a response at week 32, with response defined as having achieved both Hct control (the absence of phlebotomy eligibility beginning at the week 8 visit and continuing through week 32) and spleen volume reduction (a ≥35% reduction from baseline in spleen volume at week 32). Phlebotomy eligibility was defined as Hct >45% that is ≥3 percentage points higher than baseline or Hct >48% (lower value).


Visit www.jakafi.com/HCP to see Full Prescribing Information and learn more about Jakafi for use in PV
Ruxolitinib is a Janus kinase (JAK) inhibitor approved for the treatment of patients with polycythemia vera (PV) and myelo-/f_ibrosis (MF). The use in patients with PV has been associated with an increased risk of serious infections, serious skin/soft tissue infections including necrotizing fasciitis, and deaths due to infections.

**Dosage and Administration**

Ruxolitinib is administered orally as tablets. The recommended dose for patients with PV is 15 mg orally twice daily (BID) after a meal, or 20 mg BID on an empty stomach. The recommended dose for patients with MF is 20 mg BID after a meal.

**Adverse Reactions**

The most common adverse reactions (≥20%) in patients with PV were nausea, diarrhea, hepatomegaly, edema, epistaxis, hematoma, increased tendency to bruise, petechiae, purpura, rash, rash macular, rash papular, rash urticarial, arthralgia, and arthralgia (N=155).

**Laboratory Abnormalities**

Table 4: Polycythemia Vera: Selected Laboratory Abnormalities in the Open-Label, Active-controlled Study Up to Week 12 of Randomized Treatment

<table>
<thead>
<tr>
<th>Laboratory Parameter</th>
<th>Grade 1 Events</th>
<th>Grade 2 Events</th>
<th>Grade 3 Events</th>
<th>Grade 4 Events</th>
<th>Total Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anemia</td>
<td>58</td>
<td>0</td>
<td>12</td>
<td>2</td>
<td>144</td>
</tr>
<tr>
<td>Hypertriglyceridemia</td>
<td>15</td>
<td>0</td>
<td>0</td>
<td>13</td>
<td>28</td>
</tr>
<tr>
<td>Elevated ALT</td>
<td>25 &lt;1</td>
<td>0</td>
<td>0</td>
<td>16</td>
<td>41</td>
</tr>
<tr>
<td>Platelet counts</td>
<td>96</td>
<td>34</td>
<td>11</td>
<td>87</td>
<td>162</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>7</td>
<td>0</td>
<td>6</td>
<td>&lt;1</td>
<td>14</td>
</tr>
<tr>
<td>Asthenia</td>
<td>7</td>
<td>0</td>
<td>11</td>
<td>2</td>
<td>20</td>
</tr>
<tr>
<td>Bilirubin ALT</td>
<td>3</td>
<td>3</td>
<td>1</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>15</td>
<td>5</td>
<td>15</td>
<td>0</td>
<td>35</td>
</tr>
<tr>
<td>Platelet count</td>
<td>15</td>
<td>0</td>
<td>0</td>
<td>13</td>
<td>28</td>
</tr>
</tbody>
</table>

**Pharmacokinetics**

The exposure of ruxolitinib was evaluated in a study in healthy subjects (N=8) and in subjects with mild [CrCl 53-83 mL/min (N=8)], moderate [CrCl 38-57 mL/min (N=8)], or severe (CrCl ≤38 mL/min) renal impairment. The safety and tolerability of ruxolitinib was also evaluated in a study in patients with polycythemia vera receiving ruxolitinib at a dose of 20 mg BID (N=155).

The clearance of ruxolitinib was lower in patients with severe renal impairment compared to healthy controls (4.1-5.0 hours versus 2.8 hours). The change in the plasma half-life of ruxolitinib was 2.9 hours in healthy controls and 8.8 hours in subjects with severe renal impairment. The exposure of ruxolitinib was increased 33% and 91%, respectively following concomitant administration with the strong CYP3A4 inhibitor, ketoconazole (200 mg BID for 8 days) and the moderate CYP3A4 inhibitor, itraconazole (200 mg BID for 14 days). The clearance of ruxolitinib was lower in patients with severe hepatic impairment compared to healthy controls (4.1-5.0 hours versus 2.8 hours). The change in the plasma half-life of ruxolitinib was 2.9 hours in healthy controls and 8.8 hours in subjects with severe hepatic impairment.

**Drug Interactions**

Avoid the concomitant use of ruxolitinib with strong CYP3A4 inhibitors including ritonavir, atazanavir, and azole antifungals. Concomitant use of ruxolitinib with weak or moderate CYP3A4 inhibitors did not result in an effect on the pharmacokinetics of ruxolitinib. Concomitant use of ruxolitinib with strong or moderate CYP3A4 inducers such as rifampin, rifabutin, or carbamazepine did not result in a significant effect on the pharmacokinetics of ruxolitinib.

**Pediatric Use**

The safety and pharmacokinetics of single dose ruxolitinib (25 mg) were evaluated in a study in healthy subjects (N=8) and in subjects with mild [CrCl 53-83 mL/min (N=8)], moderate [CrCl 38-57 mL/min (N=8)], or severe renal impairment (CrCl ≤38 mL/min). In all subjects with early stage renal disease, a dose reduction is recommended [see Pharmacokinetics (12.3)]. In subjects with advanced or terminal renal disease, a dose reduction is recommended [see Pharmacokinetics (12.3)].

**Nursing Considerations**

Infants and nursing mothers receiving ruxolitinib are at risk for significant adverse effects on the fetus. The risks and benefits of ruxolitinib use should be considered in all pregnant women. The use of ruxolitinib in pregnancy is not recommended due to the potential for harm to the developing fetus. If a woman becomes pregnant while taking ruxolitinib, she should discontinue the drug until the pregnancy is terminated.

**Contraindications**

Ruxolitinib is contraindicated in patients with active tuberculosis or other active infections, including fungal infections. Do not administer ruxolitinib to patients with active tuberculosis or other active infections. Patients with active tuberculosis or other active infections should be treated with an appropriate anti-infective agent before starting ruxolitinib.

**Warnings and Precautions**

The safety and effectiveness of ruxolitinib has not been established in patients under 18 years of age. The safety and effectiveness of ruxolitinib have not been established in patients with serious infections. Patients with serious infections should be managed appropriately before starting ruxolitinib.
Kazaki

BRIEF SUMMARY: See Full Prescribing Information. See package insert.

CONTRAINDICATIONS

WARNINGS AND PRECAUTIONS: Thrombocytopenia, Anemia and Neutropenia Treatment with Jaka/f_i can cause thrombocytopenia, anemia and neutropenia (See Clinical Studies (14.2) in Full Prescribing Information). Manage thrombocytopenia by reducing the dose or temporarily interrupting Jaka/f_i. Manage anemia and neutropenia by reducing the dose or temporarily interrupting Jaka/f_i (See Clinical Studies (14.2) in Full Prescribing Information). Patients developing anemia may require transfusion of sickle cell traits or severe sickle cell disease. Seven non-melanoma skin cancers including basal cell, squamous cell, and Merkel cell cancers have occurred in patients treated with Jaka/f_i. Non-melanoma skin cancers including basal cell cancer, squamous cell cancer, and Merkel cell carcinoma have occurred in patients treated with Jaka/f_i. Patients with pancreatic exocrine insufficiency may experience greater severity in the duration of treatment. Thrombotic events including cerebrovascular accident (requiring hospitalization), deep vein thrombosis, and pulmonary embolism have been observed in patients treated with Jaka/f_i. Because adverse events associated with thromboembolic events are generally reversible with dose reduction or dose interruption, thromboembolic events should be managed by reducing the dose or temporarily interrupting treatment. Non-Melanoma Skin Cancer: The safety of Jaka/f_i was assessed in 617 patients in clinical studies with a median duration of treatment of 31 months. Non-melanoma skin cancers including basal cell cancer, squamous cell cancer, and Merkel cell carcinoma have occurred in patients treated with Jaka/f_i. The efficacy and safety of Jaka/f_i for the treatment of non-melanoma skin cancers including basal cell cancer, squamous cell cancer, and Merkel cell carcinoma have not been studied in patients with non-melanoma skin cancers. Non-Melanoma Skin Cancer in Previously Treated Patients: Jaka/f_i was evaluated in a study of previously treated patients with non-melanoma skin cancers including basal cell cancer, squamous cell cancer, and Merkel cell carcinoma. The efficacy and safety of Jaka/f_i for the treatment of non-melanoma skin cancers including basal cell cancer, squamous cell cancer, and Merkel cell carcinoma have not been studied in previously treated patients. Non-Melanoma Skin Cancer in Previously Treated Patients: Jaka/f_i was evaluated in a study of previously treated patients with non-melanoma skin cancers including basal cell cancer, squamous cell cancer, and Merkel cell carcinoma. The efficacy and safety of Jaka/f_i for the treatment of non-melanoma skin cancers including basal cell cancer, squamous cell cancer, and Merkel cell carcinoma have not been studied in previously treated patients.

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Table 2: Myelofibrosis: Worst Hematology Laboratory Abnormalities in the Placebo-Controlled Study

<table>
<thead>
<tr>
<th>Abnormality</th>
<th>Grade 1</th>
<th>Grade 2</th>
<th>Grade 3</th>
<th>Grade 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anemia</td>
<td>72</td>
<td>&lt;1</td>
<td>&lt;1</td>
<td>0</td>
</tr>
<tr>
<td>Eosinophilia</td>
<td>37</td>
<td>&lt;1</td>
<td>&lt;1</td>
<td>0</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>23</td>
<td>&lt;1</td>
<td>&lt;1</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 4: Polycythemia Vera: Selected Laboratory Abnormalities in the Open-Label, Active-controlled Study

<table>
<thead>
<tr>
<th>Abnormality</th>
<th>Grade 3</th>
<th>Grade 4</th>
<th>Grade 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin</td>
<td>20</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
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<tr>
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<tr>
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<tr>
<td>Eosinophilia</td>
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<th>Abnormality</th>
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The Republican-controlled Congress hadn’t even been in session two days when it landed its first blow in its much-publicized effort to dismantle the ACA. The House passed legislation to redefine a full-time employee eligible for employer-provided health insurance from one who works 30 hours a week to 40 hours. A few hours later, despite the threat of a presidential veto, Senate leader Mitch McConnell of Kentucky said there was no chance that the Senate would bypass the vote, setting up a showdown with President Obama and a contentious tone for the politics swirling around his signature legislation.

Meanwhile, the Supreme Court has on its docket King v. Burwell, which challenges the legality of tax credits for people who purchase health insurance in states that didn’t set up their own exchanges but used the federal version instead. If the court upholds this key component of the law, it would be a victory for Obama and the ACA. Efforts to repeal the legislation might still gather steam, but the chances of them succeeding are slim to none. Obama would veto any repeal legislation, and Republicans in the Senate will have a hard time prying away enough Democratic and independent votes to override his veto.

Short of repeal, the parts of the ACA most vulnerable to legislative meddling, besides the redefinition of full-time employment, include risk corridor payments to health plans and the tax on medical devices.

**Court to decide fate of tax credits**

The defining 2015 event for the ACA is likely to be King v. Burwell. Thirty-six states and the District of Columbia use the federal exchange. The court will hear the case in March with a decision expected by July 4.

This summer could be the make-it or break-it season for the health care law in many ways. Budget reconciliation is one tool Republicans have at their disposal to dismantle key components of ACA. Jeffrey H. Anderson, executive director of Project 2017, a conservative group that has devised a Republican alternative to the ACA, says his sources tell him that anti-ACA legislation through budget reconciliation process won’t be ready until summer. Obviously, the legislative strategy will change dramatically if the Supreme Court finds in favor of the plaintiffs and strikes down the ACA tax credits for people who bought insurance through the federal exchanges.

**Supreme Court tea leaves**

Prognosticating Supreme Court rulings is a science as precise as predicting who will win the next World Series, but Nicholas Bagley has tried. Bagley is a professor at University of Michigan Law School who writes extensively on health care policy, including a piece on King v. Burwell in the Dec. 24, 2014, issue of the New England Journal of Medicine.

The challenge to the tax credits turns on language within the ACA that limits tax credits to people who purchase coverage in exchanges established by the state. The ACA, when read as a whole, is best understood to extend tax credits to all states whether they have state-created exchanges or they use the federal backstop, argues Bagley: “The construction of the act that would deny tax credits to federally established exchanges runs counter to a whole lot of statutory clues about what Congress meant the statute to accomplish.”

A high court ruling striking down the federal-exchange subsidies would, obviously, have a far-reaching impact. Americans stand to lose $65 billion in tax credits, according to a staff report from House Democrats. The Kaiser Family Foundation has reported more than 13 million people could lose subsidies in 2016.
It’s Bagley’s prediction that if insurance tax credits in states using the federally established exchanges were eliminated, only the very sickest people would retain their insurance because healthy people would flee the market after seeing the price for insurance spike. He foresees the price of premiums on the exchanges doubling or even tripling and large numbers of people leaving the exchange market. A Rand Corp. report calls this scenario a “near death spiral” for the ACA.

A court ruling striking down tax credits on the federal exchanges would raise a host of questions about when those credits would end, notes Anderson of the 2017 Project. Would they be allowed to flow through the rest of the year, or be cut off immediately? More importantly, in Anderson’s view, a court ruling against the tax credits would create a situation in which the heart of the ACA—the exchanges, tax credits, broader insurance coverage—would only be working in 14 states.

