Wake Up, It’s Almost 2018!
OUR ANNUAL YEAR IN PREVIEW ISSUE

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In COMFORT-I* and COMFORT-II, Jakafi® (ruxolitinib) significantly reduced spleen volume compared with patients receiving placebo or best available therapy, respectively.1,3

**COMFORT-I Primary End Point: Spleen Volume Reduction at Week 24**1,2

<table>
<thead>
<tr>
<th>Patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥35% Spleen Volume Reduction From Baseline</td>
</tr>
<tr>
<td>Jakafi (n = 155)</td>
</tr>
<tr>
<td>Placebo (n = 154)</td>
</tr>
<tr>
<td>BAT (n = 65)</td>
</tr>
</tbody>
</table>

*COMFORT-I (COntrolled MyeloFibrosis study with ORal JAK inhibitor Treatment-I) was a randomized, double-blind, placebo-controlled phase 3 study with 309 patients with intermediate-2–risk or high-risk myelofibrosis.1,2

**COMFORT-II Primary End Point: Spleen Volume Reduction at Week 48**1,3

<table>
<thead>
<tr>
<th>Patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥35% Spleen Volume Reduction From Baseline</td>
</tr>
<tr>
<td>Jakarta (n = 146)</td>
</tr>
<tr>
<td>BAT (n = 73)</td>
</tr>
</tbody>
</table>

*COMFORT-II (COntrolled MyeloFibrosis study with ORal JAK inhibitor Treatment-II) was a randomized, open-label phase 3 study with 219 patients with intermediate-2–risk or high-risk myelofibrosis.1,3

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 × 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.
- Increases in hepatitis B viral load with or without associated elevations in alanine aminotransferase and aspartate aminotransferase have been reported in patients with chronic hepatitis B virus (HBV) infections. Monitor and treat patients with chronic HBV infection according to clinical guidelines.
Indications and Usage

Jakafi is indicated for treatment of patients with intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis.

Overall survival was a prespecified secondary end point in COMFORT-I and COMFORT-II.

- **COMFORT-I**: At 3 years, survival probability was 70% for patients originally randomized to Jakafi and 61% for those originally randomized to placebo.

- **COMFORT-II**: At 3 years, survival probability was 79% for patients originally randomized to Jakafi and 59% for those originally randomized to best available therapy.

Because of progression-driven events or at the physician’s discretion, patients randomized to placebo (COMFORT-I) or best available therapy (COMFORT-II) who crossed over to receive Jakafi continued to be grouped within their original randomized assignment for analysis purposes.

All patients in the control group either crossed over or discontinued.

When discontinuing Jakafi, myeloproliferative neoplasm-related symptoms may return 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 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.

Treatment with Jakafi has been associated with increases in total cholesterol, low-density lipoprotein cholesterol, and triglycerides. Assess lipid parameters 8-12 weeks after initiating Jakafi. Monitor and treat according to clinical guidelines for the management of hyperlipidemia.

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.

Please see Brief Summary of Full Prescribing Information for Jakafi on the following pages.

To learn more about Jakafi, visit Jakafi.com/HCP.

References:
Jakafi (N=155)

Table 1: Myelofibrosis: Adverse Reactions Occurring in Patients on Jakafi in the Double-blind, Placebo-controlled Study During Randomized Treatment

<table>
<thead>
<tr>
<th></th>
<th>All Grades</th>
<th>Grade 3</th>
<th>Grade 4</th>
<th>All Grades</th>
<th>Grade 3</th>
<th>Grade 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bruisingb</td>
<td>23</td>
<td>&lt;1</td>
<td>15</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Dizzinessc</td>
<td>16</td>
<td>&lt;1</td>
<td>0</td>
<td>7</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Headache</td>
<td>15</td>
<td>0</td>
<td>5</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Urinary Tract Infectionsd</td>
<td>9</td>
<td>0</td>
<td>&lt;1</td>
<td>1 &lt;1</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Weight Gain</td>
<td>7</td>
<td>&lt;1</td>
<td>0</td>
<td>1 &lt;1</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Fatality</td>
<td>5</td>
<td>0</td>
<td>&lt;1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Hepatic Zosterf</td>
<td>2</td>
<td>0</td>
<td>&lt;1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

n: National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE), version 3.0
b: includes conduction, eocchymosis, hematomas, venous/arterial hematomas, venous puncture site hematomas, increased tendency to bruise, petechiae, ecchymoses

c: includes dizziness, postural dizziness, vertigo, balance disorder, Meniere's Disease, labyrinthitis

d: includes urinary tract infection, cystitis, ureapnoea, urinary tract infection bacterial, kidney infection, pyuria, bacteriuria, bacteria urine identified, urinary infection
f: includes weight increased, abnormal weight gain; includes herpes zoster and post-herpetic neuralgia

Description of Selected Adverse Drug Reactions

Anemia: In the Phase 2 placebo-controlled study, the median time to onset of first Grade 2 or higher anemia was approximately 6 weeks. One patient (1%) discontinued treatment because of anemia. In patients receiving Jakafi, mean decreases in hemoglobin reached a nadir of approximately 1.5 to 2.0 g/dL below baseline after 8 to 12 weeks of therapy and then gradually recovered to reach a new steady state that was approximately 1.0 g/dL below baseline. This pattern was observed in patients regardless of whether they had received transfusions during therapy. In the randomized, placebo-controlled study, 60% of patients treated with Jakafi and 38% of patients receiving placebo received red blood cell transfusions during randomized treatment. Among transfused patients, the median number of units transfused per month was 1.2 in patients treated with Jakafi and 1.7 in placebo treated patients.

Thrombocytopenia: In the two Phase 3 clinical studies, in patients who developed Grade 3 or 4 thrombocytopenia, the median time to onset was approximately 8 weeks. Thrombocytopenia was generally reversible with dose reduction or dose interruption. The median time to recovery of platelet counts above 50 X 109/L was 14 days. Platelet transfusions were administered to 5% of patients receiving Jakafi and to 4% of patients receiving control regimens. Discontinuation of treatment because of thrombocytopenia occurred in <1% of patients receiving Jakafi and <1% of patients receiving control regimens. Patients with a platelet count of 100 X 109/L to 200 X 109/L before starting treatment had a higher frequency of Grade 3 or 4 thrombocytopenia compared to patients with a platelet count greater than 200 X 109/L (17% versus 7%). Neutropenia: In the two Phase 3 clinical studies, 1% of patients reduced or stopped Jakafi because of neutropenia. Table 2 provides the frequency and severity of clinical hematology abnormalities reported for patients receiving treatment with Jakafi or placebo in the placebo-controlled study.

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

<table>
<thead>
<tr>
<th></th>
<th>All Grades</th>
<th>Grade 3</th>
<th>Grade 4</th>
<th>All Grades</th>
<th>Grade 3</th>
<th>Grade 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thrombocytopenia</td>
<td>70</td>
<td>9</td>
<td>4</td>
<td>31</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Anemia</td>
<td>96</td>
<td>34</td>
<td>11</td>
<td>87</td>
<td>16</td>
<td>3</td>
</tr>
<tr>
<td>Neutropenia</td>
<td>19</td>
<td>5</td>
<td>2</td>
<td>4</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
</tbody>
</table>

Additional Data from the Placebo-controlled Study: 25% of patients treated with Jakafi and 7% of patients treated with placebo developed newly occurring or worsening Grade 1 abnormalities in alamine transaminase (ALT). The incidence of greater than or equal to Grade 2 elevations was 2% for Jakafi with 1% for Grade 3 and no Grade 4 ALT elevations. 17% of patients treated with Jakafi and 6% of patients treated with placebo developed newly occurring or worsening Grade 1 abnormalities in aspartate transaminase (AST). The incidence of Grade 2 AST elevations was <1% for Jakafi with no Grade 3 or 4 AST elevations. 17% of patients treated with Jakafi and <1% of patients treated with placebo developed newly occurring or worsening Grade 1 elevations in cholesterol. The incidence of Grade 2 cholesterol elevations was <1% for Jakafi with no Grade 3 or 4 cholesterol elevations. Clinical Trial Experience in Polycythemia Vera: In a randomized, open-label, active-controlled study, 110 patients with polycythemia vera resistant to or intolerant of hydroxyurea received Jakafi and 111 patients received best available therapy. Clinical Study (14.2) in Full Prescribing Information. The most frequent adverse drug reaction was anemia. Table 3 presents the most frequent non-hematologic treatment emergent adverse events occurring up to Week 32. Discontinuation for adverse events, regardless of causality, was observed in 4% of patients treated with Jakafi.
is metabolized by CYP3A4 and to a lesser extent by CYP2C9. The Cmax and AUC of ruxolitinib
(12.3) and CYP2C9 inhibitor fluconazole at doses of 100 mg to 400 mg once daily, respectively [see Pharmacokinetics
and Administration (2.3) Information
increased 33% and 91%, respectively following concomitant administration with the strong CYP3A4 inhibitor
b National Cancer Institute Common Terminology Criteria for Adverse Events, version 3.0
a Presented values are worst Grade values regardless of baseline
treated with Jakafi were: Weight gain, hypertension, and urinary tract infections. Clinically relevant
Other clinically important treatment emergent adverse events observed in less than 6% of patients
includes edema and peripheral edema
c includes dizziness and vertigo
a National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE), version 3.0
Abdominal Pain
Urinary tract infections
Edematous
Mucous Membranes
Abdominal Nausea
Adverse Events All Grades (%) Grade 3-4 (%) All Grades (%) Grade 3-4 (%) Headache 16 <1 19 <1 Abdominal Pain 15 0 15 <1 Shlержа 15 0 7 <1 Dizziness 15 0 13 0 Fatigue 15 0 15 3 Priapism 14 <1 23 4 Dyspepsia 13 3 4 0 Muscle Spasms 12 <1 5 0 Nasopharyngitis 9 0 8 0 Constipation 8 0 3 0 Cough 8 0 5 0 Etielna 8 0 7 0 Arthritis 7 0 6 <1 Arthralgia 7 0 11 2 Fatigue 15 0 15 3 Epistaxis 6 0 3 0 Herpes Zoster 6 <1 0 0 Nausea 6 0 4 0

Table 3: Polycythemia Vera: Treatment Emergent Adverse Events Occurring in ≥ 6% of Patients on
Jakafi in the Open-Label, Active-controlled Study up to Week 32 of Randomized Treatment

Table 4: Polycythemia Vera: Selected Laboratory Abnormalities in the Open-Label, Active-controlled
Study up to Week 32 of Randomized Treatment

Parameter

<table>
<thead>
<tr>
<th>Laboratory Parameter</th>
<th>All Grades (%)</th>
<th>Grade 3 (%)</th>
<th>Grade 4 (%)</th>
<th>All Grades (%)</th>
<th>Grade 3 (%)</th>
<th>Grade 4 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anemia</td>
<td>72 &lt;1</td>
<td>&lt;1</td>
<td>58 0</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thrombocytopenia</td>
<td>27 5</td>
<td>&lt;1</td>
<td>24 3</td>
<td>&lt;1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neutropenia</td>
<td>3 0</td>
<td>&lt;1</td>
<td>10 &lt;1</td>
<td>&lt;1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypercholesterolemia</td>
<td>35 0</td>
<td>0</td>
<td>8 0</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elevated ALT</td>
<td>25 &lt;1</td>
<td>0</td>
<td>16 0</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elevated AST</td>
<td>23 0</td>
<td>0</td>
<td>23 &lt;1</td>
<td>&lt;1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hyperuricemia</td>
<td>15 0</td>
<td>0</td>
<td>13 0</td>
<td>0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


AUC of ruxolitinib is predicted to increase by approximately 100% to 300% following concomitant administration with the combined CYP3A4 and CYP2C9 inhibitor fluconazole at doses of 100 mg to 400 mg once daily, respectively [see Pharmacokinetics (12.3) in Full Prescribing Information]. Avoid the concomitant use of Jakafi with fluconazole doses of greater than 400 mg/day.

with the strong CYP3A4 inducer rifampin in healthy subjects. No dose adjustment is recommended; however, monitor patients frequently and adjust the Jakafi dose based on safety and efficacy [see Pharmacokinetics (12.3) in Full Prescribing Information].

OVERDOSAGE There is no known antidote for overdoses with Jakafi. Single doses up to 200 mg have been given with acceptable acute tolerability. Higher than recommended repeat doses are associated with increased myelosuppression including leukopenia, anemia and thrombocytopenia. Appropriate supportive treatment should be given. Hemodialysis is not expected to enhance the elimination of ruxolitinib.
MANAGED CARE publishes original papers and feature articles dealing with diverse elements of the health care system. Among these are impartial peer-reviewed research and review articles examining clinical and financial aspects of managed care.

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The Prices Ain’t Right
By Peter Wehrwein

Economics is called the dismal science. Uwe Reinhardt was anything but dismal. When the Princeton health economist died last month at the age of 80, the remembrances were of a lively, funny, and approachable man with important things to say and clever ways of saying them.

The headline of the New York Times obit called him a “listened-to voice” on health care. Ezekiel Emanuel told the Washington Post that Reinhardt was a “great moral conscience.”

Reinhardt was on our editorial advisory board, so he was familiar and accessible. Frank Diamond, our managing editor, wrote an eloquent blog post about him, recalling—among other things—the laughs they shared after a 2013 interview. You can see the video (but not, alas, the post-interview laughs) on our website.

Reinhardt’s most enduring contribution to the never-ending discussion about what ails American health care may be a 2003 Health Affairs article provocatively titled “It’s the Prices, Stupid.”

Reinhardt and his coauthors looked at a variety of measures of health care utilization, including physician visits and hospital days per capita. They found that the United States was actually below the median of those measures for other developed countries. Yet this country is a complete outlier in health care spending. Administrative costs, “service intensity”—they’re factors. But Reinhardt and his colleagues highlighted price as the explanation for American health care spending—and so that memorable title and an abiding truth.

Some think value-based care can tame American health care spending. Others believe we can unleash market forces with health care saving accounts and the like. But they are pretty weak medicine when what the American health care dollar buys is priced so high. It remains the prices, stupid.  

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How the huge Internet retailer might transform the system.

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The Scout motto gets it right, and preparedness is getting a fresh look.

Value-based Care: 5 Not-So-Easy Pieces
There are five ways value-based health care can play out this year.

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It might make a comeback next year, but not a spectacular one.

Part 2, ACA Repeal: Star Turn for State Regulators
Well, somebody has to figure out just what’s going on.

Opioids, Part 1: Health Insurers Asked To Step Up
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Opioids, Part 2: Novel Therapies Might Be the Answer
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Medicaid: Work Requirements, Expansion in Offing
CMS chief Seema Verma wants to reshape the entitlement program.

