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Health care markets are a patchwork of ACA fixes and uncertainty.

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Recommended starting dose is 0.75 mg. Dose can be increased to 1.5 mg for additional A1C reduction.

In clinical studies, the range of A1C reduction from baseline was 0.7% to 1.6% for the 0.75 mg dose and 0.8% to 1.6% for the 1.5 mg dose; the percentage of patients achieving A1C <7% ranged from 37% to 69% for 0.75 mg and 53% to 78% for 1.5 mg.¹⁴⁻⁷

Trulicity (dulaglutide) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use: Not recommended as first-line therapy for patients inadequately controlled on diet and exercise because of the uncertain relevance of rodent C-cell tumor findings to humans. Prescribe only if potential benefits outweigh potential risks. Has not been studied in patients with a history of pancreatitis; consider another antidiabetic therapy. Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis. Not a substitute for insulin. Has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis. Not for patients with pre-existing severe gastrointestinal disease.

Select Important Safety Information

WARNING: RISK OF THYROID C-CELL TUMORS
In male and female rats, dulaglutide causes a dose-related and treatment-duration-dependent increase in the incidence of thyroid C-cell tumors (adenomas and carcinomas) after lifetime exposure. It is unknown whether Trulicity causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of dulaglutide-induced rodent thyroid C-cell tumors has not been determined.

Trulicity is contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk of MTC with use of Trulicity and inform them of symptoms of thyroid tumors (eg, mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Trulicity.

Please see Important Safety Information for Trulicity, including Boxed Warning about possible thyroid tumors including thyroid cancer, on the following page and accompanying Brief Summary of Prescribing Information. Please see Instructions for Use included with the pen.
Important Safety Information

WARNING: RISK OF THYROID C-CELL TUMORS

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Trulicity is contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk of MTC with use of Trulicity and inform them of symptoms of thyroid tumors (eg, mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Trulicity.

Trulicity is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2, and in patients with a prior serious hypersensitivity reaction to dulaglutide or any of the product components.

Risk of Thyroid C-cell Tumors: Cases of MTC in patients treated with liraglutide, another GLP-1 receptor agonist (GLP-1 RA), have been reported in the postmarketing period; the data in these reports are insufficient to establish or exclude a causal relationship between MTC and GLP-1 RA use in humans. If serum calcitonin is measured and found to be elevated or thyroid nodules are noted on physical examination or neck imaging, the patient should be further evaluated.

Pancreatitis: Has been reported in clinical trials. Observe patients for signs and symptoms including persistent severe abdominal pain. If pancreatitis is suspected, discontinue Trulicity promptly. Do not restart if pancreatitis is confirmed. Consider other anti-diabetic therapies in patients with a history of pancreatitis.

Hypoglycemia: The risk of hypoglycemia is increased when Trulicity is used in combination with insulin secretagogues (eg, sulfonylureas) or insulin. Patients may require a lower dose of the sulfonylurea or insulin to reduce the risk of hypoglycemia.

Hypersensitivity Reactions: There have been postmarketing reports of serious hypersensitivity reactions (eg. anaphylactic reactions and angioedema) in patients treated with Trulicity. Instruct patients who experience symptoms to discontinue Trulicity and promptly seek medical advice. Use caution in a patient with a history of angioedema or anaphylaxis with another GLP-1 receptor agonist as it is unknown whether they will be predisposed to anaphylaxis with Trulicity.

Renal Impairment: In patients treated with GLP-1 RAs, there have been postmarketing reports of acute renal failure and worsening of chronic renal failure, sometimes requiring hemodialysis. A majority of reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. In patients with renal impairment, use caution when initiating or escalating doses of Trulicity and monitor renal function in patients experiencing severe adverse gastrointestinal reactions.

Severe Gastrointestinal Disease: Use of Trulicity may be associated with gastrointestinal adverse reactions, sometimes severe. Trulicity has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis, and is therefore not recommended in these patients.

Macrovacular Outcomes: There have been no clinical studies establishing conclusive evidence of macrovacular risk reduction with Trulicity.

The most common adverse reactions (excluding hypoglycemia) reported in ≥5% of Trulicity-treated patients in placebo-controlled trials (placebo, Trulicity 0.75 mg, and Trulicity 1.5 mg) were nausea (5.3%, 12.4%, 21.1%), diarrhea (6.7%, 8.9%, 12.6%), vomiting (2.3%, 6.0%, 12.7%), abdominal pain (4.9%, 6.5%, 9.4%), decreased appetite (1.6%, 4.9%, 8.6%), dyspepsia (2.3%, 4.1%, 5.8%), and fatigue (2.6%, 4.2%, 5.6%).