In his blog, Commonwealth Fund President David Blumenthal, MD, noted that full repeal of the ACA is unlikely as long as Obama remains in the White House. Look for more targeted attacks—possibly through the budget reconciliation process—to gain some traction, he said. Budget reconciliation requires only 51 Senate votes to advance legislation germane to the federal budget.

A prominent target as far as health insurers are concerned is the funding of risk corridors. The program transfers money from commercial insurers who participate in the exchanges and turn a profit to plans that suffer losses, a scheme Republican Sen. Marco Rubio of Florida has derided as a “bailout.” The Government Accountability Office issued a legal opinion last year that concluded the Department of Health and Human Services would need an additional appropriation in fiscal year 2015 to make payments for the 2014 plan year. The omnibus spending bill passed in December scratched that appropriation from the budget, but HHS still can make allocations in the risk-corridor program in a budget-neutral fashion.

“Real money” is at stake
Not surprisingly, insurers are resisting efforts to dismantle the risk corridors. Getting rid of risk corridors will lead to higher premiums, says Clare Krusing, a spokeswoman for America’s Health Insurance Plans. The focus, she says, should be on changes to the law that will lower costs, like getting rid of the health insurance tax.

The health insurance tax generated about $8 billion in revenue last year, according to AHIP, and would increase to $14.3 billion in 2018. The nonpartisan congressional Joint Committee on Taxation estimated that it would generate $100 billion over 10 years. Two years ago, Rep. Charles Boustany, a Louisiana Democrat, sponsored legislation to delay the tax for two years, but the provision remains in the ACA. (Boustany, incidentally, has sponsored the latest bill to repeal the ACA’s employer mandate.) Whether repeal of the tax gets resurrected in the new Congress remains to be seen.

The 2.3% tax on medical devices had been projected to raise $29.1 billion to help fund the ACA over 10 years, but it has fallen short of its revenue target and has been problematic for the IRS to collect, according to a Treasury Department report. Repeal of the tax on medical devices has bipartisan appeal; liberal Democrats like Elizabeth Warren of Massachusetts and Al Franken of Minnesota, representing states with a strong presence of medical device companies, have joined more conservative colleagues in calling for its repeal. Senate Finance Chairman Orrin G. Hatch told CQ Roll Call he would try to move early on the medical device tax in the new Congress.

All of these maneuvers would have a significant impact on the function and funding of the ACA. Larry Leavitt, a Kaiser Family Foundation executive, has cited Congressional Budget Office estimates that the change in the definition of full-time employment from 30 to 40 hours-a-week would cost the federal budget $53.2 billion over 10 years because fewer penalties would be collected and more Americans would get coverage through Medicaid, the Children’s Health Insurance Program, and the health insurance exchanges. When you consider the $65 billion in tax credits in peril in King v. Burwell and the other sums at stake, it makes one think of the late Sen. Everett Dirksen’s observation: “A billion here and a billion there, and pretty soon you’re talking about real money.” Congress may not be able to kill the ACA with one shot, but it can hurt it with a multitude of cuts of a billion here and a billion there.
Don’t Overlook Importance Of Pharm Benefits in CDHPs

Value-based benefit design could go a long way in managing chronic conditions. Most employers have ignored this option so far.

By Thomas Reinke

Consumer-directed health plans (CDHPs) have moved out of the shadows of PPO and HMO plans and into the forefront of employer strategies for health care benefits. “Large employers are offering CDHPs or, in some cases, replacing their PPO and HMO plans because they are concerned about constantly rising health care costs and the upcoming Cadillac tax,” says Cheryl Larson, a vice president at the Midwest Business Group on Health. The so-called Cadillac tax, an ACA-mandated excise tax on health plans with rich benefits and certain early retiree plans, is scheduled to take effect in 2018. Larson says that employers who are subject to the ACA’s mandatory coverage requirements favor CDHPs because from the employer’s point of view, they are less expensive than PPO and HMO plans.

Mercer, the human resources consulting company, reported last year that 23% of employees are now covered by CDHPs, up from 18% a year ago. Larson says the majority of her group’s members—generally large employers—offer a CDHP, and a small number have fully replaced their other plans with CDHPs. These CDHPs plans typically combine high deductible coverage with either a health savings account or a health reimbursement account.

The National Pharmaceutical Council (NPC), a health care policy research organization supported by research-based biopharmaceutical companies, and the Benfield Group, a health care research and strategy company, recently surveyed employers about their CDHPs with a focus on best practices in pharmacy benefits. Given the growing importance of CDHPs in the eyes of employers, the NPC report suggests that employers need to be more attuned to the health, productivity, and longer-range cost implications of their CDHP offerings, says Kimberly Westrich, vice president of health services research at NPC.

The report’s cautionary tale is that certain employees—particularly those with high health care needs and low incomes—may wind up with financial burdens that cause them to avoid getting appropriate health care services or taking prescribed medications.

Preventive drug lists could be longer

In the NPC survey, of the employers using CDHPs, twice as many offer health savings accounts than offer health reimbursement accounts. Employees fund health savings accounts with pretax dollars, and employers often contribute as well. With health reimbursement accounts, employers reimburse employees for expenses. Prescription drugs in the savings accounts, except for preventive medications, are subject to the high deductible that employees must meet for their medical expenses. The reimbursement accounts may incorporate the typical pharmacy benefit card found in PPO plans. Chuck Reynolds, president of employer practice at the Benfield Group, says that benefit consultants have developed a standardized approach to help their clients achieve key goals of containing costs and getting employees more engaged in health care decisions without too much employee disruption and dissatisfaction. But Reynolds says there’s room for improvement. One common shortcoming: missing the opportunity to list more preventive drugs that are outside of a health plan’s deductible. The IRS has issued guidelines for defining preventive medications. Many experts contend the guidelines are vague, so there’s room for interpretation about what constitutes a preventive medication.

“We think there are opportunities to engage employers in more thorough analysis and planning for the preventive medications,” says Reynolds. Just over half of employers in the NPC survey have expanded lists. The IRS imposes penalties on prescription...
Employers need to be more attuned to the long-range cost and health implications of CDHPs, says Kimberly Westrich of the National Pharmaceutical Council.

Strategies for specialty medications are also lacking. The NPC report says the attitude seems to be that people taking those drugs will hit their deductible and out-of-pocket maximum anyway, so no special strategy is needed.

Another shortcoming in the design of CDHPs is overlooking the role of value-based features, which involve members with chronic diseases paying nothing or only small copayments for certain medications as a way to encourage adherence. CDHPs are candidates for creative value-based features for prescription drugs because of the increased financial responsibility they place on members. The NPC report indicates that only 31% of employers used a value-based design approach for prescription medications.

Many different value-based features can be included in CDHPs to promote healthy behaviors or minimize employee costs, says Westrich. One of the simplest: no copayment for drugs on the preventive drug list. Another possibility is tailoring value-based features so they fit the health profile of the employees of a particular company.

Clearer communication needed
Some employers also are linking health savings account contributions to wellness programs, says Reynolds. For example, the amount an employer contributes to an employee’s account may be raised to encourage program participation or behaviors that could lead to improvements in cholesterol levels, blood pressure, BMI, and the like.

But financial burden that lower-income workers face is a key issue with CDHPs. Larger contributions to the health savings accounts of lower-income employees is one tactic, but it doesn’t completely solve the problem.

Communication with plan members is extremely important with CDHPs, and health plans should be doing more of it, says Larson. Some members don’t get preventive care because they don’t realize they can get it at no out-of-pocket cost. Some providers may also not know that preventive care is covered outside of the deductible.

“We have to understand that there are issues of benefit literacy,” says Larson. “Plan documents need to be as clear and simple as possible.”

Employers are feeling their way toward approaches to pharmacy management in consumer-directed health plans (CDHPs). Although CDHPs could reap benefits from the value-based design, relatively few employers have taken that approach. Those who have focus on conditions most likely to affect productivity, such as diabetes and asthma.

<table>
<thead>
<tr>
<th>Conditions for which employers use value-based designs for medications</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>Diabetes</td>
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<tr>
<td>Asthma</td>
<td>100%</td>
<td>0%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>80%</td>
<td>20%</td>
</tr>
<tr>
<td>High cholesterol</td>
<td>80%</td>
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<tr>
<td>Cardiovascular disease</td>
<td>70%</td>
<td>30%</td>
</tr>
<tr>
<td>COPD</td>
<td>70%</td>
<td>30%</td>
</tr>
<tr>
<td>Smoking cessation</td>
<td>60%</td>
<td>40%</td>
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<tr>
<td>Depression</td>
<td>40%</td>
<td>60%</td>
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<tr>
<td>Other</td>
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<td>80%</td>
</tr>
<tr>
<td>Obesity</td>
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Hallucinations and delusions are common in people with Parkinson’s disease, but many antipsychotic drugs are either ineffective or worsen motor symptoms. With phase 3 testing of pimavanserin (Nuplazid) completed, Acadia Pharmaceuticals hopes to change that.

In the so-called -020 Study, which enrolled 199 patients with Parkinson’s disease psychosis (PDP), pimavanserin met its primary endpoint in significantly reducing psychosis vs. placebo and reached a key secondary endpoint for motoric tolerability. Results were published in Lancet. With a first-quarter regulatory filing planned, Acadia could have the first FDA-approved drug to treat PDP on the market by the end of 2015.

In the pipeline
Immunomedics/UCB is wrapping up two pivotal studies for epratuzumab, a humanized monoclonal antibody that targets CD22 receptors on B lymphocytes. Epratuzumab is being studied in patients with severe lupus. The primary endpoint of both trials is the percentage of subjects meeting treatment response criteria at Week 48. Early results showed a response rate of over 50% at the 12-week point, with reductions in patients’ need for concomitant corticosteroids.

Radius Health reported positive 18-month data for abaloparotide-SC, an investigational treatment for reducing fractures in postmenopausal women with osteoporosis. In the ACTIVE trial, abaloparotide-SC demonstrated an 83% greater reduction in incident vertebral fractures than placebo.

Nivolumab (Opdivo, see table) and pembrolizumab (Keytruda), both FDA-approved in the last four months of 2014, are in a race to win market share for patients with advanced melanoma. Both drugs unblock the PD-1 pathway to allow the human immune system to attack tumor cells, but how well—and how dependably—still needs to be figured out. Interim data from phase 3 trials of both drugs in patients with lung cancer are expected soon and may provide some answers.

Stem cell therapies advance
Francesco Petrella, MD, at the European Institute of Oncology, in Italy, reported that researchers had repaired a fistula in a patient’s lower airway using stem cells derived from the patient’s own bone marrow. A 42-year-old firefighter had developed the fistula after surgeons removed a lung as part of treatment for mesothelioma. Sixty days after the firefighter’s stem cell therapy, the hole was no longer visible, said Petrella, who believes this same technique may be used to treat fistulas elsewhere in the body. Petrella described the case in a letter published in the Jan. 1 issue of the New England Journal of Medicine.

Immunosuppressive therapy for relapsing-remitting multiple sclerosis (RRMS), coupled with transplantation of a patient’s blood-forming stem cells, may provide sustained remission. Three years into a study of 25 patients who received high-dose immunosuppressive therapy and autologous hematopoietic cell transplant (HDIT/HCT), nearly 80% had no increase in disability, symptom relapse, or brain lesions. The results are reported online in JAMA Neurology on Dec. 29.

Have you heard?
The FDA has changed labeling on tbo-filgrastim to allow self-administration. Until late December, Secor Biotech’s product, which stimulates production of neutrophils, required administration by a health care professional. The drug was approved in the United States under its own biologics license application, but it is classified in Europe as a biosimilar to Amgen’s Neupogen.

OncoGenex Pharmaceuticals has signed an agreement with Teva to regain rights to custirsen, now in phase 3 development. Custirsen blocks production of the protein clusterin, which may play a role in cell survival and treatment resistance.
tance in patients with prostate and lung cancers. By inhibiting clusterin, the drug could slow tumor growth to allow therapies to be more effective. Data from the AFFINITY and ENSPIRIT trials are expected late this year or early 2016.

With the goal of gaining a better understanding of disease and dysfunction, the NIH has awarded more than $28 million in grants to researchers to study how and when human genes are turned on and off. The grants fall under the Genomics of Gene Regulation Program at the National Human Genome Research Institute. Recipients include Memorial Sloan Kettering Cancer Center, Duke University, University of Massachusetts Medical School, Stanford University, and University of California–Los Angeles.

— Katherine T. Adams

Note: All clinical studies mentioned in this article are phase 3 unless otherwise indicated.
Money has another job. It’s still the root of all evil, but it’s taken on a new role lately as a tool for health plans to steer member choices.

By paying members to choose low-cost, in-network hospitals, surgical and imaging centers, infusion sites, clinical laboratories, and other care providers, health insurers have increased members’ level of engagement and fostered competition among providers. In turn, providers are lowering their prices, health plan executives say.

In New England, three plans are paying members who choose low-cost providers through the use of tools that are online, in smartphone apps, and available through 800 numbers. The plans are writing checks of $10 to $500 or more to members who shop and buy based on price. The more health plans save, the more they pay out in financial incentives.