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’NewHealth’ will force change
When copays don’t count
Get More Mileage From EHRs By Using Them Strategically

In order to get the most out of EHRs, providers need to think outside the box—the box in this case being CMS’s meaningful use requirements, according to wisdom contained in a PwC survey. The three stages of CMS’s meaningful use program dangle incentives to encourage hospitals and other health care providers to improve their electronic health records (EHRs) system for Medicare beneficiaries.

Providers complain that the program places an untenable burden on them. For instance, the American Hospital Association, representing some 5,000 hospitals, wants CMS to delay implementing Stage 3 of the program, which is set to begin in 2018.

The PwC survey found that only 25% of health care providers strongly agree that EHRs help their organizations adapt to the new health economy. In addition, only 23% strongly agree that their EHRs boosted value-based care and population health strategies.

However, those providers who strategically implement EHRs tend to have a much more positive view of them. Reducing variation in care is critical to achieving better outcomes and “strategic implementers appear to be further along on digitizing clinical documentation,” the PwC report on the survey states. In almost every strategy category, the meaningful use implementers lag the strategic implementers, according to the survey.

For instance, while 39% of implementers have had EHRs in place for less than five years, 64% of strategic implementers have had it in place. Sixty-three percent of implementers use EHRs for clinical documentation; for strategic implementers it’s 84%. Strategic implementers also are more pleased with how their systems performed.

PwC conducted a telephone interview of 300 health care provider executives in August and September of 2017. The survey, which was published in October, also included information taken from in-depth interviews with 15 executives at health care delivery systems across the country.

The survey found that while EHRs store clinical data, they do not as yet fully support population health efforts. Only 36% of providers use EHRs in their population health efforts. Just 13% strongly agree that EHRs have met their expectations for population health management.

PwC spoke to David Chin, MD, a distinguished scholar at the Johns Hopkins Bloomberg School of Public Health and Johns Hopkins School of Medicine.

“The EHR by itself is insufficient for population health analytics because patients cross systems,” he told them. He thinks that the implementation of more health information exchanges (HIEs) might be one way to address this problem. HIEs allow providers to share patient histories and data regardless of where the care is provided.

PwC’s write-up of its survey mentioned a recent study published in the New England Journal of Medicine that found that social factors and environmental exposure such as pollution account for 20% of premature deaths.

“When it comes to a person’s health and well-being, all the data in a provider’s EHR only account for one third of what is needed,” Jonathan Weiner, director of the Center for Population Health IT at Johns Hopkins University, told PwC researchers.

PwC offers several recommendations for providers. They include tightening up data governance, and considering using a vendor to construct the EHR system.

<table>
<thead>
<tr>
<th>Comparison of different approaches to EHR use</th>
<th>Meaningful use implementers</th>
<th>Strategic implementers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agree EHR has met expectations for communicating more effectively with patients</td>
<td>76%</td>
<td>92%</td>
</tr>
<tr>
<td>Face an inability to extract meaningful data from the EHR as a barrier to maximizing its benefits</td>
<td>30%</td>
<td>18%</td>
</tr>
<tr>
<td>Report operating margins of 5% or greater for the first fiscal year</td>
<td>39%</td>
<td>47%</td>
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Safety Net Hospitals And Readmissions

Broadening the Hospital Readmissions Reduction Program (HRRP) so that it is hospital-wide and not just focused on the five conditions currently included in the program would mean that safety net hospitals would be hit with higher penalties than other...
hospitals, according to a study published in the *New England Journal of Medicine*. Safety net hospitals treat a larger proportion of low-income patients than other hospitals.

It would “increase the disparity between safety net and other hospitals: The mean penalty as a percentage of base DRG payments would be 0.41 percentage points ($198,000) higher among safety net hospitals,” the study states.

The study looked at Medicare claims from 2011 through 2013 and included about 6.7 million readmissions under a hospital-wide measure and about 4.3 million readmissions under a condition-specific measure. Of the 3,443 hospitals included in the study, 688 were safety net hospitals.

When HRRP’s effectiveness became clear to most observers, experts began considering how it might be expanded. Groups such as the Medicare Payment Advisory Commission support a hospital-wide system.

Beginning in 2012, HRRP began penalizing hospitals for higher-than-normal 30-day readmission rates for Medicare beneficiaries suffering from heart failure, myocardial infarction, and pneumonia. In 2015, total hip and knee replacement and chronic obstructive pulmonary disease were added to the list.

The HRRP penalty is total payments for excessive readmissions divided by the total Medicare payments for all admissions.

The authors of the study, which was published October 19, say that there may be ways to level the playing field between the safety net hospitals and other hospitals, such as “assigning penalties within DSH [Disproportionate Share Hospital] index strata so that safety-net hospitals are not compared with other hospitals…”

The researchers work for HHS, the Harvard T. H. Chan School of Public Health, and the University of Michigan Institute for Healthcare Policy and Innovation.

Although a hospital-wide penalty system would not be good for safety net hospitals, it would address other problems, the researchers say. For instance, “it would allow the use of a single year of admissions for the determination of penalties (thereby shortening the time between performance and penalty), increase the number of clinical conditions evaluated, and modestly increase the number of hospitals meeting the volume threshold for penalty assessment.”

Also, as the study notes, a hospital-wide readmission system would “broaden hospital eligibility and provide incentives for improvement across conditions.”

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**Medicare Advantage market continues to grow**

There will be 2,619 distinct Medicare Advantage plans offered in 2018, an increase from the 2,311 offered this year, according to Mark Farrah Associates, an electronic publisher of business information that analyzes the health care marketplace. In addition, there will be a total of 640 special needs plans available next year, up from 589 this year. Special needs plans include people with one or more chronic conditions, such as diabetes, congestive heart failure, cardiovascular disease, osteoarthritis, HIV/AIDS, and mental health disorders. Beneficiaries will also have more stand-alone prescription drug plans to choose from: 795 next year, up from 757 in 2017.

According to Mark Farrah’s count, Humana will continue to be the largest player in the MA marketplace in 2018, offering 466 distinct plans. UnitedHealthcare will continue to increase the number of plans it is offering to 344 distinct plans. Blue Cross and Blue Shield Association plans, such as Anthem, continue to have a strong presence in the MA market as well. Other major players include Cigna, WellCare, Centene, and Kaiser Permanente.

**Number of distinct MA plans to be offered in 2018**

<table>
<thead>
<tr>
<th>Plan Type</th>
<th>Number of Plans</th>
</tr>
</thead>
<tbody>
<tr>
<td>Humana</td>
<td>466</td>
</tr>
<tr>
<td>UnitedHealth</td>
<td>344</td>
</tr>
<tr>
<td>Aetna</td>
<td>251</td>
</tr>
<tr>
<td>BCBS</td>
<td>175</td>
</tr>
<tr>
<td>Anthem</td>
<td>121</td>
</tr>
<tr>
<td>WellCare</td>
<td>87</td>
</tr>
<tr>
<td>Centene</td>
<td>64</td>
</tr>
<tr>
<td>Kaiser</td>
<td>51</td>
</tr>
<tr>
<td>Cigna</td>
<td>43</td>
</tr>
<tr>
<td>Centene/Health Net</td>
<td>39</td>
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<tr>
<td>Geisinger</td>
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<tr>
<td>Highmark</td>
<td>30</td>
</tr>
<tr>
<td>Tufts</td>
<td>27</td>
</tr>
<tr>
<td>Other</td>
<td>853</td>
</tr>
</tbody>
</table>


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**Technique Boosts Doc Personal Touch**

A short psychosocial intervention called BATHE (Background, Affect,
Trouble, Handling, and Empathy) for hospital patients can do a lot to increase satisfaction, according to a study published last month in *Family Medicine*. BATHE is supposed to help patients share their psychological and life problems and not just limit discussions with providers to their physical problems.

In a randomized study, researchers at the University of Virginia School of Medicine looked at 25 patients from February through March 2015, and again from February through March 2016.

Corresponding author Claudia Allen tells Managed Care in an email that the two separate time periods strengthens the study “because it means that the results were not just idiosyncratic to the particular team or situation at a given moment.”

The 13 patients in the intervention group received BATHE for five days or until discharged. The 12 patients in the control group received regular care.

BATHE increased the likelihood of patients describing their medical care as excellent. It did this because patients perceived that their physicians showed a genuine interest in them as a person.

BATHE involves asking patients four questions and making a statement to help providers better determine state of mind: “What is going on in your life?” “How is that affecting you?” “What troubles you the most about that situation?” “How have you been handling it so far?” “That sounds very scary/frustrating/sad.”

Patients ranged in age from 29 to 77 and were admitted for problems such as pneumonia, pancreatitis, and diabetic complications.

The nine residents who participated were given BATHE training that included a refresher course right before the start of the study, and they carried a copy of the BATHE questions. Other members of the medical team were unaware of the patients’ enrollment and group status.

The patients were asked to grade satisfaction on a five-point, Likert-like scale, with 1 being strongly disagree and 5 being strongly agree.

“Very satisfied with care” received a 4.08 rating from the control group but a 4.69 rating from the BATHE group.

“The added value of the intervention appears to have been to create a daily moment where the physician acknowledged the patient as a whole person rather than solely as a medical patient,” according to researchers.

There were limitations, the obvious one being small sample size but also the lack of a fidelity measure to define the extent that an intervention adhered to BATHE’s protocols.

### Medicaid Program’s Care Coordination

The Bridges to Care (B2C) program provides help to Medicaid patients who use the emergency department frequently. It steers them to primary care providers, assists them in getting prescriptions filled, and even tries to find them transportation and housing if needed. The program was developed by the Camden Coalition of Healthcare Providers, a multidisciplinary, community-based primary care program.

When applied in Colorado, the program led to 30% fewer hospitalizations, a similar reduction in emergency department visits, and a 123% increase in primary care visits in six months compared to a control group, according to a study published last month in *Health Affairs*.

“There is a perspective from multiple stakeholders that high users of the ED are difficult patients,” said the study’s lead author, Roberta Capp, MD, an assistant professor of emergency medicine at the University of Colorado School of Medicine, in a press release. “But this is the first program to show that care coordination actually works.”

Researchers with the University of Colorado implemented B2C in four types of health care organizations: an urban academic hospital, 13 federally qualified health centers, a community advocacy organization, and a mental health clinic.

They compared results of 402 B2C participants with 3,396 members of the control group. B2C participants enrolled in the program from January 2013 to October 2014.

The study was not a randomized control trial but researchers instead used “robust methodological techniques to create an artificial control group.” The authors also noted that almost a third (27.6%) of the enrollees did not complete the 60-day program.

A team made up of a primary care provider, care coordinator, behavioral health evaluator, health coach, and community health worker provided medical, behavioral, and social care services.

It cost about $500,000 to build the program’s infrastructure, and the running costs were estimated to be $640 per 60-day intervention per patient.

One of the keys to the program’s success, according to researchers, was including behavioral health. Most of the patients in the study had mental health problems.

Another important feature was the use of “hotspotting”—a data-driven process that’s meant to locate extreme patterns of utilization in an area and respond with targeted interventions. Hotspotting was an innovation of the Camden Coalition of Healthcare Providers.

### Variation Found In Prisons, Too

Unexplained variation in health care costs among America’s regions and states has long been a puzzle for providers and payers, and it seems to be a problem for prisons as well, according to a study by the Pew Charitable Trusts. “Health care spending per inmate varied dramatically in fiscal 2015, as it had in past years—from
$2,173 in Louisiana to $19,796 in California,” the report states.

Pew researchers could not determine what exactly causes the variation. One obvious possibility: States that spend less to provide health care might not be giving prisoners adequate care.

“State officials across the country need to understand whether and how these differences reflect meaningful discrepancies in value and performance,” the Pew report said.

It’s important to know exactly how the money is spent, information that’s not currently available, according to researchers. That’s in part because most state data systems don’t offer enough to create a detailed, actionable analysis. And reporting limitations were most common among states that primarily or completely outsource their prison health care delivery, the report states.

State corrections departments spent $8.1 billion on prison health care services in 2015, representing about a fifth of overall prison expenditures. It took decades of litigation to establish that prison health care must be close to the level of care that non-prisoners receive.

**Briefly Noted**

**Most cases of measles** in the United States occur among unvaccinated patients, according to the CDC. According to researchers, 69.5% of 1,789 measles cases in the country between 2001 and 2015 struck unvaccinated patients. The researchers note that endemic measles, defined as a transmission chain that lasts a year or longer, was eliminated from the United States in 2000. Measles is still very rare, with the yearly number of cases varying between 24 and 658 during the study period.** More physicians who reach retirement age** are less likely to do just that, according to a study by health care staffing company Comp-Health and as reported by Medical Economics. The desire for social interaction topped the list of why older doctors stay working. About half of the respondents said that their ideal retirement plans included working occasionally or part-time.** Baptist Health System** in San Antonio saw a 21% drop in average Medicare spending for joint replacement episodes between 2008 and 2015 after implementing a Medicare joint replacement bundled payment program, according to a study in JAMA Internal Medicine. Medicare episode expenditures declined from $26,785 to $21,208 for 3,738 episodes of joint replacement without complications and 13.8% from $38,537 to $33,216 for 204 episodes of joint replacement with complications, according to University of Pennsylvania researcher Amol Navathe and his colleagues.** HHS investigators say** that Medicare needs to take quick action against a disturbing situation: One in four cases of possible sexual or physical abuse to nursing home residents go unreported, the AP reports. “Using investigative data analysis techniques, auditors from the inspector general’s office identified 134 cases in which hospital emergency room records indicated possible sexual or physical abuse, or neglect, of nursing home residents,” the AP reports.** ADHD symptoms for children** three- to eight-year-olds improved with the use of a basic parenting skills program, according to a review of 11 studies by University of North Carolina researchers. Designed for parents with high-risk children and children with behavioral problems, the Incredible Years Basic Parent Program teaches the importance of establishing ground rules, addressing misbehavior, and setting limits. It also emphasizes incentives and praise. The UNC researchers set out to tease out whether the program was specifically effective for ADHD.** Anthem is going all in** on independent imaging facilities, mandating that beneficiaries go to them rather than the more expensive hospital-owned outpatient imaging centers, Kaiser Health News reports. Anthem wants to reduce costs, of course, and says that quality won’t suffer. Critics argue that the move will lead to fragmented care for patients.** Using trained non-clinicians** to visit high-risk patients enabled Regal Medical Group in California to cut 30-day hospital readmissions by 67%, HealthLeaders Media reports. The program is in its second year. The 67% reduction is double the reduction during the previous year. Regal is one of the largest physician practice networks in Southern California.** Whirlpool has expanded its wellness** efforts for some 4,000 workers by hiring eight onsite health care providers for the company’s 12 southwest Michigan locations, reports the Herald-Palladium of Saint Joseph, Mich. Employees can get a quick checkup that involves no copay. “Something unique Whirlpool added this year is a 49-point biometric screening that is tied into the employee’s health insurance,” the newspaper reports.** Increasing access to ICU care** didn’t reduce the death rate among older people seen in emergency departments in France, according to the results of a study reported in JAMA. In fact, it appears to have made it worse. Twenty-four hospitals were randomly assigned to either a program that promoted systematic ICU admission or to usual care. Patients in the systematic strategy group had an increased risk of death at six months (45% vs. 39%) despite increased ICU admission (61% vs. 34%).** Children’s hospitals are exempt** from federal regulations mandating they adopt bundled payment systems and value-based purchasing programs. Yet many children’s hospitals are going in that direction anyway because they see value-based care as the best way to improve quality, reports Healthcare Finance.