Gastric emptying is slowed by Trulicity, which may impact absorption of concomitantly administered oral medications. Use caution when oral medications are used with Trulicity. Drug levels of oral medications with a narrow therapeutic index should be adequately monitored when concomitantly administered with Trulicity. In clinical pharmacology studies, Trulicity did not affect the absorption of the tested, orally administered medications to a clinically relevant degree.

Pregnancy: Limited data with Trulicity in pregnant women are not sufficient to determine a drug-associated risk for major birth defects and miscarriage. Based on animal reproduction studies, there may be risks to the fetus from exposure to dulaglutide. Use only if potential benefit justifies the potential risk to the fetus.

Lactation: There are no data on the presence of dulaglutide in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for Trulicity and any potential adverse effects on the breastfed infant from Trulicity or from the underlying maternal condition.

Pediatric Use: Safety and effectiveness of Trulicity have not been established and use is not recommended in patients less than 18 years of age.

References

1. Trulicity (Prescribing Information). Indianapolis, IN: Lilly USA, LLC, its subsidiaries, or affiliates. Trulicity is available by prescription only.

2. Trulicity (Instructions for Use). Indianapolis, IN: Lilly USA, LLC, 2014.


Trulicity® (dulaglutide)

Brief Summary: Consult the package insert for complete prescribing information.

**WARNING: RISK OF THYROID C-CELL TUMORS**

- In male and female rats, dulaglutide causes a dose-related and treatment-duration-dependent increase in the incidence of thyroid C-cell tumors (adenomas and carcinomas) after lifetime exposure. Glucagon-like peptide (GLP-1) receptor agonists have induced thyroid C-cell adenomas and carcinomas in mice and rats at clinically relevant exposures. It is unknown whether Trulicity will cause thyroid C-cell tumors, including MTC, in humans, as the human relevance of dulaglutide-induced rodent thyroid C-cell tumors has not been determined.

- Trulicity is contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk of MTC with use of Trulicity and inform them of symptoms of thyroid tumors (e.g., mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Trulicity.

**INDICATIONS AND USAGE**

Trulicity® (dulaglutide) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of Use: Not recommended as a first-line therapy for patients who have inadequate glycemic control on diet and exercise because of the uncertain relevance of rodent C-cell tumor findings to humans. Prescribe Trulicity only to patients for whom the potential benefits outweigh the potential risk. This has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis. Should not be used in patients with type 1 diabetes mellitus or for treatment of diabetic ketoacidosis. It is not a substitute for insulin. Has not been studied and should be used in patients with severe gastrointestinal disease, including severe gastroparesis. Not recommended in patients with pre-existing severe gastrointestinal disease.

**CONTRAINDICATIONS**

Do not use in patients with a personal or family history of MTC or in patients with MEN 2. Do not use in patients with a prior serious hypersensitivity reaction to dulaglutide or to any of the component products.

**WARNINGS AND PRECAUTIONS**

Risk of Thyroid C-Cell Tumors: In male and female rats, dulaglutide causes a dose-related and treatment-duration-dependent increase in the incidence of thyroid C-cell tumors (adenomas and carcinomas) after lifetime exposure. Glucagon-like peptide (GLP-1) receptor agonists have induced thyroid C-cell adenomas and carcinomas in mice and rats at clinically relevant exposures. It is unknown whether Trulicity will cause thyroid C-cell tumors, including MTC, in humans, as the human relevance of dulaglutide-induced rodent thyroid C-cell tumors has not been determined. One case of MTC was reported in a patient treated with Trulicity. This patient had pretreatment calcitonin levels approximately 8 times the upper limit of normal (ULN). Cases of MTC in patients treated with lixisenatide, another GLP-1 receptor agonist, have been reported in the postmarketing period; the data in these reports are insufficient to establish or exclude a causal relationship between MTC and GLP-1 receptor agonist use in humans. Trulicity is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2. Counsel patients regarding the potential risk for MTC with the use of Trulicity and inform them of symptoms of thyroid tumors (e.g., mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Trulicity. Such monitoring may increase the risk of unnecessary procedures, due to the low test specificity for serum calcitonin and a high background incidence of thyroid disease. Significantly elevated serum calcitonin value may indicate MTC and patients with MTC usually have calcitonin values >50 ng/L. If serum calcitonin is measured and found to be elevated, the patient should be further evaluated. Patients with thyroid nodules noted on physical examination or neck imaging should also be further evaluated.