Since 2010, Anthem Blue Cross and Blue Shield in New Hampshire has generated a return of at least $3 for every $1 it has invested in its SmartShopper program, which pays members to use lower-cost services. Harvard Pilgrim Health Care figures it saved $500,000 since 2012 by cutting checks for members who pick low-cost hospitals, outpatient surgery centers, clinical laboratories, or imaging facilities. In October, another Massachusetts health insurer, Fallon Health, started dangling financial incentives to foster cost consciousness among members.

Bluegrass Family Health, a not-for-profit insurer headquartered in Lexington, Ky., has been offering financial incentives since 2011. Within three months of starting the program, Bluegrass saved more than $1,000 every time it wrote an incentive check, says Garry Ramsey, the plan’s chief marketing officer.

Just before the 2014 winter holidays, an employee of the University of New Hampshire cashed a check for $800 because she used a low-cost imaging provider. Her employer contracts with a vendor that coaxes workers and their family members into using hospitals, physicians, and other providers with lower prices. The university typically writes checks of $10 to $150 when members choose the lowest-cost services, but for any test or procedure over $3,000, it pays 20% of the savings. In this case, the university saved $4,000—$3,200 after it paid the employee—when the worker picked the lowest-cost imaging center, says Amy Schwartz, EdD, director of health care cost containment for New Hampshire’s public universities and colleges.

Disruptive innovation

Using financial incentives to guide people’s health choices is nothing new. Americans have gotten used to tiers in pharmacy benefit plans and higher coinsurance if they use out-of-network providers. But these new programs are tapping into the part of the human psyche that makes discrete financial rewards disproportionately powerful. If timed right and made explicit, a small amount of money can light up the brain’s reward systems and make a big difference in the choices we make.

Recognizing that plan members respond positively to rewards, health plans are using that leverage to their advantage. One vendor managing financial incentive programs for health insurers claims his client health plans get $6 to $7 back for every dollar they spend on financial incentives.

That’s a pretty nice rate of return. In addition, health plans and employers are getting a more significant benefit: Financial incentive programs disrupt well-worn referral patterns, causing high-cost providers that lose market share to lower their prices. When enough patients venture over to alternative providers, hospitals and physicians take notice.

Lisa Guertin, president of Anthem Blue Cross and
Blue Shield in New Hampshire, says the financial incentive her company uses is partly responsible for hospitals and physicians changing their rates to stay competitive. Some new services have also been developed, such as ambulatory surgery centers.

For health plans, this strategy of paying financial incentives is attractive because prices for common procedures and tests vary widely. In central Massachusetts, the price of arthroscopic knee surgery can range from $3,472 to $20,173, according to Fallon’s online SmartShopper tool. That means the aging tennis player or runner with bad knees could save the health plan more than $16,000 by choosing a low-cost surgeon for knee surgery instead of a high-cost one. The price range for an MRI of the knee goes from $322 to as much as $4,008, according to Fallon’s online tool. If one skier falls and hurts her knee this winter and decides to go to the low-cost facility, that saves Fallon about $3,700. Considering only cost, a $150 incentive check is worth it if it induces that skier to get the $322 MRI.

Fallon officials say some services, like MRIs, were included in the program because there’s plenty of price variation, and members seem willing to shop for them. Emergency procedures like appendectomies aren’t included because no one can shop in advance for them. The health plan included some services, like caesarean sections, that are sensitive. It might seem crass to have women shop around for a less expensive caesarean section. Ultimately, though, Fallon decided that they should be included as part of a general move toward greater price transparency in health care.

**Health plans are using financial incentives to encourage members to pick lower-cost providers. Some worry that cutting checks will crowd out quality.**

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**Price vs. value**

But too much bargain hunting could be dollar wise and thousands of dollars foolish. “Paying health plan members incentives to use low-cost providers, without consideration to quality, could end up costing everyone more,” warns Suzanne Delbanco, executive director of Catalyst for Payment Reform, a group supported by foundations and large health care purchasers. Direct financial incentives to use low-cost providers could make members suspicious of health plans and feed beliefs that they are concerned only with lowering the cost of health care, she adds: “It takes two dimensions for a health care provider to deliver care with good value: high quality and affordable prices.”

Choosing hospitals or physicians based only on price is the wrong way to go, according to A. Mark Fendrick, MD, director of the University of Michigan Center for Value-Based Insurance Design. Instead, health plans should form networks of providers that have lower rates of avoidable events that can dramatically increase costs, such as postoperative infections and hospital readmission rates, he says.

David T. Przesiek, Fallon’s senior vice president and chief sales officer, counters that if providers are in the health plan’s network, then Fallon knows they meet a certain level of quality. The age of the consumer has finally come to health plans, Przesiek says. “People want the buying tools that they get from everybody else, whether it’s retail or online.”

When Fallon asked members what shopping tools they wanted, the responses were clear: They wanted it to be as easy as buying on Amazon.

Fallon officials say, yes, for sure, the health plan does save money when its members respond to the financial incentives. But the question is whether the quality is as good. “For years, consumers paid only a copayment and had no idea what the true charges were behind the scenes,” says Lisa Guertin, president of Anthem Blue Cross and Blue Shield in New Hampshire. Financial incentives help address that problem.
carrot of financial incentives and select low-cost options. But savings for a not-for-profit insurer like Fallon result in lower premiums and better benefits, they say.

Many health plans wave the flag of transparency. But Delbanco’s organization has found that remarkably few—only 2%—of health plan members are checking prices using the tools that plans provide. Insurers need to do a lot more work engaging their members to understand that price and quality vary and that tools exist to help them make better choices, she says.

Here’s our number, call us maybe

Member engagement is one of the main goals for Harvard Pilgrim’s shopping tool, called SaveOn, says Rebecca Robak, the health plan’s senior product portfolio manager. It also saves Harvard Pilgrim money. SaveOn has generated savings of $500,000 for 2012 and 2013, although that’s before the financial incentives were paid out, according to Robak. Next to Harvard Pilgrim’s expenditures, that is not a lot of money. The real value, says Robak, lies in the engagement of members and the decisions they will make in the future after their first experience with the incentive program.

Here’s how SaveOn works: A member considering any service, apart from behavioral health care or medications, can call the SaveOn service to find a low-cost provider, but Robak says the service is for outpatient services only because “we don’t want to interfere with the patient–physician relationship.” Nurses who work for a company called Tandem Care answer the phones. If members are already scheduled to see a low-cost provider, they get a $10 check just for calling. If they switch from a high-priced to a low-priced provider, they will get a check for between $10 and $75, depending on how much the plan saves. Yet the member is under no obligation to switch.

Like Fallon, Harvard Pilgrim providers must meet a quality threshold to be in the health plan’s network. Tandem nurses are prepared to discuss provider quality ratings from sources such as Leapfrog and Hospital Compare.

If a member does decide to switch, the SaveOn nurse goes into action, booking a new appointment, calling the member’s doctor to inform her that her patient is going to a lower-cost provider, and making sure health records get to the new provider.

Paying beneficiaries to use low-cost providers while ignoring quality isn’t the way to go, says Suzanne Delbanco, executive director of Catalyst for Payment Reform.

After prior authorization, a text

Vital’s SmartShopper, formerly owned by Compass Healthcare Advisers, developed Fallon’s online shopping tool. It goes a step further by calling members scheduled for imaging. Using the information it gets from radiology management companies, Vitals knows when members of its client health plans are scheduled for radiology services. The company contacts members to let them know about lower-cost options, says Rob Graybill, vice president of SmartShopper for Vitals.

Similar to what SaveOn does, the company representatives cancel the appointment with the high-cost provider, notify the physician of the member’s decision to switch, set up a new appointment, and update the authorization so the claim processes correctly. Graybill says more than 80% of the members who are contacted wind up going to lower-cost imaging centers.

Like many health plans, Bluegrass Family Health requires patients to get preauthorization for high-cost imaging, such as MRIs and CT scans. But along with approving the service, the health plan sends a text message saying the member is eligible for a
financial reward for choosing a low-cost radiology provider. “Then, as soon as possible before they have the service, we call them to explain the reward system,” says Ramsey, the Bluegrass marketing officer.

New normal
For Graybill, financial incentives and price transparency have a growing influence on hospital and physician pricing. “We’ve seen hospital systems, independent physicians, and other providers go back to their insurance companies and offer lower rates in order to compete with other hospitals or other physicians nearby,” he says. In the past, the low-cost providers in any market didn’t have much of an advantage because Americans didn’t usually shop for health care on price. Graybill says that’s changing with high deductible coverage and use of financial incentives.

Robak, at Harvard Pilgrim, says price sensitivity is slowly taking hold in health care. “When we introduced the SaveOn program, we assumed it would be disruptive because we were redirecting patients to other providers,” she says. “Now that so many patients are shopping based on price, the hospitals and other providers are lowering their costs so that they can compete.”

Eve Oyer, president of benefits management for Tandem Care in Manchester, N.H., which staffs Harvard Pilgrim’s SaveOn effort, has seen a similar response. When high-cost hospitals and physicians see patients going elsewhere, they react. “More providers are going back to their health plans and admitting that they’re not in the ballpark competitively on prices,” she says. They generally renegotiate lower prices or restructure their services so they are less expensive. Some hospital-based labs have moved operations to less expensive offsite facilities, she says.

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Health plans see a downside of fully covered preventive care
Under the ACA, all health plans must cover preventive services in full. But from a health plan’s perspective, the problem with providing preventive care at no cost is that members have no reason to shop for low-cost providers even for relatively high cost services such as colonoscopies and mammograms, says Garry Ramsey, chief marketing officer for Bluegrass Family Health, in Lexington, Ky.

“What difference does it make to them if these services are covered at 100%?” Ramsey asks. “For patients needing these services, there’s no value to switching to a less expensive provider.”

A similar problem arises when members in high-deductible health plans reach their deductible and coinsurance levels for the year, he adds. Financial incentive programs are an ideal way to deal with problems, Ramsey says. Members are willing to shop for a provider if it means they’ll get a check for doing so.

David Przesiek, chief sales officer for Fallon Health in central Massachusetts, agrees: “We need to engage members to keep them interested in shopping by price particularly after they have exhausted their deductibles and coinsurance.”

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New Era of Health Care Spending

The slowdown in increases often happens during and shortly after recessions, but this time the trend may continue as the American economy perks up

By Frank Diamond
Managing Editor

About a decade ago, economists noticed something strange about the rate at which health care spending increased: the relentless climb started to level off. Then came the economic slowdown of 2007—some call it the Great Recession—and the slower rates of increase continued because that’s what typically happens in recessions. But then another strange thing: The flattening of the trend line persisted. Will this last? And might there come a point—unimaginable only a short while ago—when American health care spending would actually decrease?

In December, CMS actuaries reported that total spending on health care increased by just 3.6% in 2013, the smallest annual increase in national health care spending on record, which goes back to 1960. The growth in aggregate private health insurance premiums was 2.8% in 2013, down from 4.0% in 2012. Medicare spending was also part of the notable downshifting. It increased by 3.4% in 2013, down from 4.0% the year before.

For years, economists, some lawmakers, and a small slice of the public have fretted over health care gobbling up a larger and larger chunk of the country’s economy. But CMS actuaries reported that from 2009 through 2013, health care spending’s share of GDP has remained steady at 17.4%.

In an article published last month in Health Affairs that explains the spending numbers, the actuaries said the slowing down of health care spending can be viewed either as a temporary aftermath of the Great Recession or “the beginning of a new era.”

Ah, a new era. The CMS actuaries (http://tinyurl.com/spending-health) note that the crucial question is whether health spending growth will accelerate once economic conditions improve significantly.

“We’re not seeing anything that looks like a ticking up of cost increases” even as the economy recovers, says economist David Cutler. More Sovaldis could change that.

How slow can it grow?
Total national health expenditures (NHE), annual percent change from the previous year, 2000–2013

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Could Roll Into the Good Times

—and that historical evidence suggests that it will. Forget the historical evidence, says David Cutler, PhD, a health economist at Harvard: “We’re not seeing anything that looks like a ticking up of cost increases even as the economy has done better.” That’s not definitive, he adds; talking about the future of health care spending is like talking about the weather—there’s an element of chaos. Still, Cutler has more than a hunch that things aren’t going to reverse themselves as soon as the economy peps up. The Great Recession officially ended in June 2009, and last year real GDP increased by 2.4%.

Medicaid’s spurt the only deviation from a leveling off
Annual percent change from the previous year, 2007–2013

Private health insurance

Out of pocket

Spending on private health insurance premiums has decelerated faster than NHE because of lower overall enrollment, high deductibles, and provisions of the ACA such as the medical-loss ratio requirement.

Medicare

Medicaid

The growth in Medicare spending tracked with the NHE in 2012 and 2013. Overall Medicare spending was influenced by slower growth in enrollment, provisions of the ACA, and the 2013 federal budget sequester.

Annual expenditures rose by 6.1% in 2013, partly because of Medicaid growth and increases in spending per enrollee. Spending growth will continue if Medicaid is expanded in more states.

Source: CMS
What caused it?
Economists are debating the reasons behind the deceleration of health care spending. Many say that at least 70% of the slowdown was caused by the recession, according to Uwe Reinhardt, a Princeton health economist. “I belong to that group. The reason we say that is because spending also started to fall in Europe. We said there has to be a common thread here, and it is the recession.”

Other economists say that it was because of structural changes, high-deductible policies especially. Reinhardt’s side says that those structural changes did not occur in Europe, and yet it too saw spending decline.

“So we have a big fight about it and the honest answer is that economists really can’t quite agree,” says Reinhardt. “They say it was probably all of these factors and that’s the safest thing. We always end up with that. We have these heated debates among ourselves, and then we wind up always saying that it was probably all of the factors.”