— Frank Diamond
To those who say “impossible, impractical, unrealistic,” we say:

CHALLENGE ACCEPTED

We’re developing an innovative new class of medicines called RNAi therapeutics, which we believe have the potential to transform the lives of people living with rare genetic, cardio-metabolic and hepatic infectious diseases.

Learn more about our pipeline at alnylam.com
The Trump administration’s move to eliminate cost-sharing reduction (CSR) payments to insurers to hold down out-of-pocket costs for low-income people who purchase individual health plans on the ACA exchanges could have two unintended consequences. First, the cuts may wind up increasing overall federal spending, and, hence, the deficit, by driving up premium subsidies to cover the higher prices plans are charging to cover the CSRs. Second, instead of discouraging people from buying insurance on the exchanges, those enhanced premium subsidies just might create enough no-premium plans in enough counties to bring buyers back.

Latest chapter
This irony is only the latest chapter in the tortured history of CSRs. The ACA set them up as a mechanism to reimburse insurers for lowering deductibles and other out-of-pocket costs that people with incomes at 250% or less of the federal poverty rate bear when they purchase silver-level policies on the ACA exchanges. The idea, says Sara Collins, vice president of the Commonwealth Fund, was to bring those deductibles down to a level comparable to employer-sponsored insurance. “What we found in our survey data is that these payments have been extremely effective at lowering peoples’ deductibles to levels that we see actually in employer-based plans at that income level,” she says.

However, in 2014 Republicans in the House took the Obama administration to court for making the payments, and a federal judge last year ruled in their favor. In October of this year, the Trump administration announced a halt to CSR payments for the rest of this year and for next year just as insurers were scrambling to file their rates for next year.

A few days after Trump cut off CSRs, Sen. Lamar Alexander of Tennessee, a moderate Republican, and Sen. Patty Murray of Washington, a Democrat, unveiled their plan to fund the CSRs for 2018 and 2019 and restore $110 million in ACA outreach funding the Trump administration cut. At first Trump praised this brief ray of bipartisan sunshine, but then walked that back.

Without CSRs, premiums are going to go even higher, but so will subsidies that lower-income people get to pay those premiums. And in that ruling in the House lawsuit, the court noted that the ACA mandate for paying the premium tax subsidies was much clearer than that for the CSRs, so short of ACA repeal, the premium subsidies can’t be canceled in the way that the Trump administration has canceled the CSRs.

The Congressional Budget Office found that, by making the CSR payments for 2018 and 2019, the Alexander–Murray legislation would actually reduce the federal deficit by $3.8 billion over the next 10 years. Moreover, said the CBO, not making the CSR payments would increase the deficit by $6 billion in 2018, $21 billion in 2020, and $26 billion in 2026.

“It’s much more expensive to do it this way than just by paying the cost-sharing reductions, so it doesn’t make a lot of fiscal sense to proceed this way,” notes Collins. “If one wants to be fiscally conservative, the decision would likely be to make the [CSR] appropriation.”

States have taken steps
Despite the CBO numbers and its bipartisan glow, Alexander–Murray could end up on the legislative ash heap. Sen. Joe Manchin, a West Virginia Democrat, who supports the legislation, told MSNBC, “That bill is teed up and ready to go.” The question is, will McConnell let it get to the floor? And if he does, will the House act on it? Will Trump even sign it?

Many states have taken steps to mend the breach left by the cancellation of CSR payments.

Can the bipartisan Alexander–Murray bill restore cost-sharing reduction payments and bring some sanity back to the individual market?

By Richard Mark Kirkner, Contributing Editor
Scott Harrington, a University of Pennsylvania Wharton School professor who follows health insurance, says the state responses fall into four categories:

1. Direct plans to assume that CSRs would continue when calculating and filing their rates for 2018. The District of Columbia, North Dakota, and Vermont have gone this route.
2. Allow companies to file rates that spread the costs of CSRs among all exchange plans—platinum, gold, silver, and bronze. Five states—Colorado, Delaware, Indiana, Oklahoma, and West Virginia—have taken this approach.
3. Let insurers factor the cost of the loss of the CSRs into the prices for individual silver plans sold both on and off the exchange.
4. Limit insurers to factoring the cost of the loss of CSRs only to silver plans sold on the ACA exchanges.

“I think in many cases the states were pretty savvy about how they played this,” Harrington says. “When you load these reduced cost-sharing payments into silver premiums on the exchanges, it increases the amount of premium subsidies that’s available because premium subsidies depend on the second-lowest cost silver plan premium in the market.”

Use it till you lose it

Some consumers who buy insurance on the exchanges could benefit and pay nothing for coverage in 2018, Harrington notes. “Once the premium subsidy is determined, you don’t have to buy a silver plan,” he says. “You can buy a low-cost bronze plan, and there’s an increasing discussion of how in many counties throughout the country there are now going to be zero-premium plans because of increased subsidies that’s available because premium subsidies depend on the second-lowest cost silver plan premium in the market.”

Collins says. “From the consumer’s point of view, they really have to shop around.” The shortened open enrollment period this year (six weeks from November 1 through December 15) along with cuts to the navigator program make the task only more daunting.

Confused consumers

“The secondary implication of this is that consumers are just confused and it just adds to the complexity of the choices that people have this year compared to what it was last year,” Collins says. Yet, in the early days of open enrollment for exchange plans, signups were keeping pace with previous years.

Deep Banerjee, an analyst who follows health insurance for S&P Global, says all the doubts about the ACA may affect medical costs next year. “The person who has the policy is also feeling perhaps uncertainty about the future of this law, so their behavior may be different,” he says. Their utilization of medical services may go up while they have insurance because they’re afraid of losing it, says Banerjee. It is the use-it-before-you-lose-it psychology of insurance coverage.

The way forward

Two things businesses—and maybe all of us—want when planning for the future are predictability and stability. For health plans, the CSR payments have meant anything but.

Canceling of CSRs are “a continuation of things that keep changing with the Affordable Care Act,” says Banerjee. He mentions that the Senate’s 2015 action to roll back risk corridor payments, which covered losses of not-for-profit cooperative health plans set up under the ACA, contributed to that pattern of uncertainty. “It requires insurers who want to stay in the marketplace to keep adapting to the rules that keep changing,” he says. “That is not a very welcoming environment for the insurance company.”

But hope springs eternal even as we are headed into winter and when the political climate has gone haywire. “Network design changes, which really can be formative in nature, and pricing changes, which health plans have to continually make naturally, make us think there is a path forward,” Banerjee says.

That path forward would be a lot easier to see with predictable CSRs.
When they write the health care history books, 2017 will likely be remembered as much for what didn’t happen as what did.

Republicans didn’t succeed in repealing the ACA. And the ACA individual markets, while not exactly rockin’ and rollin’ in many parts of the country, didn’t spiral into death, either.

Will 2018 be another 12 months of near-misses and anticlimaxes? Kinda, yes, because we see a fog of gray area ahead.

But we are putting money on continuing debate about drug prices.

Strong federal action seems unlikely given the political theatrics in Washington, but California and other states are stepping in. Meanwhile, the PBM industry seems headed for more whitewater and increasing pressure to become more transparent. If Amazon gets into the business, everything else will seem placid in comparison.

Value-based care has some momentum. But it may fall more to the private sector to keep it going. Adding work requirements to Medicaid via waivers seems where Seema Verma is more likely to put her time and energy.

Where the country can’t afford inaction next year is in curbing the opioid epidemic. Insurers and others can’t dither, shirk responsibility, and point the finger elsewhere. Too many Americans are dying.

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Where the country can’t afford inaction next year is in curbing the opioid epidemic. Insurers and others can’t dither, shirk responsibility, and point the finger elsewhere. Too many Americans are dying.
the EpiPen’s price tag 400%). “I’m not going to say increases like that will never happen, but I think pharmaceutical companies are attempting to be more judicious.”

If such eye-popping increases for existing drugs didn’t figure prominently in the conversation at year’s end, big numbers still did. In August, the FDA approved the first CAR-T therapy, Novartis’s Kymriah (tisagenlecleucel) to treat pediatric and young adult acute lymphoblastic leukemia, priced at $475,000 per patient. Two months later, Gilead’s CAR-T therapy, Yescarta (axicabtagene ciloleucel) for certain types of large B-cell lymphomas, got the nod. The price: $373,000. More CAR-T therapies are in development, and the Institute for Clinical and Economic Review has fired up its value and pricing assessment procedure for CAR-T therapies that is scheduled to culminate with a final report on March 16 of next year.

New York-based Segal Consulting sees prices continuing to rise in the new year, with the rate of increase softening by a percentage point or two. The company’s annual outpatient prescription-drug spending increase projection for workers and early retirees is 10.3%, down from 2017’s 11.6%. For 65-plus retirees it’s 7.5% vs. last year’s 9.9%. These forecasts don’t account for PBM rebates and don’t purely reflect price, but Segal says “price inflation—not utilization—is the leading driver of trend.”

Eileen Pincay, vice president and pharmacy benefits consultant, says diabetes drugs will be a big contributor to inflation, as will specialty drugs, whose 2018 spending-rise projection of 17.7% is down just slightly from the previous year’s 18.7%. Specialty drugs accounted for more than one-third of total drug spending in 2016, Segal’s report notes, and by 2020 they’ll be almost 50%.

To explain the downward pressure on prices, Pincay cites: political pressure, an increase in the use of generics in traditional categories such as hypertension and statins, and a decline in utilization and an increase in competition in drugs for hepatitis C.

“Rx trends are the top priority for some plan sponsors,” Segal writes, “because the cost increases of pharmacy benefits now exceed the cost increases of hospital claim expenses or physician claim expenses” to create “the fastest-growing cost element of their health plans.” It says the outcry against “soaring drug prices” has been heard “from Washington to Wall Street” and in state capitals too.

One such capital is Sacramento. Starting in January, drugmakers serving the California market will be required to give 60 days’ notice to insurers and government health agencies such as Medi-Cal, the state’s Medicaid program, whenever they raise by 16% or more the price of a drug with a wholesale cost of $40 or higher. Meant to increase transparency in drug pricing, the new law will also—by 2019—require the companies to justify the price hikes. It was supported by consumer groups, hospitals, and health plans, but sharply opposed by the pharmaceutical industry.

In May, Maryland enacted a law enabling the state attorney general to impose a fine of up to $10,000 for an “unconscionable” 50%-or-higher single-year increase in the wholesale price of an essential off-patent or generic drug. Several other states were pondering similar steps.

In November, Ohio voters rejected by a 4-to-1 margin a ballot measure that would have required Medicaid, the prisons, and the state employees’ retirement system to pay no more for prescription drugs than does the U.S. Department of Veterans Affairs, which gets at least a 24% discount off regular prices.

The proposal’s defeat was blamed not only on more than $60 million spent by drug companies promoting a “no,” but also on a perception that it was a flawed and confusing measure that might actually raise drug prices for people with Medicare or private insurance. Afterward, supporters said their struggle wasn’t over because “this system we have for drug pricing in America has got to give.”

On the federal level, more than a dozen bills to address rising drug prices have been introduced in the current Congress. One is the Fair Accountability and Innovative Research Drug Pricing Act sponsored by Sens. John McCain, a Republican from Arizona, and Tammy Baldwin, a Democrat from Wisconsin. For drugs priced over $100 it would require drugmakers to justify price increases above 10% for one year or 25% for three years. The Stop Price Gouging Act, introduced by a bevy of progressive Democrats, would also call for justifying price hikes and would impose a penalty for each “unjustified” increase that would be “proportionate to the price spike.”

Meanwhile, a prominent tweeter responded to a protest move about his comments on the white nationalist rally in Charlottesville, Va., by returning to a theme he’d sounded in his Presidential campaign: “Now that Ken Frazier of Merck Pharma has resigned from President’s Manufacturing Council,” declared President Trump, “he will have more time to LOWER RIPOFF DRUG PRICES!”

To hear new FDA Commissioner Scott Gottlieb, MD, tell it, the administration is indeed trying to control drug prices—by enhancing competition. His agency has an-
nounced a “Drug Competition Action Plan” meant to “improve the efficiency of the generic drug approval process,” as he has written, and to close “loopholes that allow branded drug companies to game our rules in ways that forestall the generic competition that Congress intended.”

Meanwhile, rising drug prices remain a big concern of the public. In a poll reported in September by Politico and Harvard’s T.H. Chan School of Public Health, when respondents were given a choice of 10 priorities for Congressional action this year, lowering prescription drug prices ranked first.

Will all this noise chill drug price increases in 2018? It has already inspired symbolic action. In December 2016, Allergan CEO Brent Saunders pledged to limit price increases to 10% as part of his company’s implied “social contract.” In a blog post he advised fellow pharma execs: “Limit your price increases before we all face the impact of government regulation that stifles innovation and patient care.” By early 2017, Novo Nordisk, AbbVie, and Takeda had made similar promises, and in May Sanofi did them one better by embracing a 5.4% limit—though Sanofi suffered a PR black eye in September when it appeared to waver on its commitment, drawing a scolding from the public-advocacy group Public Citizen until it reaffirmed its pledge.

On October 17 the public was reminded just how complex a process governs what consumers pay for drugs. The Senate Health Committee held a hearing on drug prices with representatives of brand drugmakers, generic drugmakers, drug wholesalers, PBMs, and pharmacists. Watching it was a familiar experience for any parent who’d ever tried to interrogate a group of children about a mess they’d made, hearing each one’s airtight explanation why it was the other kids’ fault.

Lori Reilly of the Pharmaceutical Research and Manufacturers of America insisted that last year, brand-name drugmakers’ list price increases had poked along at 3% to 5%, while Chester Davis, president and CEO of the Association for Accessible Medicines, representing generic manufacturers, said his products faced a deflationary market.

A memorable moment occurred when Republican Sen. Susan Collins of Maine inquired about an NBC News report on a gag order said to have barred pharmacists from telling customers when it would actually be cheaper to buy a drug on their own rather than using insurance. How, she asked, could a PBM whose job it was to negotiate end up negotiating a price higher than the out-of-pocket price?

“It’s an outlier behavior,” said Mark Merritt, president and CEO of the Pharmaceutical Care Management Association, representing PBMs. “I’m not even sure if it’s a PBM or an insurer behavior.”