Pneumocystis: In Phase 2 and Phase 3 clinical studies, 12 (3.4 cases per 1000 patient years) pneumocystis-related adverse reactions were reported in patients exposed to Trulicity versus 3 in non-incritin comparators (2.7 cases per 1000 patient years). An analysis of adjudicated events revealed 5 cases of confirmed pneumocystis in patients exposed to Trulicity (1.4 cases per 1000 patient years) versus 1 case in non-incritin comparators (0.88 cases per 1000 patient years). After initiation of Trulicity, observe patients carefully for signs and symptoms of pneumocystis, including persistent severe abdominal pain. If pneumocystis is suspected, promptly discontinue Trulicity. If pneumocystis is confirmed, Trulicity should not be restarted. Trulicity has not been evaluated in patients with a prior history of pneumocystis. Counsel other antidiabetic therapies and patients with a history of pneumocystis. Hypoglycemia and inconstant Use of Insulin Secretagogues or Insulin: The risk of hypoglycemia is increased when Trulicity is used in combination with insulin secretagogues (e.g., sulfonylureas) or insulin. Patients may require a lower dose of sulfonylurea or insulin to reduce the risk of hypoglycemia in this setting. Hypersensitivity Reactions: There have been postmarketing reports of serious hypersensitivity reactions (e.g., anaphylactic reactions and angioedema) in patients treated with Trulicity. If a hypersensitivity reaction occurs, the patient should discontinue Trulicity and other suspected medications and promptly seek medical advice. Use caution in a patient with a history of angioedema or anaphylaxis with another GLP-1 receptor agonist because it is unknown whether such patients will be predisposed to anaphylaxis with Trulicity. Renal Impairment: In patients treated with GLP-1 receptor agonists, there have been postmarketing reports of acute renal failure and worsening of chronic renal failure, which may sometimes result in hemodialysis. Some of these events were reported in patients without known underlying renal disease. A majority of reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Because these reactions may worsen renal failure, use caution when initiating or escalating doses of Trulicity in patients with renal impairment. Monitor renal function in patients with renal impairment reporting severe adverse gastrointestinal reactions. Severe Gastrointestinal Disease: Use of Trulicity may be associated with gastrointestinal adverse reactions, sometimes severe. Trulicity has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis, and is therefore not recommended in these patients. Macrovascular Outcomes: There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with Trulicity.

**ADVERSE REACTIONS**

Clinical Studies Experience: Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice.

**Pool of Placebo-controlled Trials:** These data reflect exposure of 1670 patients to Trulicity and a mean duration of exposure to Trulicity of 23.8 weeks. Across the treatment arms, the mean age of patients was 56 years, 1% were 75 years or older and 53% were male. The population in these studies was 69% White, 7% Black or African American, 12% Asian or Latino, and 9% Latin American. Trulicity (0.75 mg) caused pancreatitis (1.4 cases per 1000 patient years) versus 0.2% in placebo. An analysis of adjudicated events revealed 5 cases of confirmed pancreatitis in patients exposed to Trulicity for a mean duration 52 weeks. The median age of patients was 56 years, 2% were 75 years or older and 51% were male. The population in these studies was 71% White, 7% Black or African American, 11% Asian; 32% were of Hispanic or Latino ethnicity. This patient had pretreatment calcitonin levels approximately 8 times the upper limit of normal (ULN). Cases of MTC in patients treated with lixisenatide, another GLP-1 receptor agonist, have been reported in the postmarketing period; the data in these reports are insufficient to establish or exclude a causal relationship between MTC and GLP-1 receptor agonist use in humans. Trulicity is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2. Counsel patients regarding the potential risk for MTC with the use of Trulicity and inform them of symptoms of thyroid tumors (e.g., mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Trulicity. Such monitoring may increase the risk of unnecessary procedures, due to the low test specificity for serum calcitonin and a high background incidence of thyroid disease. Significantly elevated serum calcitonin value may indicate MTC and patients with MTC usually have calcitonin values >50 ng/L. If serum calcitonin is measured and found to be elevated, the patient should be further evaluated. Patients with thyroid nodules noted on physical examination or neck imaging should also be further evaluated.