Cutler views Reinhardt’s 70/30 demarcation as adjustable: Where you draw the line depends on when you think the slowdown in health care spending really started to occur. Do you start from 2007 and the country’s financial unwinding, or do you go back to 2002, which is when many economists think the spending curve started to level. Cutler believes it started before the recession but became more noticeable during and after. The leveling off has gotten more robust and the economy has recovered somewhat, and yet we still don’t see a return to spending increases, he notes.

Beth Umland, the director of research for Mercer Health & Benefits, says pace of employment-based health care spending started to ease up about 10 years ago. From 2004 to 2007, her company’s survey found increases stabilizing at 6.1%.

“We survey about 3,000 employers every year so to have it come out that consistent every year, it was starting to feel like something magical was going on,” she says.

The magic, as Reinhardt notes, was, in part, simple pushback. Employers decided that 6% annual increases were about all they were willing to tolerate, so they figured out how to hold costs down. Umland says employers have more tools now to control health care costs than they did in the past. One of those is the consumer-directed health plan. It’s no coincidence, says Umland, that spending is slacking off during a period of rapid growth of coverage that features higher deductibles. The fact that increases in health care spending continued to taper off in 2011 and 2012 after the country started to emerge from the economic doldrums is evidence, in Umland’s view, that “health care consumerism has finally taken root.”

Cutler, Reinhardt, and Umland, track from on high, but things look different in the trenches. Alan Muney, MD, Cigna’s chief medical officer, warns that if we are indeed entering a new era of health care spending it’s just lower trend on top of baseline spending that’s still too high from years of double-digit increases.

“We’re all happy to see that moderation, but we have a long way to go to actually transform the health care system to be something we all want it to be, which is affordable with better outcomes,” says Muney. He points to antibiotic prescriptions as an example. Despite guidelines and other efforts to curb them, “We haven’t gotten the results we want.”

Comparing antibiotic prescribing with medical imaging may seem to be a stretch, except that it illustrates just what tighter management can do, according to Muney. In the case of imaging, insurers now measure requests against guidelines. “That kind of management has brought down radiology costs,” says Muney. “It also has doctors focusing more on it.”

In addition, where MRIs and other imaging tests are done is important. An MRI that might cost $600 at a freestanding radiology unit could cost four times as much at a hospital, Muney says. “It’s not just managing according to guidelines. It’s also the site of care.”

High baseline
The regional differences also matter. For more than 20 years, Dartmouth researchers have been documenting wide regional variation in practice patterns. The headline is that they’ve found no correlation
between how much money is spent on health care and the outcomes of that care. “If care is either too much too often or too little too late because clinical guidelines aren’t being followed, you’re going to get a high degree of variability clinically and therefore a wide variation in cost,” says Muney.

**Plenty of fat**

Muney believes that between 25% and 30% of all health care spending is inappropriate and wasted. “We spend $3 trillion on health care, and $1 trillion is either over- or underutilization. If there’s an inability to improve variability and outcomes, that’s a lot of baseline.”

In other words, an increase of a meager 3.6% on top of wasteful spending is still excess cost.

Umland understands Muney’s hesitancy to celebrate, but she sees real change. “We can quibble about whether we want to call it a new era. Are things different now then they were 10 years ago? It looks like it.” Nearly half (48%) of employers now offer consumer-directed plans and almost a quarter (23%) of covered employees are enrolled in one, she notes.

**“It’s just lower trend”** on top of baseline spending that’s too high, says Alan Muney, Cigna’s CMO, of the recent slowdown. Health plans still have a lot of work to do.

Even with PPOs, employers have more arrows in the quiver, such as penalties for smokers and surcharges for employees whose spouses have other means of insurance. “Yes there’s cost shifting involved,” says Umland, “but we’re also seeing employers doing more sophisticated things.” She mentions high-quality networks and getting employees to use transparency tools that make it possible to compare provider price and the quality of health care services.

Any conversation about health care spending these days invariably includes specialty drugs, with Sovaldi as Exhibit 1. Reinhardt, however, predicts that the “Sovaldi moment” will be the last hurrah of high health care spending. Payers, so far, don’t really know how to manage these breakthrough medications, but they’ll figure it out, he says. A $1,000 pill is a big attention getter because it seems so outrageous, says Reinhardt, although he notes there are actually many drugs costing a lot more both by dose and total spending and that even at $1,000 a pill, Sovaldi appears cost-effective relative to what we were willing to spend on hepatitis C already.

Besides, drug spending overall is not a big-ticket item relative to other health care spending,

**Even the Harvard faculty feels the effects of cost shifting, with some professors griping over having to pay a modest deductible for coverage.**

Reinhardt notes. Total spending on prescription drugs is still slightly below 10% of total national health expenditures. “There is not much mileage in beating up biotech and pharmacy if the goal is to control total health spending,” says Reinhardt. “My overall take is that it’s a headline-grabbing thing.”

Cutler, at Harvard, is not so sure: “If there are a lot more Sovaldis, that will materially impact health care spending,” he says. In Cutler’s opinion, the reason health care spending has leveled off is that the number of new technologies, including medications and devices, introduced into the health care system has been has been relatively low.

Muney does not take the Sovaldi moment lightly. If everyone who could benefit from Solvaldi got it, the cost would be about $300 billion a year, he says. Today, we spend about $270 billion on all prescription drugs combined.

However, Muney is also an optimist about many specialty drugs eventually helping to reduce health care spending, even if they push up spending initially. With good adherence, the medications stand to lower the spending on hospital care, physician services, and other services because chronic diseases will be better managed.

**Sovaldi vs. WalMart**

Others are optimistic about technology and innovation helping cut costs. After all, in other parts of the economy, inventiveness leads to greater efficiency and lower costs, not greater expense.

Technology fans believe, for example, that 3-D printing could reduce the cost of research and development for pharmaceutical companies by billions
Come to San Diego for AMCP’s 27th Annual Meeting & Expo, April 7–10!

It’s the one meeting that combines continuing pharmacy education, networking opportunities, and special events, all as part of the year’s largest gathering of managed care pharmacists, health plan administrators, medical and pharmacy directors, formulary decision-makers, doctors, nurses and other health care professionals.

The education sessions are designed by and for managed care professionals and experts in six Topic Tracks. Additional professional opportunities can be found in poster and pipeline sessions, satellite symposia presented by participating partners, and so much more!

Here’s a sampling of sessions and presenters ...

### Business Trends in Managed Care
- **Current Trends in Insurance Exchange Benefits and Formulary Design**
  - This session will provide a current perspective on the experience and impact of health insurance exchanges based on these first two years of implementation of the Affordable Care Act (ACA). In addition, this session will explore the future impact on employer-based programs, trends to expect throughout 2015 and beyond, and how the ACA will continue to evolve over time.
  - **Presenters:**
    - Caroline Pearson, BA
    - Lisa Murphy, MPP

### Staying On Course with Legislative and Regulatory Issues
- **Battling Fraud, Waste, and Abuse in Medicare Advantage and Part D Plans**
  - Fraud, waste and abuse (FWA) is an area undergoing rapid change that affects all aspects of health care. This panel presentation will review legislative, regulatory and program updates that affect plan sponsors’ anti-FWA efforts. The presentation will also introduce attendees to PLATO, the newest addition to CMS’ fraud-fighting toolkit, review a real-world example of drug diversion through a case study, and describe the process for reporting potential FWA.
  - **Presenters:**
    - Rosalind Abankwah
    - Michael Forman

### Global Perspectives on Formulary Management
- **Innovative Cost-Containment Strategies for Medical Specialty Drugs**
  - There is no argument that the growing availability and use of specialty medications has significantly impacted the total drug spend. In fact, it is estimated that by the end of the decade, specialty pharmaceuticals will contribute to at least half of the entire drug spend. This session will explore three medical benefit programs that can assist in managing the specialty drug costs, and their impact on potential financial impact.
  - **Presenters:**
    - Mary Dorholt, PharmD
    - Michael Forman

### The Landscape of Contemporary Managed Care Pharmacy
- **Navigating Oncology Clinical Pathways**
  - Learn different approaches to oncology pathways from different payers. Explore the evolution of the pathway development methodology, implementation, and evaluation since the first oncology care pathways were introduced, with an eye toward the impact on provider choice and patient outcomes. Anticipated trends in oncology care pathway development and implementation over the next five years will be discussed.
  - **Presenters:**
    - Robert W. Dubois, MD, PhD
    - Beth Hebert-Silvia

### Spotlight on Medication Therapy Management (MTM)
- **Improving Quality and Cost Control Using a Unique MTM Model**
  - Get an inside look at a unique MTM program which utilizes pharmacists in retail settings, as well as pharmacists in Patient-Centered Medical Home settings, to deliver MTM services. Attendees will also learn about the technology utilized to launch this initiative, and key results from the program’s first six months.
  - **Presenters:**
    - Amber Raybayan, PharmD
    - Winston Wong, PharmD

### Research and its Practical Application
- **Pharmacoeconomic Modeling: Applying Value to Formulary Management**
  - What are the clinical aspects of value assessment? How do you incorporate pharmacoeconomics in formulary value assessment in specialty medications that target diseases like chronic hepatitis C virus and multiple sclerosis? The use of pharmacoeconomic models in formulary reviews can help answer these questions and many others.
  - **Presenters:**
    - John Watkins, PharmD, MPH, BCPS
    - Dan Danielson, MS, RPh

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The Academy of Managed Care Pharmacy (AMCP) is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. Pharmacists can earn a maximum of 10 contact hours of CPE credit by attending all education sessions at AMCP’s 27th Annual Meeting & Expo (not including satellite symposia and pre-meeting programs held in conjunction with the meeting). Please visit www.amcpmeetings.org for more details.

visit the meeting website for more session details!
The education sessions are designed by and for managed care professionals and experts in directors, formulary decision-makers, doctors, nurses and other health care professionals.

It’s the one meeting that combines continuing pharmacy education, networking opportunities, and special events, all as part of the year’s largest gathering of managed care pharmacists, health plan administrators, medical and pharmacy directors, formulary decision-makers, doctors, nurses and other health care professionals.

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The education sessions are designed by and for managed care professionals and experts in six Topic Tracks. Additional professional opportunities can be found in poster and pipeline sessions, satellite symposia presented by participating partners, and so much more!

Here’s a sampling of sessions and presenters ...

Business Trends in Managed Care

Current Trends in Insurance Exchange Benefits and Formulary Design

This session will provide a current perspective on the experience and impact of health insurance exchanges based on these first two years of implementation of the Affordable Care Act (ACA). In addition, this session will explore the future impact on employer-based programs, trends to expect throughout 2015 and beyond, and how the ACA will continue to evolve over time.

Caroline Pearson, BA

Vice President

Avalere Health LLC, Washington, DC

Lisa Murphy, MPP

Director

Avalere Health LLC, Washington, DC

Staying On Course with Legislative and Regulatory Issues

Battling Fraud, Waste, and Abuse in Medicare Advantage and Part D Plans

Fraud, waste and abuse (FWA) is an area undergoing rapid change that affects all aspects of health care. This panel presentation will review legislative, regulatory and program updates that affect plan sponsors’ anti-FWA efforts. The presentation will also introduce attendees to PLATO, the newest addition to CMS’ fraud-fighting toolkit, review a real world example of drug diversion through a case study, and describe the process for reporting potential FWA.

Rosalind Abankwah

Benefit Analyst

Division of Reimbursement & Benefit Operations

Medicare Drug Benefits and Part D Data Group

Centers for Medicare and Medicaid Services, Baltimore, MD

Michael Forman

Pharmacist

Centers for Medicare and Medicaid Services, Baltimore, MD

James G. Scott

President & CEO

Appliantel Policy, Alexandria, VA

Global Perspectives on Formulary Management

Innovative Cost-Containment Strategies for Medical Specialty Drugs

There is no argument that the growing availability and use of specialty medications has significantly impacted the total drug spend. In fact, it is estimated that by the end of the decade, specialty pharmaceuticals will contribute to at least half of the entire drug spend. This session will explore three medical benefit programs that can assist in managing the specialty drug costs, and their potential financial impact.

Mary Dorholt, PharmD

Vice President and Clinical Practice Lead, Specialty

Express Scripts, St. Louis, MO

Jennifer Malin, MD, PhD

National Pharmaceutical Council, Washington, DC

Robert W. Dubois, MD, PhD

Chief Science Officer

National Pharmaceutical Council, Washington, DC

Beth Hebert-Silvia

Managing Director Pharmacy

Blue Cross Blue Shield Rhode Island, Providence, RI

Research and its Practical Application

Pharmacoeconomic Modeling: Applying Value to Formulary Management

What are the clinical aspects of value assessment? How do you incorporate pharmaco economics in formulary value assessment in specialty medications that target diseases like chronic hepatitis C virus and multiple sclerosis? The use of pharmaco economic models in formulary reviews can help answer these questions and many others.

John Watkins, PharmD, MPH, BCPS

Pharmacist Manager, Formulary Development

Penn Blue Cross, Voorhees, NJ

Dan Danielson, MS, RPh

Pharmacy Manager, Clinical Services

Penn Blue Cross, Seattle, WA

Kai Yeung, PharmD, MS, PhD Candidate

Pharmaceutical Outcomes Research and Policy Program

University of Washington, Seattle, WA

CONTINUING EDUCATION — GETTING THE CPE CREDIT YOU NEED

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www.amcpmeetings.org

visit the meeting website for more session details!