“No, it’s not an outlier,” countered Thomas E. Menighan, executive director and CEO of the American Pharmacists Association, when he got his chance. “It’s common.”

When Tennessee Republican Sen. Lamar Alexander, the committee chair, asked simply whether rebates are necessary—wouldn’t simply lowering prices be more transparent?—nobody really had an answer.

Ian Reynolds, an associate manager with the Drug Spending Research Initiative at the Pew Charitable Trusts, notes that CMS projects that spending on prescription drugs will continue to increase faster than overall health spending in the coming years.

A growing emphasis is now placed on what patients pay out of pocket. That, Reynolds believes, is one takeaway from the recent Senate hearing. “A central question,” he says, “is how much of the discounts that payers negotiate with manufacturers is being passed along to plan sponsors and how much they’re keeping.”

— Timothy Kelley, Senior Contributing Editor
A few months ago Linda Cahn was pondering how a retailing giant might change the current PBM business model of convoluted contract language, secret side deals, opaque pricing structures, and the like. “A Walmart, Costco, or Amazon could create a truly transparent PBM,” said Cahn, a PBM consultant and an ardent critic of the industry. “That would implode the current model.”

Well, we may soon find out. As 2017 wound down, Forbes, Bloomberg, Barron’s, CNBC, and Marketwatch were rife with reports that Amazon was this close to diving into the PBM marketplace. And when Amazon takes a plunge, the wake usually swamps the competition.

The first hint that Amazon was sizing up the PBM market came in May, when CNBC reported that the company was hiring a general manager to lead its pharmacy business. The network followed up in September with a story saying Amazon had “ramped up” its conversations with “middle-market” PBMs (presumably after Amazon checked its website to see if it had any in stock).

A few analysts think Amazon ultimately won’t fill its prescription to become a PBM. The PBM industry thrives in a thicket of regulations and licenses that might be difficult even for Amazon to master. Amazon is also used to direct payment from gazillions of customers. Its PBM would be dealing with third-party payers.

Amazon’s experience

Of course, if Amazon buys an existing PBM it likely will have all the regulatory, licensing, and bill processing components in place. Amazon does have some experience in the prescription drug business, although it was on the retail side of the selling universe. In 2000 it held a 40% stake in Drugstore.com. That’s when Drugstore.com paid Amazon $105 million over three years to be a “featured shopping tab on the Internet e-tailers site,” according to an AdAge article. Amazon eventually sold Drugstore.com to Walgreens, which closed the website last year.

Industry analysts have noted that if Amazon were to get into the prescription drug business, it might benefit from the brick-and-mortar presence it now has in many of the most affluent and well-insured ZIP codes in the country by virtue of its $13.7 billion acquisition of Whole Foods this year. The company would be well positioned to open in-store pharmacies in those tony places. People would be able to pick up organic bananas, hormone-free milk, grass-fed beef, and their statins all in one trip.

Amazon’s poking around the PBM market hasn’t gone unnoticed by CVS, Express Scripts, or Optum. They recognize the threat an Amazon PBM would pose. So if Amazon wants to get into dispensing prescription medications, why can’t a PBM get into health insurance?

CVS and Aetna, the country’s third largest health insurer by revenue and members, are exploring a proposed $66 billion merger. According to Reuters, the merger would allow the blended company to negotiate prices with pharmaceutical manufacturers and control the out-of-pocket costs customers pay for each drug.

A CVS–Aetna mashup could have a domino effect. Other PBMs, insurers, and pharmaceutical companies would look for a dance partner. Of course, Optum is already a subsidiary of UnitedHealth Group. Optum itself expanded this year with its $1.3 billion acquisition of the Advisory Board’s health care business. Meanwhile, Anthem is partnering with CVS to form a new PBM to be called IngenioRx that will get up and running in 2020 after Anthem’s contract with Express Scripts ends.

Cahn sees a chance for a giant jolt of transparency if Amazon were to get into the PBM business. She would like to see the company insist that manufacturers simultaneously submit the net discount price for each of their drugs for the subsequent six months. Amazon could then publicize every drug’s actual price, by drug and by therapeutic category. That way, she says, everyone—plans, patients, and doctors—would know the real price before they buy or prescribe.

“Consumers in high-deductible plans would finally have a means to know the actual prices of every drug, which all PBMs today hide,” she says. “Amazon would thus impose price competition. It would grow exponen-
tially and the existing marketplace model would crumble overnight.”

— Robert Calandra
Disasters
IN THE WAKE OF THE 2017 ANNUS HORBILIS, PREPAREDNESS RULES TO GET TOUGHER

Disaster seems to be a new kind of normal, still unpredictable but no longer unexpected. It’s impossible to say what calamities 2018 will bring, but payers, providers, and regulators are going into the new year with an armamentarium of tools—and new requirements—for responding when large numbers of people suddenly have new health care needs.

Telehealth is one of the tools. After Hurricane Harvey battered Texas and Louisiana in August, LiveHealth Online, a subsidiary of Anthem, announced it would provide free telehealth services to any resident of those states who had been impacted by the storm. It made the same offer to all Florida residents in September after Hurricane Irma raked the state. LiveHealth Online President John Jesser says no one at the company questioned the need to offer the service at no cost to anyone in those states, regardless of whether they were Anthem customers. “This was really about how we could get in there to help people who need help,” he says. American Well and MDLive were among those also offering free services to consumers because of the hurricanes.

Cigna responded with a free, 24-hour telephone helpline for people affected by hurricanes and also set up a helpline following the mass shooting in Las Vegas. “We just think it’s the right thing to do,” says spokesperson Mark Slitt. “It’s part of our sense of corporate responsibility.” LiveHealth Online also offered free telehealth services in Las Vegas.

Insurers in Florida and Texas also helped out after the hurricanes by relaxing some rules—eliminating higher charges for out-of-network care, for example.

But the disasters of 2017 also revealed some severe shortcomings in preparedness. In Florida, 14 residents of the Rehabilitation Center at Hollywood Hills nursing home died after Hurricane Irma knocked out power to the air conditioning system—even though, according to

Police cordoned off the Rehabilitation Center at Hollywood Hills, which had no air conditioning after Hurricane Irma knocked out power in much of Florida. Fourteen people died at the center, and there are now a dozen bills under consideration in the Florida legislature that would toughen nursing home regulation. (John McCall, South Florida Sun-Sentinel/TNS via Getty Images)
Vegas oddsmakers will take a bet on almost anything. As of this writing, the New England Patriots are 6:1 favorites to win the Super Bowl. French President Emmanuel Macron is the leading choice for Time’s Man of the Year. The over–under on how many people will watch Game of Thrones’ season 8 premiere is 11.5 million—and we don’t even know yet when HBO will air the show.

But wagering on the direction of health care in the United States—ah, that’s a fool’s game. What course will value-based care take in 2018? “That’s the $50 million question, right?” quips Deborah Gersh, a partner at Ropes & Gray and co-chair of its Health Care Practice Group.

Former HHS Secretary Tom Price’s hostility toward the Center for Medicare & Medicaid Innovation initially sparked talk that Washington might back away from the value-based movement; CMS’s abrupt cancellation of several episode-payment models and its exclusion of 134,000 clinicians from the Merit-based Incentive Payment Program in 2018 provided grist for the mill. In reality, the message was that a post-Obama HHS favors choice over mandates, with CMS Administrator Seema Verma asking stakeholders for fresh ideas about care delivery and payment models.

It’s too early to handicap what that may mean for value-based care in 2018, but some themes are emerging.

1

VALUE-BASED CARE CAN’T BE DONE ONE SLICE AT A TIME.

In a March essay in Stat, Rita Numerof, co-founder and president of her eponymous consulting firm in St. Louis,
and David B. Nash, MD, dean of the Thomas Jefferson University College of Public Health, argued that many of today’s value-based efforts amount to minor modifications to the fee-for-service model, with added incentive payments for reporting certain data or meeting certain cost benchmarks. It’s not the sort of stuff that moves the needle, AthenaHealth’s Paul Levy wrote in an April blog. Levy, former CEO of Beth Israel Deaconess Medical Center in Boston, noted that the financial incentives physicians earn for meeting benchmarks often fall below the revenue they give up to save payers money.

“Health care is an ecosystem,” says Kate Willhite, product executive for Value-based Solutions at Skygen, a benefit-management technology company. “Most solutions up to this point have addressed only a segment of stakeholders and a few dimensions of changing the landscape.”

Bill Kramer, executive director for national health policy at the Pacific Business Group on Health, says that to really encourage innovative care delivery requires paying for quality, rewarding consumers for choosing high-value providers, and using meaningful performance measures. The current crop of value-based programs haven’t produced great results, he says, because they tend to pull only one of those levers, but a PBGH-administered program, Employer Centers for Excellence Network, pulls all three.

Given a tryout by Boeing and Lowe’s, ECEN bundles payments for total joint, spinal, and bariatric surgery at high-performing hospitals, waives out-of-pocket costs for employees who choose an ECEN center of excellence for these procedures, and tracks clinical and patient-reported outcomes. The pilot, now expanded, reduced unnecessary surgeries and referrals to inpatient post-acute care, cutting total costs in the process. “If Medicare were to adopt this kind of program, it could have an effect throughout the health care system,” predicts Kramer.

2

NEW VALUE-BASED MODELS WILL TAKE AIM AT VARIATIONS IN CARE.

In the coming weeks, CMS will roll out its voluntary, next-generation Bundled Payments for Care Improvement program. Clay Richards, CEO of NaviHealth, expects strong health system interest in the program, which CMS says will qualify as a MACRA Advanced Alternative Payment Model. NaviHealth, which helps payers and providers manage post-acute care, isn’t alone in being bullish on bundles; a McKesson report issued last year predicted that bundles will grow faster than capitation arrangements in the years ahead.

Bundled payments, says Richards, have been “a great way to create alignment among physicians, hospitals, post-acute providers, and ancillary providers around a care plan.” Their success in pruning variations in care is especially critical in the post-acute setting, he adds, because post-acute care accounts for 20% to 25% of a payer’s medical-loss ratio. With that much money on the table, post-acute referral patterns become important to hospitals and a change agent for insurers.

Hospitals can’t tell Medicare fee-for-service patients where to seek post-acute care, but in the commercial world, the question “Who’s in the network?” is a powerful motivator of patient behavior. To that end, expect hospitals to leverage their relationships with high-performing providers in shared commercial networks.

In parallel, commercial insurers will continue to gravitate toward offering health plans with narrow networks to reduce care variation, believes David Hom, chief evangelist at SCIO Health Analytics. “As a result, provider groups will increasingly need to demonstrate the value of their services to health plans, particularly those that own risk,” he says.

It all adds up to a perfect storm—one that tracks with Richards’s observation of a much stronger mutual interest in payer–provider partnership over the last 24 months. “The data we have at the physician, hospital, and post-acute provider levels that can highlight the quality and variance that’s not leading to best outcomes, I think, have opened up very different conversations,” he says.
THE PATIENT MAY GAIN A STRONGER VOICE.

Manage care all you want, but if the patient isn’t engaged, the exercise may be a triumph of process over outcomes. Many experts would like new value-based models to rely on innovative ways to engage patients.

Four decades of study and experimentation—starting with the Rand Health Insurance Experiment—have looked at how dipping into patients’ wallets affects people’s health and health care choices. The Rand results, for example, showed that cost sharing reduced the use of effective and less effective health care services by about the same amount.

At an October symposium marking the 50th anniversary of the University of Pennsylvania’s Leonard Davis Institute of Health Economics, several speakers agreed that better benefit design would nudge patients toward more valuable medical services—much as ECEN waives deductibles and coinsurance for patients who choose its centers of excellence. Employers may be in the vanguard here: A June PwC report found that only 28% are considering offering high-deductible health plans as their only benefit option to employees in 2018, down from a high of 44% in 2014.

Granularity in provider-level data, such as in Medicare Compare, may also serve to engage patients while stimulating the consumerism value-based benefit designs need to thrive. “I can look at the stats and see which car I want to buy, but can you really look at the stats and say, ‘This guy’s a better surgeon?’” asks Gersh of Ropes & Gray. “Is he only operating on people under 40? Or does he have the super-complex cases in a rural area?”

Kramer at PBGH thinks a lot about performance measurement—a natural, given his position on the board of directors at the National Quality Forum. Though he acknowledges the difficulty of capturing patient-reported outcomes and crafting measures for them, he says attention to PROs is critical for engaging patients.

“When people talk around a kitchen table about who’s a good doctor or what’s a good hospital, they don’t know what internal clinical measures the hospital or physician practice captures,” he says. “What they talk about is, ‘After my hip surgery, was I able to bend over and pick up my grandkids again?’”

THE TAIL COULD WAG THE DOG.

For years, CMS has set the tone and private health plans have followed. Now, in asking for market-driven ideas for a CMMI makeover, Verma may be letting the private sector lead the way.

A receptive ear couldn’t come fast enough for employers, whom Kramer says are “frustrated with the slow take-up and spread” of models they pioneered and believe could drive health-system change. One such initiative, PBGH’s Intensive Outpatient Care Program, focuses on medically complex patients, giving them a dedicated contact and integrating behavioral needs. A 28% reduction in admissions and a 56% drop in missed workdays were achieved by a pilot program at Boeing (that is, a test of the outpatient care program, not a regimen for people who test-fly its planes). After that, PBGH got a CMMI grant to try out the outpatient care program in Medicare, rolling it out to 25 sites in five states.

Among Gersh’s provider clients, care coordination is a key lever for health-system improvement. “You see not only the providers doing it, but a lot of the mergers have that in mind, too, to provide continuity of care,” she says. Likewise, diversification is prominent—medical-device companies now offer management-support services to providers, for instance—and it’s reasonable to think that such vertical partnerships may figure into the models CMMI ultimately embraces.

VALUE-BASED CARE WILL CREATE HAVES AND HAVE-NOTS.

CMS’s pullback from mandatory bundles made some providers who spent time and money preparing for them wonder where it all left them, especially in light of new CMS data showing that hospitals have benefitted financially from the gain-sharing activity permitted under the mandatory bundles. “We’ve advised our clients that they will be able to deploy that model in the new bundled payment program, so it was a worthwhile investment,” says Richards at NaviHealth.

Despite the uncertainty at the federal level, many of Gersh’s clients recognize that value-based care is here to stay and are buying into its initiatives. “The folks who are moving full steam ahead because they think it’s going to be this way will have greater leverage and bargaining power,” she says.

As for those who aren’t “all in,” an Ernst & Young report last July was telling. EY painted a gap between large and small health systems’ core capabilities for ad-
A year ago you probably couldn’t find a Las Vegas bookmaker willing to give odds that the ACA would still be the law of the land in 2018.

In gamblerspeak, it was off the board. With control of both houses of Congress and the presidency, the GOP could finally make good on their seven-year promise to repeal and replace President Barack Obama’s signature health care legislation.