Sessions and presenters are as of January 1, 2015, subject to change. Visit www.amcpmeetings.org for updates.
New techniques could make for cheaper, more convenient blood tests. And, as Umland points out, expensive as specialty drugs are, they could reduce health care spending in the long run if people are cured or spared years of treatment with medications that are less expensive but not as effective. For instance, there’s a full-on assault against AIDS. The drug vorinostat is seen as a possible weapon in the “shock and kill” approach, which seeks to unmask dormant HIV-carrying cells and kill them.

“I think the future of spending increases as sort of Sovaldi versus WalMart,” says Cutler. “Sovaldi on the one hand is expensive and adds to short-run spending. Who knows about the long-run?”

Then there’s the WalMart effect: Efficiency that drives prices down through scale, standardization, and tough-minded purchasing. “It’s really a question about which will be bigger: the Sovaldi effect, or the WalMart effect?” says Cutler.

The “magic” began about 10 years ago when employers held health care spending increases to about 6% for three years, says Beth Umland of the consulting firm Mercer.

Historically, American health care has benefited little from the WalMart effect and experienced heaps of the Sovaldi one. Cutler says that lopsidedness is changing, particularly since the signing of the Affordable Care Act in 2010.

The ACA’s effects on spending are just beginning to be felt, says Cutler, directly, in the form of payment reductions to hospitals, home health agencies, and Medicare Advantage plans but also indirectly: “The ACA has fostered a climate where people understand that the medical system is going to change in a way that cost savings are going to be rewarded relative to volume increases,” says Cutler. “The extent to which that continues is going to depend to a great extent on policy.”

Coordination matters
Drug costs aren’t likely to derail the new era, agrees Umland. The wild card—for employers—is the ACA employer mandate, which requires businesses with 100 or more workers to offer coverage to all who clock in for 30 or more hours per week. Most employers already offer coverage to their full-time employees but under this new rule, about a third of large employers have had to extend coverage to workers who were formerly not eligible, says Umland. “If many of these employees take up coverage, employers could spend significantly more on health benefits.”

What will Congress do?
That wild card may be offset by another one: politics and Republican control of both houses of Congress. Reinhardt says that when it comes to controlling health care spending, Republicans have tended to walk the walk. “They have never hesitated to beat up on the health care industry when they get fed up with it.” He ticks off examples: President Nixon, price controls; President Reagan, DRGs; President George H. W. Bush, resource-based relative value scales.

Reinhardt also mentions the Balanced Budget Act of 1997, a Republican idea to reduce payments to providers and hospitals. “Democrats are like drunken lovers at the bar,” says Reinhardt. “They talk about a lot of lovemaking but it’s all talk and little action. Republicans pretend they hate regulation, but they don’t hesitate in the least to use it. Think about it: The pro-market Reagan basically introduced Soviet pricing for Medicare—the DRGs—where the central government sets prices for the whole country.”

What will matter are policies that affect providers and patients, says Cutler. “If we stay with the fee-for-service world, you make money by doing more. In the bundled payment world you make money by being more efficient. That will absolutely affect how much care is given.”

Harvard has recently made a modest move toward coverage with higher deductibles for its faculty and staff, and some professors have objected. So even the Harvard faculty is feeling the effects of the changes in American health care and how the dollars flow through the system. Who pays for what, where, and when—it’s all up for grabs.

“In reality, we’re not just observers,” says Cutler. “We can actually affect things through policy and through the incentives we create. It is possible that we are entering an era of very low cost increase, if not cost reduction. On the other hand, that’s going to depend to a great extent on policy. And policy can do things that can make that be more likely or make that be less likely.”
Chronic Care Management Payments: Another Step Away from Fee-For-Service

But EHR use is a potential obstacle, and beneficiaries may balk at paying for what they once got at no charge

By Michael D. Dalzell
Senior Contributing Editor

Baby step by baby step, CMS seems determined to get away from the perverse incentives—and disincentives—associated with fee-for-service medicine. Medicare’s Chronic Care Management (CCM) payments, intended to encourage greater care coordination, is the agency’s latest move toward a post-fee-for-service world.

The new payment scheme rewards medical practices for what some were already doing without being paid for it. Starting this year, practices can claim a monthly, non-visit-based payment for chronic care services provided to each qualified Medicare beneficiary (see details on page 34). The national average is $42.91, although it will vary depending on the geographic practice cost index. The initial reviews are favorable. Allison Brennan, MPP, a senior advocacy adviser for the Medical Group Management Association, says CMS is moving in the right direction and care coordination payments might have sundry benefits, including prevention of unnecessary hospitalizations.

But as is so often the case in health care, the devil lurks in the details of the doing. When it comes to compliance with regulations governing the payment, providers are long on uncertainty and, so far, CMS has been short on guidance.

You need an EHR, but for what?
Electronic health records (EHRs) may be the biggest source of uncertainty and a trouble spot. Practices that file a claim for the CCM payment are required to create a patient-specific, comprehensive care management plan, spend 20 minutes each month in care management activities, and record it all in the EHR.

The distribution of multiple chronic conditions
People with multiple chronic conditions are a challenge for all payers but especially for Medicare because older adults are far more likely than younger age groups to have two or more chronic conditions.

Source: “Multiple Chronic Conditions Among U.S. Adults: A 2012 Update,” CDC, April 17, 2014
EHR. But there’s nothing in current EHR designs to capture this information.

EHR documentation and billing structures are tied to specific face-to-face encounters, whereas the CCM code pays for activities outside of the patient visit, notes Rishi Agrawal, MD, physician champion for EHR implementation at La Rabida Children’s Hospital in Chicago. “The patient summary portions of EHRs are often hard-coded in a way that prevents enhancement into a CCM plan, says Rishi Agrawal of La Rabida Children’s Hospital.

When this functionality is built into the EHR, care coordination will become part of a workflow. Until then, there’s probably going to be a lot of extra and unproductive work to document care coordination, says Bruce Landon, MD, MBA, a health care policy professor at Harvard Medical School. Still, the exercise is likely to make many practices, including those taking on risk as accountable care organizations (ACOs), think about what’s best for their patients, says Landon: “You can have someone staring at a computer screen, twiddling thumbs, which doesn’t sound like a very good use of time. Or, part of what they can be doing is to say, ‘These patients have conditions X, Y, and Z. Let’s make sure they are up to date with all of their recommended preventive care and disease monitoring activities.’”

All of this assumes that a practice has an approved EHR system in place. Despite the federal requirement that Medicare-eligible professionals demonstrate meaningful use (MU) stage 1 by 2015 or face a penalty, not all practices are there yet; many small and rural offices have been put off by cost. During the comment period for the proposed final CCM rule, MGMA pressed CMS to drop the EHR requirement.

Half a loaf is better than none, though, and while CMS did not drop the EHR requirement from its final rule, it did agree to separate payment eligibility from a controversial clause requiring practices to demonstrate compliance with MU stage 2. “We were pleased that CMS moved off that very onerous requirement,” says Brennan, noting that practices that bought an MU stage 1-compliant EHR a few years ago may not yet be ready to shoulder the expense of upgrading to stage 2.

Chronic Care Management (CCM) payment
What: Pays medical practices a nonvisit fee for care-coordination activities on behalf of a Medicare beneficiary. Activities must be documented in an EHR.
Who: Applies to fee-for-service and MA beneficiaries with two or more chronic conditions expected to last 12 months.
How: Patients must consent in writing to the service and designate a primary care practice. Practice files a claim under CPT code 99490.
Why: $42.91 average payment (depending on geography) is designed to encourage primary care practices (including ACOs) to devote more resources to care coordination. For those already doing so, the money can add up: $10,000 per year for every 25 patients.

*Does not apply to practices taking part in the CMS Multi-payer Advanced Primary Care Practice Demonstration or the Comprehensive Primary Care Initiative.

Money complicates things

One hurdle to the provision of chronic care management services may come from patients themselves. Nonvisit care management is a Part B benefit for which patients will be charged; CMS said it did not have statutory authority to waive a patient’s Part B coinsurance obligation. To a fee-for-service patient, the monthly 20% coinsurance adds up to about $100 per year out of pocket, which may be a hardship for some. It’s also possible that patients may balk if they don’t understand what they’re getting for this new out-of-pocket expense. From a patient perspective, these chronic care services are not going to be particularly tangible, notes Landon.

More importantly, he adds, the prohibition on waiving a patient’s Part B financial obligation raises tricky issues. Practices may have to decide whether to invoke policies requiring patients to agree to chronic care management services. “I can imagine there will be some physician offices that say, ‘Look, if you want to stay here, then you’ll have to consent to making these payments. Otherwise, feel free to find someone else,’” says Landon, who described these concerns with Samuel Edwards, MD, MPH, in an opinion piece published in the New England Journal of Medicine late last year.

There will be a period when care coordination will mean a lot of unproductive documentation, says Bruce Landon of Harvard University Medical School.

If a practice were to allow some patients to opt out of CCM services while requiring others to stay in, then equity issues come into play, says Landon: “What’s going to happen if a bunch of your patients are paying the fee and others aren’t, yet at the end of the day they are getting the same or similar services?”

Equally unclear is how Medicare Advantage physicians will be reimbursed for the service. Citing compensation complexities, health plans contacted for this article didn’t want to talk about how payment would be administered to providers. Many plans already compensate physicians—whether specifically, as part of capitation, or through a performance incentive—for similar activities. The CMS program is an effort to nudge fee-for-service Medicare in a direction health plans have been going for years.

Previously, non–face-to-face care management was bundled into the evaluation and management visit. Practices that have reorganized into medical homes and ACOs have plowed millions into care management activities, leading them and CMS to agree that the old way of doing things wasn’t enough. How much help these new chronic care payments will give in recouping on those investments remains to be seen.

One commenter told CMS that chronic care management would take more than twice as long as the 20 minutes each month it has allotted. Others argued that an average of 20 minutes per month over a year, which works out to four hours a year, may make more sense. Twenty minutes a month is “a silly way to organize that, because the way care coordination really goes is kind of bumpy,” says Landon.

But as providers gain more experience with chronic care management and how it is paid for, the specifics are bound to be refined. For now, it’s another change that may eventually untie the knots of fee-for-service medicine.

Michael D. Dalzell is a former managing editor of Managed Care and a New Jersey-based independent journalist.

Specialists can get in on the act, too

Although the CCM payment is intended to encourage care coordination activities in primary care, specialists can also claim it. For some patients with multiple chronic conditions, such as diabetes and end-stage renal disease, it’s not unusual for a specialist to function as their primary care physician. In those cases, it’s OK for the specialist to claim the payment, says Bruce Landon, MD, MBA, a health policy professor at Harvard Medical School.

What’s not OK, he adds, is when a specialist tries to bill for the service for a patient who sees a primary care physician. “If someone has a primary care physician, this kind of management is exactly his job,” says Landon. “Some physicians might use this to try to collect a fee from patients when they’re not really acting as their primary care physician.”
Researchers from Kaiser Permanente, Weill Cornell Medical College, and worldwide registries are voicing the importance of tracking the safety and effectiveness of medical devices through the use of device registries.

Most Americans use a medical device during their lifetimes, and it has been estimated that tens of millions will receive an implantable device. But public health and regulatory agencies are unable to track these devices once they are bought or used by a patient. The lack of a registry makes it difficult for the medical community and patients to gain accurate, evidence-based information for assessing comparative outcomes or for tracking recalls after implantation.

In a supplement published in the December 2014 issue of the Journal of Bone & Joint Surgery, Kaiser Permanente and Weill Cornell took the lead in analyzing data from seven registries in the International Consortium of Orthopaedic Registries (ICOR), focusing on the performance and safety of hip and knee implants and the risk of surgical revision. The registries that were studied included those maintained by Kaiser Permanente and Health East, a Minnesota-based system of hospitals and primary care clinics, along with registries in Australia, Italy, Norway, Spain, and Sweden—all seven being ICOR members.

The findings of the FDA-sponsored study stress the importance of registries and unique device identification (UDI) implementation for postmarket surveillance of medical devices in the United States and worldwide. Prior research has found that electronic health record systems cannot identify devices and link them to an individual patient’s outcome data, but registries can.

For the FDA, which has made the development of device registries and the creation of a UDI system for medical devices a priority, the study provides a basis for how registry evidence can be used. The agency plans to develop a national medical device registry and guidelines on governance and other processes.

Medical device tax

Minnesota U.S. Rep. Erik Paulsen plans to file another bill to roll back the 2.3% medical device tax. Paulsen, a Republican, co-introduced the bill with Wisconsin Democratic Rep. Ron Kind on Jan. 7.

Previous attempts to eliminate the levy generated widespread support in the House but were never brought to a vote in the Senate. The excise tax on sales of medical devices sold in the United States was written into the ACA to support Medicaid expansion for uninsured Americans and took effect in January 2013. The tax applies to a wide range of medical items, from bedpans to pacemakers, and has been projected to raise about $30 billion a year over 10 years. Proponents say that killing the device tax would spur hospitals and insurers to demand relief from taxes or spending cuts they accepted under the ACA—possibly jeopardizing funding of ACA initiatives over the next decade.

For their part, device manufacturers are unsure which products are subject to the tax. Mobile health apps and software, in particular, are a source of confusion. It is unclear whether they are subject to the excise tax once they are approved by the FDA and on the market.

10 best apps for oncologists

CancerNetwork.com has released its list of the 10 Best Oncology Apps for oncologists. Some of the apps are free while others are subscription-based or carry a download fee:

- **Cancer Rx**, from MedPage Today/CollabRx, locates cancer trials, peer-reviewed literature, and news about major cancer fields. Users can enter patient data and receive suggested therapies with links to pertinent articles/references.
- **BrownZine** integrates an institutional library with an e-journal collection of full-text articles, with references, that can be downloaded as PDFs.
- **Micromedex**, publishers of one of the major drug compendia, provides users with information on medications, such as name, class, and adverse effects.
- **Calculate**, by QxMD, provides a complete source of calculations and formulas by medical specialty and specific decision-support tools.
MEDICAL DEVICE MONITOR


<table>
<thead>
<tr>
<th>Date</th>
<th>Manufacturer</th>
<th>Device name</th>
<th>Use and notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec. 8, 2014</td>
<td>Johnson &amp; Johnson/DePuy Synthes</td>
<td>VEPT/VEPTR II vertical expandable prosthetic titanium rib devices</td>
<td>Treatment of thoracic insufficiency syndrome (chest, spine, and rib deformities in children). The devices were previously available only under humanitarian device exemption regulations.</td>
</tr>
<tr>
<td>Dec. 11, 2014</td>
<td>MP Biomedicals</td>
<td>HTLV Blot 2.4</td>
<td>First confirmatory assay for human T-cell lymphotropic virus. Distinguishes between HTLV-I and HTLV-II.</td>
</tr>
<tr>
<td>Jan. 5, 2015</td>
<td>Medtronic</td>
<td>IN.PACT Admiral drug-coated balloon</td>
<td>Paclitaxel-coated balloon to prevent scar tissue from forming around leg treatment site in patients with peripheral artery disease.</td>
</tr>
</tbody>
</table>

Sources: FDA, manufacturers’ news releases

- Johns Hopkins ABX Guide offers information on the management, treatment, and diagnosis of infectious diseases that most commonly affect cancer patients.
- PubMed on Tap can search either PubMed or PubMed Central to gain access to medical literature.
- The National Comprehensive Cancer Network provides a list of all NCCN guidelines for direct download.
- Medscape is a reference tool and a source of medical news and treatment guidelines.
- inPractice Oncology is a subscription-based resource that provides access to PubMed literature, various treatment guidelines, and a clinical trial registry.
- Draw MD can be used to communicate visual information to patients, such as where an incision would be made during a biopsy. Breast health, general surgery, and urology are some of the medical specialties covered.

CancerNetwork.com also named its “app to watch”: OhMD, which facilitates secure texting between physicians and patients. The app requires that the physician’s organization adopt it for use. The app’s developers say it will help providers meet the messaging criteria of stage 2 of the CMS’s meaningful use requirements.

Short takes
A survey by A&D Medical found that consumers are eager to use wireless wearable medical devices to monitor weight and blood pressure. Of more than 2,000 participants, 74% of men ages 55 to 64 and 73% of women ages 18 to 34 were concerned about their weight. Experts have noted that those who wear medical devices are usually young and healthy; older individuals with health problems like hypertension are not enthusiastic adopters, primarily because of cost.

As wearable devices carrying private medical information become more common, regulators are trying to come up with realistic privacy-protection mechanisms.

—Katherine T. Adams
New Hope for Newborns With Rare Deforming Disease

A device for thoracic insufficiency syndrome that has been evolving for years is now more widely available

Thomas Morrow, MD

Thoracic insufficiency syndrome (TIS) is a collection of rare disorders of the thoracic skeletal system affecting about 4,000 newborns in the United States each year. TIS may cause pulmonary failure because of decreased lung volume: The ribs fuse together, the thoracic spine twists and rotates, and the patient may slowly suffocate unless reconstruction is done to multiple ribs and the spine, and is repeated as the child grows.

TIS is sometimes secondary to trauma. It may also be caused by resection of large tumors from the chest wall and surgical separation of conjoined twins.

Other cases are associated with well-defined genetic disorders and disorders that are less well characterized from a genetic perspective but also cause deformities of the bones in the thorax. These disorders include constrictive chest wall syndrome; progressive congenital, neurogenic, or idiopathic scoliosis without rib fusion; and hypoplastic thorax syndrome, which includes Jeune’s syndrome, also called asphyxiating thoracic dysplasia; Ellis-van Creveld syndrome, also called mesoectodermal dysplasia, and Jarcho-Levine syndrome, which has gone by nearly a dozen different names.

As you might imagine, the deformities can come in a wide variety of forms because each of these conditions can affect the ribs and individual vertebrae in different ways.

Early surgical interventions include fusion of the vertebrae to prevent twisting and turning and insertion of custom manufactured expandable instruments called “growing rods.”

The rib cage in children with TIS has a variety of missing, fused, and deformed ribs. The fused ribs needed to be split apart and kept apart with spacers. Missing ribs have been replaced with artificial ribs of a fixed size or cadaver bone. In some cases, surgeons have resorted to splitting the breastbone—anything to allow the lung space to expand, not only for respiration but also growth of the child.

The Vertical Expandable Prosthetic Titanium Rib (VEPTR) addresses many of the deformities of the rib cage and spine. The device was developed by Robert Campbell Jr., MD, a surgeon at Children’s Hospital of Philadelphia, who spent 25 years refining it. It consists of curved titanium rods that are surgically attached to the ribs, lumbar vertebra, or sacrum. VEPTR is perhaps the most configurable device ever approved by the FDA. Because there is no standard presentation, any device for the condition either needs to be entirely customized or capable of being assembled, like parts of an erector set, to create a unique solution for each child.

Increasing life expectancy

According to an FDA staff report, VEPTR is the only treatment available that allows the chest cavity to be enlarged vertically, providing room for the lungs to grow and improving the function of the lungs and heart, thereby increasing the life expectancy of these terminally ill children. The VEPTR is also unique because it treats the deformities of both the spine and thorax. Moreover, it can be adjusted through minor surgery as the child grows. Other devices need to be replaced, and that often requires major surgery.

The FDA originally approved Campbell’s VEPTR device in 2004 under its special humanitarian device exemption for conditions that affect small numbers of people. Late last year,
the agency gave the device 501(k) clearance, which means it can now be used more widely. The 501(k) clearance was based upon a single-arm, nonrandomized, prospective multicenter trial done in two phases. The children served as their own control because there is no “typical” pattern on which to create a control group.

All subjects in the study were children six months or older, up to the age of skeletal maturity, which is typically at 15–17 years of age. The endpoints included increases in thoracic spinal height, hemithoracic height and width, and scoliosis correction.

Because the patients are young and sometimes developmentally delayed, standard pulmonary tests often can’t be done. This study used “assisted ventilator rating” outcomes as an endpoint instead. Those ratings reflect whether a child needs supplemental oxygen and other kinds of assistance to breathe.

Because the 257 patients treated were growing, the study device would periodically require expansion or replacement of its components. Each child was expected to need many adjustments as a normal course of treatment. Surgeons performed 1,538 surgical procedures during the study’s 14 years. Twelve children died but in the opinion of the investigators none of the deaths were related to the device. The results can only be termed remarkable: 92% of the subjects displayed either stabilization or improvement in a statistic called assisted ventilator rating, which sums up indirect measurements of pulmonary function and quality-of-life measurements. Radiographic success was measured across four different types of deformity. Some of the subgroups had 100% of patients reaching the predetermined goal. In most of the 24 individual measures, more than 3 out of 4 of subjects reached the goal.

Not all the studies of VEPTR have been positive. Last year, surgeons at the University of Pittsburgh Medical Center reported that the forced vital capacity of their VEPTR patients improved during six years of follow-up but that it didn’t keep up with the child’s growth. They also observed increased chest wall stiffness and increased thoracic kyphosis. TIS is a life-threatening and, in some patients, a terminal condition that almost without exception requires some sort of surgical intervention. The previous static surgical treatments were unable to adapt to the growing child’s needs. No prior treatments were able to address the various deformities effectively. The development of the VEPTR now provides the potential benefits of continued spinal growth, decreased deformity, and improved breathing ability.

This device is the result of more than two decades of development and is another example of how continual refinements over long periods of time can lead to Tomorrow’s Medicine.

![VEPTR device can be configured for rib-to-rib, rib-to-lumbar lamina, and rib-to-ilium (not pictured) attachment.](source: Depuy Synthes)
The use of electronic health records has come a long way since 2010, but EHRs cannot stand alone, warns a PwC report. The next challenge is integrating mobile health devices into the EHR and the provider–patient relationship.

The consulting company interviewed 1,000 physicians and physician extenders—nurse practitioners, physician assistants—to discover how they use digital technology and some of the concerns they have about incorporating it into clinical practice (http://tinyurl.com/digital-study).

The number of providers using smartphones and tablets is increasing. For example, in 2010, about 1 in 8 (12%) used mobile devices to check medical records. In 2014, the survey found that almost half (45%) do.

But there's still a ways to go. About a third of physicians do not use mobile devices, and few do so for state-of-the-art tasks like monitoring hospitalized patients.

PwC says that the next five years will be critical for the shift from mobile devices being just add-ons for convenience to tools for effective clinical practice.

One major influence on that transition may be the increasingly competitive environment that providers are working in. Because people are paying a greater share of their health care bills, they are getting more demanding, so they may pick providers who are savvy about mobile devices and how best to incorporate them into patient care, according to PwC. “Soon, smartphone technology could be the primary means for initial contact with the health care system via video consult,” say the PwC authors.

### What providers do with mobile devices

<table>
<thead>
<tr>
<th>Activity</th>
<th>2010</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access electronic medical records</td>
<td>12%</td>
<td>14%</td>
</tr>
<tr>
<td>Prescribe medications</td>
<td>7%</td>
<td>21%</td>
</tr>
<tr>
<td>Review images</td>
<td>11%</td>
<td>20%</td>
</tr>
<tr>
<td>Communicate with patients</td>
<td>6%</td>
<td>17%</td>
</tr>
<tr>
<td>Receive data from a medical device</td>
<td>12%</td>
<td>17%</td>
</tr>
<tr>
<td>Initiate and track a referral</td>
<td>N/A</td>
<td>14%</td>
</tr>
<tr>
<td>Conduct clinical consult from different location than patient</td>
<td>N/A</td>
<td>14%</td>
</tr>
<tr>
<td>Monitor patients who are hospitalized</td>
<td>N/A</td>
<td>17%</td>
</tr>
<tr>
<td>Receive data from mobile app patient uses to track data</td>
<td>N/A</td>
<td>14%</td>
</tr>
</tbody>
</table>

INTRODUCTION
As sales of prescription opioid analgesics in the United States have quadrupled in the last decade, there has been an accompanying rise in emergency department (ED) visits and hospitalizations involving adverse events with these medications. In fact, the problem is so serious that for every death caused by prescription opioids, there are 10 treatment admissions for abuse, 26 opioid-related ED visits, 108 people who abuse and are dependent upon opioids, and 733 people using prescription opioids for nonmedical purposes (CDC 2012). Although the public health focus has been on the number of deaths from prescription opioid overdose (nearly 17,000 in 2011, which equates to 46 deaths per day or 1 death every 36 minutes [CDC 2014]), the number of opioid-related poisoning events leading to hospitalization is also of concern. For example, a study based on 2009 data estimated prescription opioids to be responsible for 108,106 admissions following ED care in the U.S. population (Inocencio 2013). This same report estimates the prevalence of prescription opioid overdoses at 130 per 100,000 lives. Therefore, a health plan or payer with 1 million lives can expect over 1,300 prescription opioid analgesic overdoses to occur annually.

Although significant numbers of persons suffer the life-threatening respiratory depression of opioid overdose as a result of abusing opioid medications, the data suggest that the majority of patients experiencing opioid overdose neither have an identified history of substance abuse, nor are they “doctor shoppers,” and they have only 1 prescriber for their opioid overdose, including chronic pulmonary disease (Hasegowa 2014), renal or hepatic disease, trauma, depression, sleep apnea, and use of extended-release or long-acting opioids (Boyer 2012, Zedler 2014). Drug-drug interactions involving inhibition of CYP450 metabolic pathways have also been implicated (Tennant 2011).

Opioid analgesic overdose encompasses a range of clinical findings, including the classic toxidrome of apnea, stupor, and miosis. The sine...
Economic Impact of Naloxone Autoinjector

The NAI provides standard fixed dosing for adult and pediatric subjects, eliminating the variability of assembling a needle and syringe and manually drawing up the prescribed dose of naloxone. The inclusion of a fully automatic retractable needle system lessens the potential of inadvertent sharp injury. Functionally, the voice instruction system and light-emitting diode (LED) visual cues help guide a user through the administration steps (Evzio 2014). Finally, each NAI carton contains a trainer for practice. The trainer is part of an educational component in the introduction of NAI that includes ensuring patients, family members, and caregivers have information on the appropriate use of NAI in case it needs to be used in a suspected overdose emergency.

The cost-benefit analysis for a health plan involves balancing the projected annual pharmacy cost of NAI against the potential for medical cost reduction associated with opioid-related morbidity and mortality. Accordingly, an economic model was developed to study the financial impact of the use of the branded NAI compared with the current standard of care (emergency professional administration of naloxone), with particular emphasis on drug costs, costs of emergency department treatment, cost of hospitalization, costs associated with cardiac resuscitation, and costs related to fatalities.