Turns out, repealing the ACA and crafting a replacement acceptable to the party’s disparate factions isn’t so easy. Who knew health care—and health care politics—would be so complicated?

Republicans did come close. In July party leaders tried to get a slimmed-down repeal and replace bill through the Senate. But Republican Sen. John McCain of Arizona, recovering from brain surgery, scuttled that gambit, not just casting the decisive no vote but flashing a thumbs down for emphasis.

Meanwhile, President Trump declared the ACA “dead” and saying “there is no such thing as Obamacare anymore.” The administration slashed marketing and other funds for programs designed to boost enrollment in ACA exchange plans and cut cost-sharing reduction payments.

As we went to press, it was uncertain how enrollment for ACA coverage in 2018 would play out. Early on, though, the number of signups was high.

Meanwhile, a fog of uncertainty also engulfed the compromise legislation negotiated by Sen. Lamar Alexander, a Tennessee Republican, and Patty Murray, a Washington Democrat. Virtually every description of that bill described it as “propping up” the ACA for a couple of years. And it would, in fact, fund the cost-sharing reduction payments for two years and put some money back into consumer outreach. In a bid to get Republican support, the legislation would make it easier for states to get ACA waivers and create so-called copper plans with low premiums and high deductibles (essentially, catastrophic insurance).

But for 2018, one thing is clear. As Richards says, “The sooner we can get some predictability with the federal government and how to move forward, the sooner everybody will feel much better.”

— Michael D. Dalzell, Senior Contributing Editor

Deborah Gersh, Ropes & Gray

managing value-based agreements. Among those with annual revenues of less than $1 billion, few have embraced value-based strategies—putting them at a disadvantage with payers.

Gersh thinks this is less about buy-in than the fact that any hospital has only so many dollars. “There will be resource challenges for organizations, especially those that do not fare as well under value-based care,” she says, citing inner-city and rural hospitals as those suffering the most. Some did not anticipate the costs of technology and data security, she says, and those without enough money for such things “may not be able to keep up with the incentives for reimbursement, which will impact care and recruiting of doctors. It’s a domino effect.”

It’s a challenging time to be in health care, for sure. Perhaps not since Lyndon Johnson made Harry Truman Medicare beneficiary number 1 has so much change roiled the industry. However well-meaning value-based initiatives are, it takes a Rubik’s cube of health care entities to pull them off. The pursuit of the right combination is pushing American health care toward bigger systems—hospital systems, vertical integration—and it’s an open question whether the unintended consequence of consolidation will be higher prices that nullify the savings created by value-based initiatives.

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ACA Repeal

HEADED FOR A WHIMPER, NOT A BANG?

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Meanwhile, President Trump declared the ACA “dead” and saying “there is no such thing as Obamacare anymore.” The administration slashed marketing and
posed including a repeal of the ACA individual mandate in the tax reform plan. Then Democratic victories in the November 6 election took the wind out of Republicans’ tattered sails and made some wonder if they would let the push to repeal the ACA fade away in 2018 after all the near-misses in 2017.

Some readings of the public opinion polls suggest that a whimper of an ending, not a banging one, might be the prudent course for the GOP’s repeal and replace urges (although prudence is definitely part of the Trump political appeal). According to an average of polls calculated by Real Clear Politics, more Americans have had an unfavorable opinion of the ACA than a favorable one since it was signed into law—until mid-January of this year when the ratio flipped. The trend toward a favorable opinion inched along through this year. By the end of October, Real Clear Politics’ poll averages showed that 51% of Americans have a favorable opinion of the ACA compared with 39% with an unfavorable one.

— Robert Calandra

**Kaiser Health Tracking Poll: The public’s views on the ACA**

![Graph showing public views on the ACA from 2010 to 2017](chart)

*Source: Kaiser Family Foundation*

While Republicans in Congress tread on local insurance markets in their tug-of-war with Democrats over the fate of the ACA, state insurance commissioners are being drawn into the debate in new ways, a trend likely to continue in 2018.

The Senate Health, Education, Labor and Pensions Committee, where many of the ideological skirmishes take place, hosted a panel of five states’ commissioners in September. The regulators hailed from both red and blue states and had widely varying views on policy, but they brought a unified message, courtesy of the insurance industry: The unpredictability of federal policy is killing us. “Uncertainty related to payment of cost-sharing reductions, high premiums, and weakened enforcement of the individual mandate have placed our individual health insurance markets at serious risk,” Washington State Commissioner Mike Kreidler told the panel.

Insurance is all about risk, but as an industry it’s as risk-averse as they come. The business has developed a real headache from anticipating the constantly changing outcome of Republicans’ on-again, off-again efforts to abolish the federal level of insurance regulation that the ACA created. Insurers have also suffered indigestion from White House threats to end key subsidy payments that were propping up markets in many states.

Congress spent much of this year skirmishing over health care, and Republicans were relieved—at least initially—to change the subject to tax reform in late

**ACA Repeal, Part 2**

*STAR TURN FOR STATE REGULATORS AS INSURANCE MARKETS WILL CONTINUE TO BE A PARTISAN BATTLEGROUND*
October. But health insurance coverage and the fate of the ACA will almost certainly leak into 2018 as a big story.

State insurance commissioners are not typically a high-profile lot, but the limelight seems to be finding them. Beyond rancor or simple advantage-seeking, much of the argument in Washington about health care travels that rutted path to disagreements about the role of the federal government and whether more power should be handed down to the states.

Insurance commissioners are either elected (11 of them) or appointed (the rest). Kaiser Health News compiled a handy, interactive profile of each state’s commissioner, finding a variety of models. In some states insurance oversight isn’t the whole job—some also oversee fire protection or serve also as state auditor. Many come from the insurance industry. Former Texas regulator Bob Hunter puts it bluntly: “Almost all of them will do whatever the insurance companies tell them to do.”

Whether in a red or blue state, the state commissioner jobs do require decent working relationships with insurance companies, particularly in precarious times as insurers threaten to leave some areas with no ACA coverage because of poor market conditions or dithering in Washington, D.C. Some regulators had to MacGyver clever fixes to keep all their counties covered; their bag of tricks included offering flexibility in plan designs and premium rates.

Current and former commissioners contacted for this article say they are frequently asked by federal officials for their input. “Insurance commissioners have been consistently visible in Washington, D.C., over the years,” says Julie Mix McPeak, Tennessee’s top insurance regulator and president-elect of the National Association of Insurance Commissioners.

At the same time, former Maine commissioner Mila Kofman, who now runs the insurance exchange in Washington, D.C., says the ACA repeal debate marked the first time she’s seen a group of current and former commissioners come together to press Congress on a specific issue. Eleven current and 25 former commissioners signed a Sept. 25, 2017, letter urging federal lawmakers to reject the last-last-last-ditch effort to disable the ACA, the bill sponsored by Republican Sens. Bill Cassidy of Louisiana and Lindsay Graham of South Carolina.

Kofman says she can’t predict whether that same group will be heard from again, but doesn’t rule it out.

Schooling lawmakers

The commissioners’ major role in federal policy is educating lawmakers on the complexities of insurance, which is nothing if not arcane. “One cannot know everything there is to know about insurance, and it is important members of Congress continue to engage commissioners on critical policy matters,” comments McPeak.

Kreidler, a former member of Congress himself, agrees that insurance regulators are in an important position to work with lawmakers on continuing fixes to health insurance markets. He just wishes they’d listen before they draft legislation rather than after. “We’re in a more reactionary role, which is probably not the most constructive or effective method when it comes to developing a new health insurance system for the country,” Kreidler says. “Insurance commissioners can be a valuable partner in these conversations, but it will take more time than Congress seems willing to spend.”

Many of the health policy ideas pursued by the Republican administration and Congress would shift regulation of health insurance to states. That would be welcomed by the state commissioners who believe they know better than federal bureaucrats how to manage their local markets. Among them would be Oklahoma Insurance Commissioner John Doak, who, unlike his colleagues who protested the Graham–Cassidy bill, appreciated that it would provide block grant funding to states. Doak told the Senate in September: “What we really need is an innovative, long-term solution that returns power back to the states to implement ideas tailored to fit each state’s specific needs.”

— Jan Greene
"Do something!" seems to be the message to health insurers about the opioid epidemic from patients, physicians, and addiction experts.

The numbers alone suggest a pressing need to take action. A staggering 33,000 Americans died of opioid-related deaths in 2015, the most recent year for which complete data are available. The number of deaths from opioids are likely to be even higher in 2016 than in 2015 once the final count for that year is in.

Blame for the epidemic had focused on drugmakers, drug wholesalers, and physicians who prescribed opioids too liberally. This fall, fingers pointed at health insurers. Investigative reporting showed that coverage policies that restricted access to less addictive medications might have helped fueled the epidemic. Managed Care and other outlets also reported on how prior authorization and other policies created barriers to addiction treatment. “With no relief from the epidemic in sight, we will see continued pressure on insurers to do what they can and to consider changing their UM policies as we enter 2018,” says John Santilli, a pharma industry consultant for Access Market Intelligence.

Insurers were on the receiving end of many of the 56 recommendations in the report issued by the Trump administration’s commission on opioids in November. The commission proposed, for example, that insurers modify payment policies that discourage the use of nonopioid treatments for pain and remove pain survey questions from patient satisfaction scores so providers won’t have an incentive to prescribe opioids.

Some of the recommendations from the Trump commission overlapped with those from a report issued two days earlier by the Clinton Foundation and the Johns Hopkins Bloomberg School of Public Health. The Clinton–Hopkins report called on insurers to cover naloxone, the drug that can reverse an opioid overdose in an emergency.

Perhaps most concerning to insurers was the emphasis the Clinton–Hopkins report put on a story reported jointly by Pro Publica and the New York Times that showed that many insurers may worsen the opioid epidemic by not covering pain medication like a buprenorphine patch, sold under the brand name Butrans, that is less addictive than many opioids.

In our April 2017 issue, Managed Care covered the problem caused by health insurers limiting prescriptions

Drugs involved in U.S. overdose deaths, 2000–2016

Source: National Institute on Drug Abuse
or requiring prior authorization for treatment drugs for opioid addiction.

David Aaron Cooke, MD, an internal medicine specialist and assistant professor at the University of Michigan commented on the Pro Publica and Times article, “It is indeed much easier to get insurers to pay for more addictive and risky treatments than safer ones. They dislike paying for Butrans in any form, despite the fact that it is a lower risk opioid than the alternatives.” In a telephone interview with MANAGED CARE, Cooke said he has often had patients do well on Butrans but then health insurers often stopped covering it. Instead, insurers switch patients to medications such as Purdue Pharma’s MS-Contin or methadone, both of which have much higher risks of addiction than the buprenorphine patch, he said. When insurers do not act quickly to cover appropriate medications for addicted members, those members frequently overdose and many die, Cooke added.

Two other reports in the fall also addressed steps health insurers can take. Research presented at the annual meeting of the American College of Emergency Physicians showed that 55% of patients who visited the emergency room for substance misuse had mental health issues and 60% were severely traumatized as children. One takeaway: Greater access to mental health providers are needed nationwide.

The Government Accountability Office also weighed in with a report saying that HHS should establish performance measures with targets that would encourage access to medication-assisted treatment for opioids.

— Joseph Burns, Contributing Editor

Opioids, Part 2

NOVEL THERAPIES COULD HELP WEAN AMERICANS OFF OPIOIDS

A n all-hands-on-deck response to the opioid epidemic will continue to be one of the major health care stories in 2018. But the epidemic took off partly because pain and its control are a black box that has resisted firm scientific understanding and safe and effective treatment. Drugmakers, for the most part, have continued to rely on opioid receptor agonists for their new medicines, although that could change next year.
So far, though, most of the new pain drugs coming from manufacturers have been iterations of the legacy opioids with extended-release (ER) and abuse-deterrent (ADF) formulations. Examples include Xtampza ER, an extended-release, abuse-deterrent form of oxycodone; Vantrela ER, a hydrocodone bitartrate; Arymo ER, a morphine sulfate; and Troxyca ER, an extended-release formulation of oxycodone and naltrexone.

The ADF opioids incorporate ingredients that extend the release and lower the maximum concentration of the agonist, which is supposed to thwart the effect of crushing the drugs and snorting, smoking, or injecting them to achieve high concentrations that provide a high. While this sounds good, the problem is that these formulations do not address the most common form of abuse—simply swallowing more of the pills. In fact, the extended-release products may actually contribute to increased opioid overdoses and deaths because they extend the opioid level overtime to dangerous levels as individuals take repeated doses.

“The ADF products are not a magic bullet—and they are very expensive,” says Mary Lynn McPherson, a pharmacy professor at the University of Maryland. “Most payers do not pay for them as first- or second-line therapies.” The low-cost formularies offered by PBMs typically rely on the legacy generic opioids.

The unmet need in pain management is for truly novel agents. The opioids remain the go-to products because they target the mu opioid receptor, which has been shown to be the most effective pathway to reduce pain. The holy grail for drug developers is an agent that stifles pain without producing the euphoria and addiction of opioids, says McPherson. To that end, she says, there is renewed interest in ketamine, which has a unique mechanism of action and has been used on battlefields.

Christopher Milne at Tufts’ Center for the Study of Drug Development says tanezumab is a new pain drug in development that should be watched in 2018. The monoclonal antibody has a novel mechanism of action that targets nerve growth factor (NGF) rather than the opioid receptors. NGF levels increase as a result of injury, inflammation, or chronic pain. Tanezumab selectively binds to nerve growth factor, limiting the protein’s ability to stimulate pain-signaling neurons. Tanezumab is being jointly developed by Pfizer and Lilly and is being tested in osteoarthritis and chronic low back pain. It was granted fast-track status by the FDA in June 2017. The phase 3 global clinical development program for tanezumab is currently ongoing with six studies in approximately 7,000 patients. We may see some results reported in the coming year.

It has been a fairly bumpy road for tanezumab. The FDA imposed a partial clinical hold on it and all other anti–nerve growth factor antibodies in December 2012 because of changes in the sympathetic nervous system of mature animals. In early 2015, the FDA lifted the hold on the tanezumab development program after a thorough review of nonclinical data characterizing the sympathetic nervous system response.

— Thomas Reinke, Contributing Editor

The Medicaid program is political putty. Its breadth and depth at any given time are molded by politics (big-picture and the nitty-gritty stuff), attitudes toward health insurance in general, and coverage for poorer Americans in particular.

Next year the program may prove to be more malleable than ever.

CMS administrator Seema Verma is pushing to add work and other requirements for some Medicaid beneficiaries by way of Section 1115 waivers.