The objectives of the model were to estimate (1) the number of appropriate patients for NAI therapy, (2) the net pharmacy costs for NAI brand prescriptions, and (3) the difference in medical resource utilization and costs between the NAI treatment group and a risk-matched control group administered the current standard of care (i.e., emergency medical service resuscitation and naloxone administration) over a 3-year time horizon in a hypothetical commercial health plan with 1 million adult members.

Evzio (naloxone hydrochloride) autoinjector

settings (Throckmorton 2014). In recent years, some communities have developed opioid overdose education programs that distribute naloxone “kits.” The kits usually contain two doses of naloxone plus gloves, needles, and syringes, along with brochures and ancillary medical supplies such as rescue breathing masks (Coflin 2013). Other programs provide kits with prefilled glass syringes for intranasal administration of naloxone utilizing a separate mucosal atomization device (Doe-Simkins 2014), but the intranasal route is not approved by the FDA, and safety or efficacy data with this route of administration are limited (Zedler 2014).

Under its priority review program, the FDA recognized the need for broader access of naloxone, especially by family members and other caregivers in a position to administer naloxone to a patient during an opioid overdose event. The agency approved the Evzio (naloxone hydrochloride) autoinjector in April 2014, which rapidly delivers a single dose of naloxone via a handheld autoinjector that can be carried in a pocket or stored in a medicine cabinet (FDA 2014). This is significant because laypersons now have available to them a naloxone product approved for use by non-health care professionals (FDA 2014).

The objectives of the model were to estimate (1) the number of appropriate patients for NAI therapy, (2) the net pharmacy costs for NAI brand prescriptions, and (3) the difference in medical resource utilization and costs between the NAI treatment group and a risk-matched control group administered the current standard of care (i.e., emergency medical service resuscitation and naloxone administration) over a 3-year time horizon in a hypothetical commercial health plan with 1 million adult members.
KEY POINTS
Assuming a health plan covering 1 million people and various criteria and assumptions developed by the researchers:

- 4,356 people will be deemed appropriate for naloxone autoinjector (NAI) prescriptions, according to criteria developed by the researchers
- Number of people who actually get a prescription will grow from 218 (5% of those deemed appropriate) in Year 1 to 2,527 (50%) in Year 3 as awareness of NAI increases
- In Year 3, total acquisition cost of the NAI is $1,456,407 (PMPM = $0.12), assuming a wholesale acquisition cost of $575 per prescription
- In Year 3, the net cost of NAI (the acquisition cost offset by lower ED and hospitalization costs) is $481,000 (PMPM = $0.04)
- Over a 3-year period, NAI will prevent 3.6 fatal overdoses
- In Year 3, cost per death avoided is $192,400 but that is highly dependent on assumptions about the incidence of overdoses

Methods
An Excel-based deterministic cost model was developed to estimate the combined pharmacy and medical resource costs to a health plan or other population-based health care organization owing to prescription opioid overdose events for appropriate patients dispensed NAI compared with matched control patients without NAI. The model assumes the latter group will receive some other form of naloxone administration in the event of a prescription opioid overdose. Medical resources included in the model are ED visits, hospitalizations, and cardiac resuscitations, as well as cost associated with deaths due to prescription opioid overdose.

Default values were provided for model parameters from the published literature where available. For modeling purposes, variables used for appropriate patient selection are shown in Table 1 with the values used in the base case analysis. To be deemed appropriate for NAI, two criteria were used in this sample representative patient population. First, patients had to be evaluated as either “chronic opioid users,” defined as patients with long-term prescription opioid use >120 days of supply over 6 months (Leider 2011), or as “at risk” acute or short-term opioid users. Examples of “at risk” short-term users are those with a prior opioid overdose episode or with comorbid respiratory disease such as asthma, sleep apnea, or chronic obstructive pulmonary disease who may be exposed to opioids. Second, patients were included based on a selection of risk factors that were most associated with opioid overdose in a Veterans Health Administration (VHA) study (Zedler 2014). These included having a history of drug dependence, minimum of one hospital admission in the past 6 months, and history of >100 mg MEDD (see Table 1 for prevalence of each of the selected risk factors). Upon meeting these criteria, 5% of these patients were assumed to receive an NAI prescription in Year 1, 20% in Year 2, and 50% in Year 3.

These uptake figures were con-

| TABLE 1   NAI patient selection |
|-------------|-------------------------------|
| Variable category | Model variable | Default (base case) value | Source |
| | Number of adult members in health plan | 1,000,000 | Base case assumption |
| | Payer type | Commercial | Base case assumption |
| | Prevalence of chronic and at-risk acute opioid users | 2.4% (= 1.3% chronic + 5% of 21.4% acute) | Leider 2011 |
| | Refill failure rate (failure to refill after NAI shelf-life expiry) | 20% | Base case assumption |
| | NAI prescriptions per patient during 1 year | 1.1 (= 90% x 1) + (10% x 2) | Base case assumption |
| | NAI shelf life (months) | 20 | Base case assumption |
| | % of chronic and at-risk acute opioid users receiving NAI prescription | Based on prevalence of drug dependence, hospitalization, and MEDD >100mg/day | Base case assumption |
| | Probability of appropriate patient getting prescription and filling (uptake) | 5%, 20%, 50% for Years 1, 2, and 3 | Base case assumption |
| | WAC per NAI prescription | $575 | Kaléo |
| | Member copayment per prescription | $51 | KFF 2012 |
| Risk factors for appropriate patients | History of drug dependence prevalence | 0.6% | Zedler 2014 |
| | ≥1 inpatient stay in last 6 months prevalence | 12.6% | Zedler 2014 |
| | Morphine equivalent daily dosage ≥100 mg/day prevalence | 6.0% | Zedler 2014 |
considered reasonable, given the novel nature of NAI. The model assumes that 90% of the appropriate patients receive one NAI prescription and 10% receive two NAI prescriptions (on the basis of such factors as being prescribed opioids such as buprenorphine that may require >2 doses of naloxone or living in rural locations with extended emergency medical service response times). Additionally, the model was built so that all but 20% of NAI prescriptions are replaced after 20 months owing to shelf-life expiration. NAI prescription costs to the health plan and member copayments are provided in Table 1 (page 43).

Model variables for medical resource utilization are shown in Table 2 with the values used in the base case analysis. The incidence (events per year) of opioid overdose in the appropriate NAI patient population was 3.4% (Inocencio 2013, Kaléo data on file). The probability of resource use (probability of use per overdose event) for the control group was 100% for ED visits, 57.6% for hospital (inpatient) admission (Hasegowa 2014), 2.2% for cardiac resuscitation (Sporer 1996), and 11.8% for death (Dunn 2010). The probability of resource use for the NAI group was assumed to be 75% of the control group probability for all resources except ED, which was assumed to be the same as the control group.

Cost per resource use for the control group was $2,695 for ED visits (probabilty of use per overdose event) for the control group was 100% for ED visits, 57.6% for hospital (inpatient) admission (Hasegowa 2014), 2.2% for cardiac resuscitation (Sporer 1996), and 11.8% for death (Dunn 2010). The probability of resource use for the NAI group was assumed to be 75% of the control group probability for all resources except ED, which was assumed to be the same as the control group.

Cost per resource use for the control group was $2,695 for ED visits

<table>
<thead>
<tr>
<th>TABLE 2</th>
<th>Medical resource utilization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variable category</td>
<td>Model variable</td>
</tr>
<tr>
<td>Overdose incidence</td>
<td>Incidence of prescription opioid overdose among appropriate patients</td>
</tr>
<tr>
<td>Medical resources: probability of use per opioid overdose event</td>
<td>ED visits: NAI group</td>
</tr>
<tr>
<td>Medical resources: probability of use per opioid overdose event</td>
<td>ED visits: control group</td>
</tr>
<tr>
<td>Medical resources: probability of use per opioid overdose event</td>
<td>Hospital admission: NAI group</td>
</tr>
<tr>
<td>Medical resources: probability of use per opioid overdose event</td>
<td>Hospital admission: control group</td>
</tr>
<tr>
<td>Medical resources: probability of use per opioid overdose event</td>
<td>Cardiac resuscitation: NAI group</td>
</tr>
<tr>
<td>Medical resources: probability of use per opioid overdose event</td>
<td>Cardiac resuscitation: control group</td>
</tr>
<tr>
<td>Medical resources: probability of use per opioid overdose event</td>
<td>Fatalities: NAI group</td>
</tr>
<tr>
<td>Medical resources: probability of use per opioid overdose event</td>
<td>Fatalities: control group</td>
</tr>
<tr>
<td>Medical resources: cost per use</td>
<td>ED visits: NAI group</td>
</tr>
<tr>
<td>Medical resources: cost per use</td>
<td>ED visits: control group</td>
</tr>
<tr>
<td>Medical resources: cost per use</td>
<td>Hospital admission: NAI group</td>
</tr>
<tr>
<td>Medical resources: cost per use</td>
<td>Hospital admission: control group</td>
</tr>
<tr>
<td>Medical resources: cost per use</td>
<td>Cardiac resuscitation: NAI group</td>
</tr>
<tr>
<td>Medical resources: cost per use</td>
<td>Cardiac resuscitation: control group</td>
</tr>
<tr>
<td>Medical resources: cost per use</td>
<td>Fatalities: NAI group</td>
</tr>
<tr>
<td>Medical resources: cost per use</td>
<td>Fatalities: control group</td>
</tr>
<tr>
<td>NAI administration</td>
<td>Probability NAI is administered in the event of opioid overdose for patient with dispensed NAI prescription</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TABLE 3</th>
<th>Patient counts for base case: NAI group vs. control group*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year 1</td>
<td>Year 2</td>
</tr>
<tr>
<td>At-risk opioid users</td>
<td>23,700</td>
</tr>
<tr>
<td>Number of appropriate NAI patients</td>
<td>4,356</td>
</tr>
<tr>
<td>Patients dispensed NAI</td>
<td>218</td>
</tr>
<tr>
<td>Patients with opioid overdose event</td>
<td>7.4</td>
</tr>
<tr>
<td>Patients with opioid overdose event where NAI is utilized</td>
<td>5.9</td>
</tr>
<tr>
<td>Reduction with NAI</td>
<td>NAI</td>
</tr>
<tr>
<td>…resulting in emergency department visits</td>
<td>0%</td>
</tr>
<tr>
<td>…resulting in hospital admission</td>
<td>25%</td>
</tr>
<tr>
<td>…resulting in cardiac arrest (survival)</td>
<td>25%</td>
</tr>
<tr>
<td>…resulting in fatal overdose</td>
<td>25%</td>
</tr>
</tbody>
</table>

*For hypothetical health plan with 1 million adult members
InInocencio (2013), $38,784 for hospita-

tal (inpatient) admission (Inocencio

2013), $94,916 for cardiac resuscita-

tion (Paulsen 2012), and $3,112 for

death (Paulsen 2012). T_h e cost for the

NAI group was assumed to be 75% of

the control group cost for ED visits

and 56% for hospital admissions (75%

of control group daily cost and reduc-

tion in length of stay from 4 to 3 days),

based on the assumption that patients

who are administered NAI in a timely

fashion are likely to have fewer se-

vere opioid overdose symptoms by the

time they reach the ED. With the re-

cent availability of NAI, data speci/f ic

to interventions with NAI are not yet

available. T_herefore, the cost for the

NAI group for cardiac resuscitation

and death was assumed to be the same

as the control group cost.

T he probability of administering

the NAI device in the event of an opi-

oid overdose was assumed to be 80% based on previous models and associ-

ated data of naloxone use in suspected

opioid overdose emergencies (Coffin

2013).

In addition to the base case analysis

using the values in Tables 1 and 2, sen-

sitivity analyses were conducted vary-

ing the probability of use and cost of

medical resources for the NAI group

(as a percentage of control group

probability and cost), the incidence of

opioid overdose, and the probability

that NAI is administered in the event

of an opioid overdose.

RESULTS

T he results of the base case analy-

sis are shown in Tables 3 and 4. In

Table 3, the number of at-risk opioid

users (all chronic users plus a sub-

population of acute opioid users) in
each year for a health plan with 1 mil-

lion adult members was estimated to be

23,700. Of these, 18.4% met the

requirement of having at least 1 of the

3 criteria for NAI selection (history

of drug dependence, hospitalization

in last 6 months, or history of >100

mg MEDD), resulting in 4,356 ap-

propriate patients each year. Based

on the assumed NAI uptake over the

3-year period, this resulted in 218 pa-

tients with NAI prescriptions in Y ear

1, 929 in Y ear 2, and 2,527 in Y ear 3.

Table 3 shows the number of expected

overdose events for these patients (in

both the NAI and control groups) and

the number of NAI patients in which

the product is administered. In Y ear

3, the 2,527 NAI patients (and their

matched controls) were expected to

experience approximately 86 opioid

overdose events. T he bottom of Ta-

ble 3 shows the number of patients

in each group who access each type

of medical resource. For the 3-year

period, fatal overdoses in the NAI co-

hort totaled 11.1 vs. 14.7 for the con-

trol group. In Y ear 3, 2.5 deaths (10.1

– 7.6) were estimated to be avoided.

Table 4 shows the NAI net acquisi-

tion costs and medical resource costs

for NAI and control groups for the

base case of 75% of ED and 56% of

NAI.
hospital costs for NAI as compared to controls, 80% likelihood of use of NAI in the case of opioid overdose, and incidence of overdose of 3.4%. The estimated total acquisition cost of NAI rises from approximately $125,000 in Year 1 (per member per month [PMPM] = $0.01) to nearly $1.5 million in Year 3 (PMPM = $0.12). This cost is offset by estimated medical resource savings of approximately $84,000 in Year 1, increasing to approximately $975,000 in Year 3. The resulting total net cost (NAI less offsets) in Year 3, which is when NAI uptake is assumed to plateau, is approximately $481,000 (PMPM = $0.04). The cost of medical resources to treat the estimated 86 opioid overdose events for the control group in Year 3 is approximately $2.4 million.

**Sensitivity analyses**

The incremental cost of NAI treatment, taking into account both drug acquisition cost and potential medical cost offsets, is highly dependent on the reduction in medical resource costs due to NAI treatment. For example, the NAI acquisition cost is offset completely when medical resource costs for the NAI group are 46% below control group costs. NAI acquisition cost is also completely offset if the incidence of overdose increases from 3.4% to 5.1% due to more frequent indicated uses of NAI with resulting medical resource savings. Table 5 (see appendix, page A49) shows the estimated cost offsets when the probability of NAI administration is reduced from 80% to 50%. Net costs (NAI less offsets) in Year 3 rise from approximately $481,000 (PMPM = $0.04) in the base case to approximately $847,000 (PMPM = $0.07).

Table 6 summarizes the results of the base case and the sensitivity analyses for medical resource cost reduction, incidence of opioid overdose, and probability of NAI administration.

### TABLE 6 Summary of base case and sensitivity analysis

<table>
<thead>
<tr>
<th>Scenario</th>
<th>3-year average incremental cost for NAI group compared with control group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Base case (25% cost reduction, LOS reduction from 4 to 3 days, and 3.4% incidence of opioid overdose, 80% NAI administration probability)</td>
<td>$233,172</td>
</tr>
<tr>
<td>Base case with 50% NAI administration probability</td>
<td>$410,438</td>
</tr>
<tr>
<td>Base case with 46% medical resource cost offset</td>
<td>Zero (Break-even)</td>
</tr>
<tr>
<td>Base case with 5.1% incidence of opioid overdose</td>
<td>Zero (Break-even)</td>
</tr>
</tbody>
</table>

**Cost per death avoided**

In the base case, the cost per death avoided is approximately $192,400 (2.5 deaths avoided in Year 3 for an incremental cost of $481,000). The cost per death avoided is highly sensitive to the incidence of overdose. Raising the overdose incidence from 3.4% in the base case to 4.0% lowers the cost per death avoided to $103,940 (three deaths avoided in Year 3 for an incremental cost of $308,974). An overdose incidence of 5% yields a cost per death avoided of $5,952 (3.7 deaths avoided in Year 3 for an incremental cost of $22,116). Break-even (NAI acquisition cost is offset by medical resource savings) occurs with an overdose incidence of just under 5.1%.

**DISCUSSION**

The FDA and other federal, state, and local entities have made deaths due to opioid overdose, and in particular prescription opioid overdose, a high priority. In response to this public health emergency, government agencies are beginning to produce recommendations relating to naloxone coprescription for certain high-risk patients on opioids, and a growing number of municipalities are supplying their first responders, including police departments, with training and naloxone. For example, the Department of Health and Human Services and SAMHSA recently released an update to their Opioid Overdose Toolkit recommending the prescription of FDA-approved naloxone, including NAI, to certain patients on opioids at high risk, such as those “taking high doses of opioids for long-term management of chronic malignant or nonmalignant pain” and “those who are on certain preparations that may increase risk for opioid overdose such as extended release/long-acting preparations,” among others (SAMHSA 2014). In addition, states are enacting laws to provide immunity to laypersons who administer naloxone (Network 2014, Davis 2014). Additionally, the U.S. attorney general recently called overdoses from heroin and prescription medications an “urgent health crisis” and is recommending that all first responders carry naloxone.

The feasibility of caregivers or other laypersons responding to opioid overdose in a community setting rests on two key concepts. First, the ability to recognize life-threatening respiratory depression does not require medical training. Second, the safety profile of naloxone favors administration even if an opioid overdose is only suspected but not confirmed. This is because if a patient is taking opioids but there is not an overdose event, the risk associated with naloxone administration is limited to withdrawal, which in nonpostoperative settings has not been shown to be life-threatening with the exception of the neonate patient population (SAMHSA 2014, Compton 2013, Evzio 2014).

The limiting factor in naloxone reaching its full public health poth-
tial benefit has been its availability only in parenteral formulations requiring manual administration by a trained professional. With the FDA’s recent approval of Evzio, the first NAI that includes labeling for family member or caregiver use in nonmedically supervised settings, the landscape has changed dramatically (FDA 2014).

Although it is not the responsibility of third-party payers to solve the nation’s opioid overdose public health crisis, a payer’s decision to reimburse NAI may depend on these beliefs: (1) the provision of a naloxone preparation to patients for use by family, caregivers, friends, or coworkers is essential to saving lives in opioid overdose situations, (2) use of FDA-approved products is preferable over formulations that are not approved by the FDA, and (3) medical cost offsets based upon credible data or conservative assumptions justify the drug purchase costs and reimbursement. These considerations must all be put into the context that there continues to be significant growth in opioid overdose adverse events and their resulting costs.

With respect to the economics, the base case analysis in the model indicates that net NAI acquisition cost for a hypothetical health plan with 1 million adult members is likely to plateau at approximately $1.5 million annually. The net costs of NAI use (NAI acquisition cost less medical resource offsets) are primarily dependent on (1) the expected reduction in the probability of use and cost per use of medical resources, (2) the expected overdose incidence in the NAI-prescribed population, and (3) the probability that NAI will actually be administered following an overdose.

A further reduction in probability of resource use (for hospitalization, cardiac resuscitation and death) and cost per use (for ED and hospitalization) from 25% to 46% resulted in the net NAI acquisition cost being completely offset by medical resource savings. Similarly, increasing the expected overdose rate in these high-risk patients from 3.4% to 5.1% resulted in a complete offset of NAI acquisition cost. In studies of heroin users, the probability that a distributed naloxone kit was used each year was 13.6%, which indicates that our estimates of opioid overdose may be low (Coffin 2013).

However, these cost offsets may potentially be reduced by a lower NAI administration rate in the event of an opioid overdose. The base case offsets of $975,000 in Year 3 were reduced to $610,000 when the probability of administration was reduced from 80% in the base case to 50% (Table 5, appendix). In support of the 80% base case figure, this value was reported by Wagner in a study of heroin users (Coffin 2013). In other studies, 85% of heroin overdoses were witnessed, indicating that caregivers or other laypersons are an important factor in reversing overdoses using naloxone (Coffin 2013). Studies are in progress to determine actual usage of NAI in the event of a suspected opioid overdose.

The more practical issue involves providing NAI to patients at increased risk for opioid overdose, as the model’s incidence of overdose events in the NAI-prescribed population is highly dependent on patient selection. The 1.1% of patients on long-acting or extended-release opioids are easily identified, but the percentage of patients on short-acting opioids at increased risk is not as easily identified from an administrative claims database, nor can recommendations for prescribers be as straightforward.

The clinical implications of the modeling suggest that the expanded utilization of naloxone using NAI is likely to save lives and result in less severe morbidity of patients entering the ED. Opioid overdose patients receiving NAI prior to an ED visit are expected to use fewer ED services and have fewer hospitalizations. The economic implication is that utilization of NAI will result in medical cost offsets that can achieve break-even or better, negating the acquisition cost of the drug.

This study aims to provide a basis for further investigations and, pending real-world experience, serves to prompt additional research and analysis into this growing public health concern and the role of naloxone.

Limitations
The major limitation of this study is the reliance on naloxone experience in the community setting, primarily among heroin users. Additionally, the risk factors chosen for this sample representative patient population are not inclusive of all the risk factors associated with opioid overdose. As it is unclear how much overlap there is among all the possible conditions in the Zedler study (Zedler 2014), to include all risk factors would have resulted in a substantial overstatement of chronic and “at-risk” opioid users deemed appropriate for NAI (i.e., >90%). Although VHA provides a large national database from which to sample, the population comprises primarily older white males who receive most of their health care within a single closed system. Therefore, more work needs to be completed to identify risk factors associated with nonfatal and fatal overdose in a more demographically generalized population.

Studies, however, are currently ongoing to gather additional information that will help to inform the model. For example, the probability of NAI administration in the event of an opioid overdose needs to be determined after obtaining an appropriate amount of reliable data from the community setting.

This is a first-generation analysis based on the evidence available at this time, and as payers collect data
on the use of NAI, the projected cost of various formulary policies will become more accurate. Furthermore, the objective of this study was to determine the cost efficiency of the use of NAI vs. the current standard of care based on product acquisition cost and reasonable assumptions for medical cost offsets. Therefore, we did not assess quality-adjusted life-years (QALYs) and other quality-of-life measures.

**CONCLUSION**

Opioid overdose is a serious and growing health concern in the United States that is largely preventable. The introduction of Evzio, the first FDA-approved naloxone autoinjector labeled for administration by non-healthcare professionals, such as family members or caregivers, allows for earlier intervention during a suspected opioid overdose emergency. Third-party payers must decide whether or not, and how, to reimburse for this potentially life-saving intervention. With this decision in mind, an economic model was developed to estimate the economic burden to a health plan. A base case analysis through a representative simulation demonstrates that anticipated medical cost offsets can be achieved to cover the cost of NAI.

**REFERENCES**


### APPENDIX

**TABLE 5** Costs for base case analysis with 50% probability of NAI administration

<table>
<thead>
<tr>
<th></th>
<th>Net drug acquisition cost</th>
<th>Total cost of ED visits</th>
<th>Total hospital cost based on NAI patients</th>
<th>Total cost of cardiac arrest (survival)</th>
<th>Total cost of fatal overdoses</th>
<th>Cost of medical resources</th>
<th>Total costs (drug acquisition + medical resources)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Year 1</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NAI used</td>
<td>$125,552</td>
<td>$17,464</td>
<td>$117,519</td>
<td>$13,532</td>
<td>$2,373</td>
<td>$150,888</td>
<td>$276,440</td>
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<tr>
<td>Control group</td>
<td>$19,959</td>
<td>$165,302</td>
<td>$15,465</td>
<td>$2,711</td>
<td></td>
<td>$203,437</td>
<td>$203,437</td>
</tr>
<tr>
<td>Cost differential</td>
<td>$105,603</td>
<td>($2,495)</td>
<td>($47,783)</td>
<td>($1,933)</td>
<td>($339)</td>
<td>($52,549)</td>
<td>($73,003)</td>
</tr>
<tr>
<td>As a %</td>
<td>(13%)</td>
<td>(29%)</td>
<td>(13%)</td>
<td>(13%)</td>
<td>(26%)</td>
<td>(26%)</td>
<td>36%</td>
</tr>
<tr>
<td><strong>Year 2</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NAI used</td>
<td>$535,690</td>
<td>$74,514</td>
<td>$501,416</td>
<td>$57,735</td>
<td>$10,123</td>
<td>$643,787</td>
<td>$1,179,477</td>
</tr>
<tr>
<td>Control group</td>
<td>$85,158</td>
<td>$705,288</td>
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<td>$450,532</td>
<td>($10,645)</td>
<td>($203,872)</td>
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<td>($1,446)</td>
<td>($224,211)</td>
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<td>As a %</td>
<td>(13%)</td>
<td>(29%)</td>
<td>(13%)</td>
<td>(13%)</td>
<td>(26%)</td>
<td>(26%)</td>
<td>36%</td>
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<tr>
<td><strong>Year 3</strong></td>
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<td>$156,967</td>
<td>$27,521</td>
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<td>$179,391</td>
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<td>($28,941)</td>
<td>($554,278)</td>
<td>($22,424)</td>
<td>($3,932)</td>
<td>($609,574)</td>
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<td>As a %</td>
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<td>(13%)</td>
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<td>(26%)</td>
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<td><strong>3 year total</strong></td>
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<td>($886,334)</td>
<td>($1,231,315)</td>
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<td>(26%)</td>
<td>36%</td>
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<tr>
<td><strong>Mean</strong></td>
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<td>As a %</td>
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<td>(29%)</td>
<td>(13%)</td>
<td>(13%)</td>
<td>(26%)</td>
<td>(26%)</td>
<td>36%</td>
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</table>
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The medium-term forecast for Medicare spending has brightened considerably, according to the boards of trustees of the Social Security and Medicare trust funds. The boards’ most recent projections are that per-capita increases in Medicare spending will be lower than previous projections and that Medicare spending as a whole will grow more slowly than spending in the private sector. Medicare spending is now expected to be about $2,400 less per beneficiary in 2019 than projections made four years ago predicted.

The change in Medicare spending projections is partly because of the ACA and provisions that affect reimbursement formulas, such as the penalty for hospitals with high rates of preventable readmissions. This provision alone led to 150,000 fewer readmissions between January 2012 and December 2013, according to an HHS report issued late last year.

Demographics are still tugging the projections for overall spending upward. Total Medicare spending is expected to climb from 2019 to 2023 as baby boomers get older and become eligible for coverage. In fact, the trustees’ actuarial crystal ball predicts that, as a percentage of GDP, Medicare costs will surpass Social Security in 2052.