Meanwhile, Maine residents voted in November for an ACA-type expansion of Medicaid over the objections of the Republican governor. Campaigns for similar ballot initiatives in Utah and Idaho are gearing up. And the fate of the popular Children’s Health Insurance Program (CHIP) was unknown as we went to press. (Technically, CHIP isn’t part of Medicaid, but they are often grouped together because both extend insurance to low-income Americans.) The House passed legislation in early November that would reauthorize the program for another five years, but most Democrats voted against it because the money came from the ACA’s Prevention and Public Health Fund—another Republican move, say Democrats, to sabotage the ACA.

Medicaid is both huge and balkanized. It now covers about one in every five Americans, which works out to about 62 million people. That’s a larger slice of the payer pie than Medicare (14%; 45 million people) but considerably smaller than employer-sponsored coverage (49%; 157 million people). Mainly by their design—it’s been a federal-state hybrid since its inception—Medicaid programs vary widely from state to state.
The Kaiser Family Foundation predicts that growth in Medicaid enrollment will slow next year to 1.5% from 2.7% in fiscal year 2017. Even so, total spending is projected to rise by 5.2%, compared with a 3.9% increase in fiscal year 2017. Prescription drug costs and higher payment rates to certain provider groups are among the reasons for the uptick in spending.

Verma made her reputation revamping Indiana’s Medicaid program when Mike Pence was governor. Indiana expanded Medicaid under the ACA but also received a Section 1115 waiver, so it’s not surprising that as CMS administrator Verma is wielding the waivers as a way to reshape Medicaid programs along conservative-Republican lines. The Indiana Medicaid program she designed as a consultant to the state created a tier of Medicaid that pairs high-deductible coverage with a health savings account in pretty much the way commercial insurers do with their high-deductible plans. Other features of the Healthy Indiana Plan, as it is called, required beneficiaries to make “contributions” analogous to premiums and used higher co-pays to discourage inappropriate use of the emergency department.

Early in her tenure in the top job at CMS, Verma signaled an endorsement of work requirements. She and her then boss, Tom Price, mentioned them in an open letter to governors in March. In a speech she gave last month to the National Association of Medicaid Directors, Verma endorsed “community engagement”—work or community service—as a condition for “able-bodied” people to get Medicaid coverage and accused the Obama administration of the “soft bigotry of low expectations” for opposing such a requirement. By some counts, eight states have submitted requests for Section 1115 waivers that would involve imposing some kind of work or service requirement on Medicaid beneficiaries in their states. The new year could bring a flurry of approvals and, at least in those states, a Medicaid version of Bill Clinton’s “end of welfare as we know it.”

Many progressive groups and experts see the work requirements as antithetical to the purpose of the 1115 waivers—and Medicaid more generally. Judy Solomon, vice president for health policy at the Center on Budget and Policy Priorities, a nonpartisan research and policy institute, says the waivers are supposed to be used to increase Medicaid access and coverage. Some of the pending

**Status of state action on Medicaid expansion**

As of Nov. 8, 2017

Source: Kaiser Family Foundation
In an administration that seems to relish blowing up bureaucracies, leaving chaos and uncertainty in its wake, the fact that no one foresees any great disruption in how the understaffed Federal Trade Commission views health system and hospital mergers makes it an outlier in Trump World.

That won't mean a whole lot in 2018 for possible mergers like the CVS–Aetna deal. Health insurance antitrust is pretty much the purview of the Department of Justice.

Solomon also says the Trump administration “doesn’t think [Medicaid] expansion is consistent with the core mission of Medicaid.”

“It’s not clear if the Trump administration even wants to encourage the conservative version of Medicaid to go forward,” adds Joan Alker, executive director of the Center for Children and Families at the Georgetown University McCourt School of Public Policy.

Yet Medicaid expansion may be gathering momentum that will carry into 2018. Presuming that Republican Gov. Paul LePage’s immediate post-election objections are overcome, Maine will become the 32nd state to expand Medicaid, according to a tally kept by the Kaiser Family Foundation.

In recent years, there has been “a groundswell of efforts in Utah to pass some sort of Medicaid expansion,” says RyLee Curtis, spokeswoman for the pro-expansion Utah Decides Healthcare. In November, CMS approved a waiver for limited expansion in Utah that will provide coverage for up to 6,000 adults, and particularly benefit the homeless. The state will pay about $30 million annually for that limited expansion, while the federal government will pitch in approximately $70 million.

The 2018 ballot initiative would be a vote on full expansion that would cover up to about 100,000 Utahans. It includes a 0.15% sales tax increase. When the expansion is fully implemented in 2021, it would cost Utah taxpayers about $90 million, while drawing in perhaps $800 million in federal funds, Curtis says. The groups that favor Medicaid expansion still need to collect enough signatures to get it on the ballot.

Expansion advocates in Idaho are taking a similar tack. A group called Reclaim Idaho has submitted paperwork to get the ballot initiative on the November 2018 ballot. According to the Kaiser Family Foundation, about 22,000 Idaho residents are in the “coverage gap” that exists in nonexpansion states: people who make too much money to be eligible for the state’s Medicaid program but too little to qualify for ACA financial assistance.

— Susan Ladika

Hospital Consolidation

FTC COULD BE A STICK IN THE SPOKES OF HOSPITAL Mergers

In an administration that seems to relish blowing up bureaucracies, leaving chaos and uncertainty in its wake, the fact that no one foresees any great disruption in how the understaffed Federal Trade Commission views health system and hospital mergers makes it an outlier in Trump World.

Acquisitive appetite: Hospital are gobbling up other hospitals

But in the case of Sanford Health’s acquisition of Mid Dakota Clinic in North Dakota, the FTC still holds sway. In June, the agency challenged the deal, claiming that the merged entity would control 75% or more of primary care and other health services in the Bismarck–Mandan metropolitan area. Sanford Health is a 39-hospital system with 1,300 physicians in nine states; Mid Dakota Clinic is a multidisciplinary practice of 90 practitioners in Bismarck–Mandan. The FTC sought an injunction to block the merger until it could hold a hearing in Washington near the end of November.

The FTC can have up to five commissioners. They’re nominated by the president and confirmed by the Senate to serve seven-year terms. But at the moment, the commission has only two members, the acting chair, Maureen Ohlhausen, a Republican, and Terrell McSweeny, a Democrat who worked for Joe Biden when he was a Senator and then for the Obama White House. Their terms end in 2018 and 2021, respectively.

The Trump administration has said it will nominate Joseph J. Simons as FTC chairman. Simons, a partner in the Washington office of the New York law firm Paul, Weiss, Rifkind, Wharton & Garrison and co-chair of its antitrust group, was director of the FTC’s Bureau of Competition during the George W. Bush administration from 2001 to 2003. (Three other names have been floated for the other two open seats—one Democrat, one Republican—but the White House hadn’t acted on them by the time we went to press.) A confirmation of Simons might not bode well for health system executives eyeing mergers.

It was during Simons’ FTC years that the agency “resurrected its hospital merger enforcement program by doing its retroactive study of consummated mergers and bringing the Evanston case against one of those mergers, which it won,” says Bruce Sokler, antitrust chair in Mintz, Levin, Cohn, Ferris, Glovsky and Popeo’s Washington office. The Evanston case ended with an FTC order that required what was then known as Evanston Northwestern Healthcare to negotiate managed care contracts separately from Highland Park Hospital, which it had acquired.

2017 has seen plenty of mergers and acquisitions: Kaufman Hall, the consulting firm, counted 87 deals through the third quarter, so by the end of the year the total may exceed the 102 deals made in 2016. And there’s really no question that the overall trend is toward bigger and bigger health care systems.

**Regulatory layer**

Some of the notable deals this year include Steward Health Care’s acquisition of Iasis Healthcare, which will make Steward the largest for-profit system in the country; Partners HealthCare’s proposed acquisitions of the Care New England system in Rhode Island and the Massachusetts Eye and Ear Hospital in Boston (both were pending as we went to press); the merger of Greenville Health System and Palmetto in South Carolina; and the partnership of the Carolinas HealthCare System and UNC Health Care of Chapel Hill in North Carolina.

When it comes to hospital and health system mergers, there is another regulatory layer beside the FTC. States (attorneys general, health and insurance departments, legislatures) also play a major role, notes Martin Gaynor, a professor of economics and health policy at Carnegie Mellon University in Pittsburgh. In the Sanford Health case in North Dakota, the state attorney general has joined the FTC in challenging the merger. The North Carolina attorney general, Josh Stein, is reviewing the Carolinas–UNC Health Care of Chapel Hill in North Carolina.

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Another case worth watching is the pending merger of Mountain States Health Alliance and Wellmont Health System in Virginia and Tennessee. The FTC filed challenges with health departments in both states, although, interestingly, both state health departments approved the merger this fall.

— Richard Mark Kirkner, Contributing Editor

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**Respondents noted several areas of quality improvement after an acquisition**

- **Increased HCAHPS scores** 27%
- **Reduced readmissions** 23%
- **Reduced physician appointment wait times** 17%
- **Reduced mortality** 17%

Source: Deloitte, “Hospital M&A: When Done Well, M&A Can Achieve Valuable Outcomes,” 2017
Better for Patients, or Better for Business—Do We Really Have To Choose?

By Zachary Hafner
Advisory Board

It has been a busy year in health care. From the passing of the American Health Care Act by the House in May to the subsequent rejections of ACA repeal legislation by the Senate in July, “repeal, replace, or repair” questions loom large on what the next wave of health care reform means for provider and payer strategy.

Despite the unknowns, it seems clear that a number of trends will dominate the 2018 health care landscape. For one, tackling cost challenges and reducing the price of care will continue to be a major theme. Downward price forces including dilution of commercial coverage, shifting demographics and payer mixes, and deregulation—coupled with upward cost pressures such as rising pharmaceutical spend and specialized labor shortages—create inevitable margin challenges across the board.

Meanwhile, the cost-cutting measures Washington is pursuing all but assure further compression is coming down the pike; for example, the House budget proposal stands to cut federal Medicare dollars by $487 billion between now and 2027. A CBO analysis of the impact of these cuts projects a 60% increase in the share of hospitals with negative profit margins by 2025.

Another likely trend that will persist in 2018 is the rise of consumerism and expansion of the consumer-driven marketplace. Delivering value is paramount, and consumers are putting particularly heavy emphasis on access, convenience, and competitive pricing. Meeting these market demands requires doubling down on innovation, infrastructure, and, in many cases, new partnership strategies. But investing in these areas is pricey—and in an era of shrinking margins is “better for patients” always “better for business”?

No-regret investments

While there are no silver bullets per se, there are some no-regret moves that will allow you to do more with less while driving increased value for customers. One place to start: stamping out unwarranted clinical variation, which can substantially move many of the value dials but requires true collaboration across payers and providers to be impactful. Another no-regret move: being clear about your value proposition. In a retail marketplace with highly activated consumers, being able to articulate and deliver on a meaningful differentiated value proposition is key. This cannot just be another jargon-filled marketing message; rather, it must permeate all aspects of your business. A third: realizing full value from your IT investments. Electronic medical records are some of the most costly health care investments ever made, yet the value proposition in many cases remains elusive. Investing here in both optimization and innovation to drive greater value will allow you to not only facilitate better outcomes in the aforementioned areas but also fuel future avenues of growth.

Continue 2017 priorities

Many of these initiatives may feel familiar—and I hope they do. They dominated the 2017 landscape, and more than likely your organization has been working on them for a while now. With 2018 strategic planning underway, recognize that all of these initiatives are interrelated and that by doubling down on one you will only improve the others. Engage with consumers, achieve clinical economies of scale, and improve outcomes by fully leveraging your data and analytics assets to detect conditions earlier, support more accurate and specific treatment decisions. Integrate disparate capabilities in consumer-relevant areas (e.g., price estimation, scheduling, referral management) to improve delivery on the patient journey and differentiate on customer experience. And so on, and so forth.

As we look ahead to 2018, let’s work toward changing the headline to “Better for Patients IS Better for Business.” Although it may be tempting to take a cautionary approach toward the investment, by putting the best interests of the consumer at the center of all we do, we can all be better positioned for the next era of health care reform—no matter what gets thrown our way.

Zachary Hafner leads the Advisory Board’s strategy consulting practice.
The Self-driving Patient: How Health Care Will Catch Up

By Bruce Pyenson and Gillian Woollett

21st century change has yet to really reach health care. Amazon can predict our next purchases, but medical specialists have trouble coordinating our prescriptions. Most people haven't sent or received a fax in years, but doctors and hospitals still depend on them. So many aspects of our lives and economy are being customized, dematerialized, accelerated.

How will health care catch up? We believe a vanguard of tech-savvy patients will lead the way.

But thinking that doctors' waiting rooms will be the access point to high-tech health stations is like imagining a stagecoach pulled by genetically modified super stallions. Or that stain-free clothes will be made with foot-pedaled sewing machines.

Medical science is the best it has ever been, and the United States continues to lead the world. Yet the speed of care, let alone its improvement, feels glacial, especially when you are sick. Transforming health care isn't just a matter of removing a few bugs here and there from a glitchy system. More fundamental, root-and-branch change is needed. Just as some communities go straight to cell phones without ever having landlines, we believe some aspects of our health care infrastructure could be entirely replaced with consumer-focused systems that are continuously evolving. That kind of change has the power to eliminate sluggish, wasteful aspects of American health care that add to overhead, encourage redundancy, and preclude access.

Early adopters create ‘NewHealth’

We believe that early adopters of a new kind of health care that we are calling “NewHealth” will push the American health care system in this direction. Patient-focused drug development and “right to try” drugs that are not yet approved are just hints of what this new system offers.

A whole array of technologies could drive large-scale, rapid shared learning. Instantly available smart technology will bring a new level of convenience and accuracy to diagnosis and treatment. And care will improve as providers are forced to respond to patient demands that they provide NewHealth.

Initially, NewHealth may be more expensive. We believe, though, that early adopters will happily pay more because it offers immediate value to them. Arguably, the change is already underway in a minority of patients who have researched innovative solutions and seek out health care providers that will provide them. Examples are patients who insist on peritoneal dialysis or unapproved uses for drugs. And these patients already want to engage with their providers as partners in better and more personal care. Providers who don't engage may fall by the wayside if their need for deference runs contrary to the progress the patients expect.

A democratizing influence

Across the world, health care availability is variously treated as a right or a privilege depending on one's place of residence and available resources. Yet we're always left with the question of how much care is accessible and for whom, how that decision is made, and who pays the bill. Like education, but perhaps even more so, health care can have far-reaching con-
sequences. Differences in the quality of care we receive can alter our lives, so some people are healed or their condition well managed while others suffer illness, life-long disability, or even face death.

Can smart technology help people overcome the otherwise intractable socio-economic determinants of health? Can it bring better care to all, like quality public education has made us all better off? Even though your smart phone cannot transplant a heart, it will be able to signal when you need immediate help. NewHealth can help democratize medical expertise and frame an individual's medical needs in the context of their real life. Knowing when to ask for additional help through use of the NewHealth tools will bring personalized medicine to millions.

Our health care system wasn't designed; it started as a house and grew, unsystematically, room by room, floor by floor, into an immense, complicated castle. Some of the original floor tiles are still there, and an observer can pick out how each generation added different bricks to the walls. How the creative disruption of our health care system will unfold is far from certain, but examples of imminent success should inspire and challenge our thinking:

1. Self-driving cars are here and seem likely to become ubiquitous soon. Can the self-driving patient be far behind? Or are they already here, scattered among the population, with a few patients taking control, owning their own outcomes, and inspiring others by their examples?
2. Early adopters believe that current smart technology can be used for routine diagnosis, prescribing, and monitoring of many health conditions and that technology can perform those functions smarter, faster, more conveniently, and more consistently than health care professionals can.
3. Advanced smartphone-enabled diagnostics (e.g. candidiasis in possible HIV patients) are finding a home in the developing world where convenience doesn't mean saving time and trouble but avoiding arduous, unaffordable journeys to reach care that is priced higher than what many people can afford.

Inertia, regulation will be in the way
But we're not yet there. NewHealth may be coming, but it hasn't yet reached the critical mass where it can expedite delivery, link outcomes to interventions, and reduce waste.

And there will be problems and setbacks. Both over- and under-treatment are definite risks of self-guided care. Every new drug is not another thalidomide or penicillin, but experience will broaden our understanding of consequences of different medical choices. Impatient sufferers won't wait, and early adoption won't be without its hazards. A death associated with a patient's misinformed self-directed care is, of course, a death, but perhaps those deaths sting less than any of the 100,000+ annual U.S. deaths today already caused by medical errors.

How can we help NewHealth thrive? Regulators could, of course, support disruptive innovation, just as communications regulators did in the 1980s. Many skilled professionals in health care would welcome such progress, despite what others say are their vested interests. These professionals will welcome and be sought after by early adopters. Other professionals may overtreat self-misguided patients, but their outcomes will be expensive.

A challenge will be to optimize change without forcing patients or providers to violate laws, and regulators will need to protect the less well-informed from charlatans. For sure, some vulnerable patients and others will need—or want—some pieces of our established, more paternalistic health care; patients won't soon be performing their own operations. So NewHealth will challenge the health care system from the outside, but it will also force the system to improve, in our estimation. And in our democratic, pluralistic society, we should expect and appreciate that different people will reach different conclusions even when facing the same choices.

NewHealthers: A noticeable minority
We believe that change is inevitable but will be slowed by inertia and regulatory or monopolistic barriers. Some providers will resent less obedient patients, but others will enthusiastically support more individually appropriate solutions and take risks with their patients. It's likely that the early adopters (most likely the more affluent and educated) will soon become a noticeable minority in some physicians' offices. Some health care providers and insurers will see the opportunity and evolve to support these individuals. The rest of us should cheer them on, however disruptive they may at first appear—or we will die waiting too.

Bruce Pyenson is a principal and consulting actuary at Milliman in New York City and a MedPAC commissioner. Gillian Woollett is a senior vice president at Avalere in Washington, D.C.
**VIEWPOINT**

**Copayments Not Counting Toward the Deductible Could Have Unintended Consequences**

By Jeremy Schafer and Ami Gopalan

Mrs. Anderson considers herself to be “living with cancer.” For the past year and a half since her diagnosis, she has been treated with an oral drug that keeps her cancer at bay. Even with her commercial insurance, Mrs. Anderson would struggle to afford her deductible and coinsurance were it not for the help of a copay assistance program offered by the manufacturer. With her treatment costing more than $14,000 per month, Ms. Anderson tends to hit her out-of-pocket maximum of $6,550 early in the year.

This year, things changed. Ms. Anderson noticed in January after getting her prescription that while the copay assistance program seemed to be functioning normally, the deductible didn’t budge despite her out-of-pocket payment. The same thing happened in February. By June, she had hit the copay program annual limit, and a big, unaffordable drug bill arrived.

Mrs. Anderson is not real, but we invented her to illustrate the experience of many patients whose drug coverage is managed by a PBM.

Doesn’t count against the deductible

Starting this year, many PBMs rolled out a new type of cost-share program that will not count copay assistance

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**Doing the math**

**Base assumptions:**

1. The oral oncologic costs $14,000 per month.
2. Mrs. Anderson’s plan has 25% coinsurance for a drug in this tier.
3. Mrs. Anderson benefits from a copay assistance program that limits her out of pocket expense to $25 per month.
4. The copay assistance program has an annual cap of $20,000.

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**Scenario 1:** With copay assistance counted as part of out of pocket maximum

- Copay assistance: $25 monthly patient payment, $20,000 maximum benefit
  - What Mrs. Anderson pays (annual maximum $6550)
    - $25
    - $25
    - $0
    - $0
    - $0
    - $0
    - $0
    - $0
    - $0
  - Payer outlay for medication\(^1\)
    - $10,500
    - $10,950
    - $14,000
    - $14,000
    - $14,000
    - $14,000
    - $14,000
    - $14,000
    - $6,500

**Scenario 2:** With copay assistance not counted as part of out of pocket maximum

- Copay assistance: $25 monthly payment, $20,000 maximum benefit
  - What Mrs. Anderson pays (annual maximum $6550)
    - $25
    - $25
    - $25
    - $25
    - $25
    - $3,500
    - $2,050
    - $0
  - Payer outlay for medication\(^1\)
    - $10,500
    - $10,500
    - $10,500
    - $10,500
    - $10,500
    - $11,950
    - $56,000

\*September–December cells consolidated for space.

\*Possible rebates not included.
dollars toward a patient’s deductible and out-of-pocket maximum. Any money Ms. Anderson pays out of her own pocket including clinic visits, medical procedures, and prescription drugs will continue to count toward her deductible and out-of-pocket maximum; however, any contribution made by a manufacturer through a drug copay assistance program will not count. Copay assistance programs are increasingly used by patients like Ms. Anderson to cover copay or coinsurance expenses; meaning these new PBM programs are having impact.

From the manufacturers’ point of view, copay programs end up supporting patients for more months of the year since meeting the out-of-pocket maximum takes longer. The result has been savings for some payers because manufacturers wind up paying more of the annual drug cost.

But for Mrs. Anderson and others like her, new cost-sharing programs might result in some hardship. In the past, a copay assistance program would discontinue only after the patient has met his or her out-of-pocket limit, which can happen early in the year. The employer and the payer would then foot the bill for drugs and medical services for the remainder of the year, shielding her from many medical bills.

In the new scenario, the copay program could pay more per month, every month, until the program’s limit is reached. The program limits vary by manufacturer but range from $10,000 to $30,000 or more. But because the copay program contribution isn’t counted toward the deductible or out-of-pocket maximums, Ms. Anderson can end up paying more of her medical bills than she did before.

A menu to pick from

Based on public information (which, admittedly, there isn’t much of) and our own conversations with people who work in the industry, these programs are being implemented by major PBMs, including Optum, CVS, Prime, and Express Scripts. They are usually limited to members utilizing the PBM’s exclusive specialty pharmacy network.

PBMs have a menu of cost-share programs for patients to consider. The programs range from a version that merely precludes the copay assistance from counting toward the deductible to one that actually adjusts the patient’s cost share to maximize the copay program annual benefit limit. Therapeutic categories targeted so far include inflammatory conditions, multiple sclerosis, cancer, hemophilia, and hepatitis C. Interestingly, both preferred and nonpreferred drugs appear to be targeted by these programs, resulting in payers benefiting from upfront savings as well as back-end rebates.

We both previously worked for payer organizations, so we understand the rationale for creating and implementing these cost-share programs. They allow benefit design to work as intended by ensuring that only the patient’s actual expenditures count toward out-of-pocket limits instead of counting both the patient and manufacturer’s contributions.

**Effects on adherence**

But there may also be some unintended consequences. Payers may recall the annual peaks and valleys in Medicare D drug utilization as patients navigated the donut hole or decreases in adherence at the beginning of the year with the implementation of a high-deductible plan design. Similar situations could develop here. Patients with specialty conditions are frequently on multiple drugs and have a higher use of health care resources. If patients struggle to afford their out-of-pocket expenses, they may stay adherent to the expensive drug that has the copay assistance but not to other drugs or services. Moreover, adherence to the specialty drug could fall off sharply if patients hit the copay program limit and cannot afford therapy. The result could be a negative impact on patient health.

Payers have the capability to monitor a patient’s utilization of drugs and health care services. We would encourage payers implementing cost-share adjustment programs to monitor their members for instances of forgoing necessary services. In addition, payers should be aware of copay program limits and have solutions for patients who hit the maximum as multiple studies have linked high out-of-pocket cost with nonadherence. Solutions could include helping patients get connected to additional cost-share support programs for the medication or implementing per prescription cost share caps of less than $200.

Cost-share adjustment programs mark the latest innovation in the back and forth between payers and manufacturers. In the era of value-based care, payers should be mindful of the potential impact of new programs and monitor for any unintended consequences.

Jeremy Schafer is a senior vice president at Precision for Value, and Ami Gopalan is a vice president at the company. Precision for Value is a market access-focused agency headquartered in Gladstone, N.J.
Interview by Peter Wehrwein

Drug prices are in the news. Have they gone up or are they being talked about more? I think the answer is yes and yes. They have gone up, and they are being talked about more.

I guess drug prices as a percentage of health care costs have gone up? Let’s take that issue for a minute. Most people look at the [CMS] Office of the Actuary numbers on drugs and the health care pie. The Office of the Actuary does a great job of doing our estimates for us. They define carefully each piece of that pie, and there’s a piece that’s commonly labeled “prescription drugs.” Most people don’t bother to read that “prescription drugs” is really just outpatient retail prescriptions through community pharmacies. It doesn’t include drugs dispensed through hospital outpatient departments; drugs administered in the hospital; drugs administered in the physician’s office; drugs administered at home health agencies; or drugs administered through various other special providers.

If one takes drugs through all channels—the other pieces of the national health care pie: hospitals, physician offices, dentist offices, nursing homes, home health, and the distribution and channels—drugs are about 20% of the health care dollar, not 10%.

So our health care pie is structured in a way that about half of the drug spend is hidden, and it just so happens that the part of the drug spend that’s growing the fastest is the part that’s not explicit. The part that’s hidden is the part that’s growing the fastest.

And that has to do with the increased use of so-called specialty pharmacy. No, it’s not just specialty pharmacy. These are drugs administered in a doctor’s office. These are drugs administered in a hospital outpatient clinic.

They’re not even in the pharmacy benefit. They’re in the medical benefit of an insurance plan. And people don’t even realize it’s there, and yet, this accounts for one third to one half of all drug spend.

Where does one get that 20% number? First of all, I find it appalling that we don’t publicly track it and report it.

I’ve been tracking it and looking for ways to identify the amount of drug revenue, again, not just drug company payments, but drug revenue and distribution costs in each of those pieces of pie. So, you look at the MedPAC reports on drugs in the hospital and the all-payer claims databases that Minnesota and several other states have.

The transcript of this interview has been edited for length and clarity.
In Minnesota I had the opportunity to work with our all-payer claims database. We have all medical claims and pharmacy claims. All health transactions. And I’ve identified all of the health transactions of Minnesota, which ones are drugs or drug-related, and added up the cost. And, in fact, in Minnesota in 2013, drugs accounted for about 20% of the total health care spend.

The answer is that researchers like you have to sort of go into databases and claw and scratch this information out.... Right. There’s no easy, quick-and-dirty way to do it or track it. This is a place where I think our government should develop a trend line that allows us to track total drug spend.

Pharma will come along and tell you, well, that’s not right; the number is really 14%. And what they’re saying is the amount of revenue drug companies get is only 14% of the health care dollar. They don't want to take into account the supply and distribution costs—the wholesalers, PBMs, and other things that add on to that.

But as an economist, I’m interested in, at the end of the day, what’s the total amount of transactions, whether it’s for the drug product, its distribution, or administration.

What's the net cost in the drug sector at the end of the day? It’s 20%.

Is that percentage of the drug spend increasing because of the nature of the drugs that are getting approved? Or does it have to do with companies jacking up prices? The answer is yes and yes. You know, we have these wonderful new drugs, CAR-T drugs, that just came on the market. And I applaud them and their innovativeness, and they can add value to the marketplace. They are as close to a near-cure as we have, along with hepatitis C drugs. And I applaud them, but they came in at really unheard of prices—half-million dollars per patient. That’s just for the drugs, not the cost of administering them and the other health care.

So, on the one hand, these drugs are a great advance therapeutically, but it comes on at a price that really is—you can’t call that a market-based price. The price was offered and it’s sort of take it or leave it. Most insurance plans, Medicare, and Medicaid are apparently going to cover them.

I’m not criticizing these drugs, but we don’t have a market-based price structure to set that price.

The lack of a market-based price—is that especially pronounced in those hidden areas that you’ve described as opposed to the prescription drugs available through the community pharmacy? Yes and no. You’re right that each has a different market dynamic. Drugs like the CAR-T therapies, they come in at a really high price, and then may not increase much in price over time. If you start at a half-million dollars per course of therapy, you don’t have to raise your price much for a while. You started pretty high up on the mountain.

But other drugs in other settings that didn’t start as high up the mountain as CAR-T are also raising their price. Sometimes it’s the price at market entry that’s the issue. Sometimes it’s the price of a drug and its change in price over time.

I think part of what we’re seeing in the pharmaceutical marketplace is a lot like what we see in other industries when they’re faced with dramatic uncertainty. The pharmaceutical marketplace keeps hearing rumbles that maybe Congress—or maybe this or that president—is going to do something about drug prices.

When that uncertainty is there, that doesn’t result in those drug companies slowing their rate of growth in price increase. In fact, it accelerates it because they realize there’s uncertainty ahead, and we could be facing price controls or market-based criteria that put pressure on us more than we have right now. So, while we can, we’re going to raise our prices. We’re going to move up the mountain in terms of price levels, so that if we do get pressed or regulated in terms of pricing, we’ll be starting from a higher place on the mountain.

So, uncertainty feeds this.

What other sectors have this dynamic—grabbing as much profit as you can in advance of regulation? Sometimes it’s in advance of regulation; sometimes other market uncertainties. What happened with gasoline prices as we had these hurricanes in Texas? Prices went up.

Do you think Part D coverage has been a factor in the increasing amount of money spent on drugs? Yes. When you expand coverage and you don’t do anything to manage or control or improve the cost structure in the market, you’re going to see more money spent.

Is there anything that you see in the way Part D is designed where it could be redesigned in a way to push back on drug costs or price? Sure. Part D is administered through—I forget how many—about 2,000

We need [a] bona fide rate regulation review body that can meaningfully evaluate the information presented by drug companies.
business entities across the country. Now, imagine if I was the CEO of a company like Best Buy here in the Twin Cities, and I go to each of their store managers and say, “Look, you’re each on your own. We want each of you to negotiate the best price you can with

Insurance companies don’t put their own money into paying for somebody else’s health care. The payer is either the individual person or an employer.

Samsung, and with each of the electronics manufacturers. Each of you negotiate the best price you can, but we’re not going to buy corporately and centralized, and we’re not going to negotiate better prices for you.”

That’s the way we set up our Medicare program. We’ve set up 2,000 business entities that offer Part D drug plans nationwide. We’ve told each of them, “Go negotiate your best deal with the drug companies.” But we’re not going to negotiate using the leverage in aggregate of all of the Medicare programs as a single entity.

We set it up to be a marketplace mechanism, but we said, “Don’t use any of the tools of the market.” It doesn’t work. This is like Adam Smith’s invisible hand, expecting it to work while we put handcuffs on it.

Don’t they have power through the formulary? That doesn’t negotiate prices. And the formulary is driven by each of the 2,000 plans. Again, are you going to get the best price at a Best Buy store if each store negotiated its own prices? No, you’re not. That’s what we’re saying. So, you’re telling me that 2,000 formularies are going to get a better price than Medicare as a whole, negotiating prices? I don’t think so.

I’m thinking about various factors that have come into play coincidental with rising drug prices and cost. It seems that there’s been a concentration of market power in fewer PBMs. I was reading this morning that CVS, Optum, and Express Scripts control 80% of the market? Do you think some of what we’re seeing as far as drug prices are concerned could be attributed to PBMs and their market power? And maybe their secret deals, discounts, and rebates? Well, I want to say up front that PBMs are an important part of our pharmaceutical marketplace. They provide many valuable services. But, they also have some hidden behaviors that are detrimental to the market. And PBMs are not subject to regulation like insurance companies. There’s no oversight body for PBMs in the marketplace. Nobody is holding them accountable for their behaviors in the marketplace. Other than employers.

But I work for many different employers and consulted for them, and even the best of employers don’t have the staff, the wherewithal, the ability to make fully informed decisions with how they interact with PBMs because it’s such a complex marketplace and difficult to sort out what the net effect of various behaviors are. And many behaviors are hidden. Rebates account for about one third of all the money we spend on drugs these days. The top dollar line we spend on drugs, about one third of it goes back in rebates. That’s the equivalent of employers and individuals and the government giving drug companies a loan for a third of their revenue, and then, waiting a year to collect it back, interest free.

And the PBMs get administrative fees on top of that. They make far more from their fees from manufacturers than they do from their clients.

If you make more from the upstream supply source, the manufacturers, than you do from your downstream client, whose interest are you going to serve? Don’t think too long about it.

I’m not against PBMs. I’m just saying the market is structured in a way that we have reverse, perverse economics. And the PBMs and drug companies get together and agree in their context that rebates are proprietary and confidential, and we can’t disclose them.

So, we talk about value-based health care, but we tell the physician, “We can’t tell you the net price.” We tell the pharmacists we can’t give them the net price. We tell the patient we can’t give them the net price. We tell the employer we can’t give them the net price.

I assume that you are in favor of the various pieces of state legislation that would force PBMs to disclose some of their rebate and discount deals with manufacturers. We need some kind of disclosure, but frankly, many of the state proposals I see are so poorly written that they simply add administrative cost, and they won’t functionally change the information that people have available and use. A lot of states require disclosure to someone at the state government, and it will be held proprietary and confidential. So, what have we gained?

Do you think there ought to be PBM regulation—some national agency regulating PBMs? At some level, I think there may be a need for some type of regulatory body, because frankly, what you see in the health care marketplace—and in the drug space in particular—is once you have some disclosure rules in place, if you don’t ask the right things or report the right things, it doesn’t help. And second, even if we get them to report certain things and they’re helpful
Well, I think that helps. As long as it’s truly transparent.

So, I think ultimately what you need is a body that is overseeing them that can adapt with the marketplace. Don’t get in the way when they’re doing good things to help the health care outcomes of the public, and they’re helping to do it at reasonable cost. But raise questions when the cost is not reasonable, or when they’re taking capital out of the market without improving health care.

A few years ago I interviewed Steve Miller. He talked about how Express Scripts got tough with Gilead and managed to cut the price of the hepatitis C drugs because of its bargaining power. It was fairly persuasive. Do PBMs do some good stuff like that? Get prices down through their negotiating power? Well, they can. There are times that they do. But there are also things that they either tolerate or create that add cost that we don’t know about, too.

What are you thinking of? I think one is PBMs adding spread on top of the cost of generics. They pay a network pharmacy $25 per generic prescription. They turn around and bill the employer $40 for that. Most employers don’t know that. Most employers didn’t intentionally agree to that. And yet, that adds to the cost structure in the marketplace.

PBMs also have preferred networks. Often the preferred networks actually cost the employer more than the nonpreferred networks. But they think they’re going to get a better deal from it.

Or PBMs push or require mail order. We assume that mail order is cheaper, but it’s not. There are times we can find that the cost of mail order prescriptions is higher than what the same prescription would have cost at retail. So, there are examples where PBMs develop revenue streams from behaviors that are hidden, and that cost the client more rather than less. And clients often are not able to discern that.

Give me an example of either the mail order or non-preferred network being more expensive? I’d rather not. I’d encourage you to go look at the National Community Pharmacist Association. They have a PBM website.

Let’s talk about value-based pricing, which is held out as a way to respond to drug prices and cost. I like the definition that Anna Kaltenboeck and Peter Bach used in an opinion piece for Stat: value-based pricing links a drug’s price to a transparent measure of its benefit. Do you think that’s a good definition? Well, I think that helps. As long as it’s truly transparent.

And transparent to everyone, not just selective audiences, again, like the state agency, or just the employer, but we can’t tell the physician. Or just the physician, but we can’t tell the patient. We have to look at what they mean by “transparent.”

Here’s my first reaction to value-based pricing: You’re exactly right. One needs to have definitions to anchor the discussion, because without that, you can easily be talking about totally different things and think you’re agreeing. To a health system trying to provide the most health care they can with the limited resources they have, “value” means basically what Peter Bach is describing—delivering the same or greater outcome for equal or lower price. So, how much you’re getting for the money you’re spending.

But if you turn it around for a corporation, a hospital, a health system, a drug company, their goal is to make profit for their investors, for their stockholders. To stockholders, what does value mean? Value means getting the most return for the money they’ve invested. It has nothing to do with outcome and health care.

In my reading about value-based pricing—the Bach version, if you will—there are a couple flavors. One is outcomes-based pricing—the drug company is only going to get paid if the drug produces a certain outcome. But one criticism is that companies will just jack up the price from the start. Is that a problem with outcomes-based pricing? Well, I would frame it a little differently, but I think it is the same basic issue. Let’s assume that the value-based description and definition you’ve brought forward from Peter Bach is what we’re talking about. Drug companies only bring up value-based pricing if they intend to raise the price. I’ve never heard a drug company asked to talk about value-based pricing to reduce the price. So, basically, they’re operating from a one-sided hypothesis—our drug is worth more, and you should be paying us more. And then it’s down to, “How much can we get out of you.” Have you ever seen one try to lower the price with value-based pricing?”

I’ve only seen it in the context of when they’ve already set a high price. I was surprised that the CEO of Novartis made a statement, something to this effect: We had intended to charge seven or eight hundred thousand dollars for this drug [Kymriah], and we decided to come on the market at $475,000. So, is that value-based pricing, that they came in at $475,000 versus $700,000? Is that value-based pricing? No. That’s just, “We took a lower price than we thought we were going to take before.” But neither price is justified. We don’t know that either of them is right. And they haven’t provided any information to justify it.

Here’s the other problem with value-based. Value-
based says, “Basically, what is the value of the effect this drug can have in the marketplace to a patient?” Let’s say this drug saves a person’s life. Now, Peter, if I asked you what your life is worth, and I asked you to get a concrete dollar value in mind, you’ll pick a number.

There are systematic ways of examining this with QALYs, right? No, no, but that isn’t what they—I’ll get back to that.

So, you pick a value, and I’ll ask you how much you have in your bank. When I do that exercise almost everyone thinks they’re worth more than they have in terms of personal resources. So, how are we going to pay for health care if we all think....

Well, that’s a function of the people you hang around with. If you hang around with people who lived in North Oaks*, or whatever... Well, I hang around with all crowds, and I make that point to all crowds.

The point is that if you’re sitting in the ER, having a heart attack, you don’t sit up and say, “Wait, how much is this going to cost?” We don’t make value-based decisions in health care because it’s about life and death and we aren’t rational when we think about that.

Here’s the second thing. Let’s assume that a person’s thinking and they realize, OK, this may or may not prolong my life; I’ll have a better quality of life, maybe, maybe not. How much is that worth? Often in those econometric studies that use QALY’s, they all assume that optimal care would have been delivered and paid for, and this drug will save this much off of what optimal care would have cost without the drug. But, we don’t have the resources to pay for optimal care for everybody in society to begin with. So, by definition, that escalates the cost above the resource structure that we have in society. Follow that?

Yeah, I do, but to me, you’re throwing the baby out with the bath water. It seems that you could crunch numbers with QALY’s and take data from the largest clinical trial available, or even some real-world evidence results, and you figure this drug, you know, is worth three QALY’s, which we tend to price at about $200,000, and you arrive at a price. You could enforce some systematic, rational thinking on drug prices in an ICER-type way. I agree we need to encourage rational thinking on drug prices. I applaud ICER for what they do, but I think there are fundamental issues, even in their method. What is the value of a QALY? And if you look back at the history, it’s not particularly well grounded in terms of either resources available in society, or the basis on which that QALY is set. And then, how do you escalate that over time? So, what is a life worth? And I don’t think there’s a....

* North Oaks is an affluent Twin Cities suburb.

In terms of you asking me how much my life is worth, that’s not who is being asked the question. It’s the payer that’s being asked the question. But who pays for health care? Insurance companies don’t pay for health care. Yes, they process transactions, but insurance companies don’t put their own money into paying for somebody else’s health care. They take money out with each transaction. The payer is either the individual person, or an employer on behalf of an individual in lieu of giving them salary; or government by taking taxes from individuals. But you are the payer.

Yeah, but it all gets put into the meat grinder of our social and political and economic arrangements, you know, we pay a lot in this country for health care. But if we don’t break that cycle, it won’t change. My worry is we’re going to hit a point where we will have a crash-and-burn, and we’ll have to answer the question: Is this health system too big to fail? Is this drug company too big to fail?

I think the resources flowing into health care without rational, economic decision making, it’s a bubble that’s going to burst at some point in the not-too-distant future.

You’ve pointed out that these prices are way out of whack. How do you push back against these private entities’ pricing things the way they are? I think that’s a relevant and appropriate question—how do you push back? Because now, we have a system where when a new drug, whether it’s a new molecular entity or just a new combination, comes on the market, basically, our health care pie is structured in a way that about half the drug spend is hidden, and it just so happens to be the part of the drug spend that is growing.

it has to be covered by our Medicare and Medicaid programs. And for all practical purposes, it has to be covered by most commercial insurers, or they might be subject to lawsuits from their employees and covered lives, saying, “Hey, you took care of their problem, but not mine. Why am I paying insurance? You’re supposed to cover everything.”

So, we have a marketplace where if you get FDA approval, saying your drug is better than placebo, which is all FDA is authorized to evaluate, you get on the market, and you have to be covered, and the drug company can set whatever price they want. And, we don’t have any meaningful ways to push back on price.

So, how can you do that? I’m not saying we should
I got a good deal, but maybe it’s not good for the system in general. But even for the person, it’s not good. I would remind people that premiums are out-of-pocket costs just as much as copays are. They just happen at a different time.

People don’t notice their premium cost. They don’t. That’s my point. It doesn’t mean it’s not a cost. It just means we don’t incorporate that in our decision making. So, it’s easy to fool some of the people most of the time.

I’m really not trying to be an off-the-wall kook. I’m trying to help us step back and evaluate the basic assumptions we’re making about this marketplace, and about how cost, value, and drugs work. And I think we’ve all gotten locked into a certain framework and failed to step back and see how out of alignment it is with a market-based system. This is not a market-based system.

What would you call it? It’s a protected monopoly.

I think people have noted that drugmakers are afforded monopoly power. But then Congress says we want to keep drugs as a free market. How can you make that statement when we also admit that it’s a monopoly-based system? Too incredible. We have this cognitive dissonance. It’s this, but this, and yet, they’re incompatible. We haven’t resolved that. So, I’m not sure we fully comprehend that.

On the editorial pages of the Wall Street Journal they say one of the responses to this situation is speedier FDA approval, with the notion that that would lead to more competition. That’s sort of what Gottlieb is pushing, I think. It is. I think it helps with the margins, but speedier approval doesn’t bring a new generic company into the marketplace for a very small niche generic product, that’s marginally profitable to begin with. And when generic drug companies have consolidated, we have fewer of them. Speedier approval doesn’t make more people come into that market.

What about biosimilars? They were the ACA answer to the biologics. They were supposed to bring generic-like pressure into this market, right? Well, they were supposed to, but we’ve implemented biosimilars by adding a four-digit code at the end of the biosimilar name that makes it a unique proprietary name, even though it’s called a non-proprietary name. So, we’ve done things structurally in the regulation of biosimilars that have pretty much neutered the market power that biosimilars could bring. Yes, we’ll see 10, 15, maybe 20% reduction price of biosimilars. But we won’t see 70, 80, 90% reduction price like we’ve seen with traditional drugs and generics.

Is there any model for what you’re talking about in another country, or in another part of the American economy? Yeah. It’s close to the Canadian patent medicine price review board, but I would extend it not only to patent medicines, but also to generics.

Do you have a sense that this is a little bit of Neverland thinking on your part? Well, it is, but I think continuing to pay the prices we are experiencing in the pharmaceutical market is pretty much a Neverland, also.

You were quoted in a couple stories about websites are trying to do with drug prices what Expedia and others have done with airline prices—aggregate and allow easy comparison. Do you see it accomplishing much? I think there’s a fundamental difference. Those sites often focus on and take advantage of copay coupons in the marketplace. They don’t always focus on the net cost to the full cost to the consumer. If I’m shopping for airline prices, my employer doesn’t buy my airline tickets for vacation. I have to pay the full cost of that. But if I’m shopping for a prescription, and I get a copay coupon online that reduces my copay from $50 to zero, I think I’m saving money. But if that prescription ends up costing my employer $600 instead of $50, all I’ve done is fool myself into thinking I’m saving money when actually I’ve increased the cost structure for health care of my employer, and next year, they raise my premiums on health care, increase my cost share, or they have less money to give me in salary.

I got a good deal, but maybe it’s not good for the system in general.

But even for the person, it’s not good. I would remind people that premiums are out-of-pocket costs just as much as copays are. They just happen at a different time.

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