Pneumocystis: In Phase 2 and Phase 3 clinical studies, 12 (3.4 cases per 1000 patient years) pneumocystis-related adverse reactions were reported in patients exposed to Trulicity versus 3 in non-incritin comparators (2.7 cases per 1000 patient years). An analysis of adjudicated events revealed 5 cases of confirmed pneumocystis in patients exposed to Trulicity (1.4 cases per 1000 patient years) versus 1 case in non-incritin comparators (0.88 cases per 1000 patient years). After initiation of Trulicity, observe patients carefully for signs and symptoms of pneumocystis, including persistent severe abdominal pain. If pneumocystis is suspected, promptly discontinue Trulicity. If pneumocystis is confirmed, Trulicity should not be restarted. Trulicity has not been evaluated in patients with a prior history of pneumocystis. Counsel other antidiabetic therapies and patients with a history of pneumocystis. Hypoglycemia and inconstant Use of Insulin Secretagogues or Insulin: The risk of hypoglycemia is increased when Trulicity is used in combination with insulin secretagogues (e.g., sulfonylureas) or insulin. Patients may require a lower dose of sulfonylurea or insulin to reduce the risk of hypoglycemia in this setting. Hypersensitivity Reactions: There have been postmarketing reports of serious hypersensitivity reactions (e.g., anaphylactic reactions and angioedema) in patients treated with Trulicity. If a hypersensitivity reaction occurs, the patient should discontinue Trulicity and other suspected medications and promptly seek medical advice. Use caution in a patient with a history of angioedema or anaphylaxis with another GLP-1 receptor agonist because it is unknown whether such patients will be predisposed to anaphylaxis with Trulicity. Renal Impairment: In patients treated with GLP-1 receptor agonists, there have been postmarketing reports of acute renal failure and worsening of chronic renal failure, which may sometimes result in hemodialysis. Some of these events were reported in patients without known underlying renal disease. A majority of reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Because these reactions may worsen renal failure, use caution when initiating or escalating doses of Trulicity in patients with renal impairment. Monitor renal function in patients with renal impairment reporting severe adverse gastrointestinal reactions. Severe Gastrointestinal Disease: Use of Trulicity may be associated with gastrointestinal adverse reactions, sometimes severe. Trulicity has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis, and is therefore not recommended in these patients. Macrovascular Outcomes: There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with Trulicity.
symptomatic hypoglycemia occurred in 85% and 80% of patients when Trulicity 0.75 mg and 1.5 mg, respectively, was co-administered with prandial insulin. Severe hypoglycemia occurred in 2.4% and 3.4% of patients when Trulicity 0.75 mg, and 1.5 mg, respectively, were administered with placebo. Trulicity 0.75 mg and 1.5 mg, respectively. Persistence of sinus tachycardia (reported at more than 2 visits) was reported in 0.2%, 0.4%, and 1.6% of patients treated with placebo, Trulicity 0.75 mg and Trulicity 1.5 mg, respectively. Episodes of sinus tachycardia, associated with a concomitant increase from baseline in heart rate of ≥15 beats per minute, were reported in 0.7%, 1.3%, and 2.2% of patients treated with placebo, Trulicity 0.75 mg, and Trulicity 1.5 mg, respectively. In patients exposed to Trulicity, Sinus tachycardia was reported in 3.0%, 2.8%, and 5.6% (HR) of 2-4 beats per minute (bpm). The long-term clinical effects of the increase in HR have not been established. Adverse reactions of sinus tachycardia were reported more frequently in patients exposed to Trulicity. Sinus tachycardia was reported in 3.0%, 2.8%, and 5.6% of patients treated with placebo, Trulicity 0.75 mg, and Trulicity 1.5 mg, respectively. Of the 64 dulaglutide-treated patients that developed dulaglutide ADAs, 34 patients (0.9% of the overall population) had dulaglutide-neutralizing antibodies, and 36 patients (0.9% of the overall population) developed antibodies against native GLP-1. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, the incidence of antibodies to dulaglutide cannot be directly compared with the incidence of antibodies of other products. Hypersensitivity: Systemic hypersensitivity adverse reactions sometimes severe (eg, severe urticaria, systemic rash, facial edema, lip swelling) occurred in 0.5% of patients treated with Trulicity in the four Phase 2 and Phase 3 studies. Injection-site Reactions: In the placebo-controlled studies, injection-site reactions (eg, injection-site rash, erythema) were reported in 0.5% of Trulicity-treated patients and in 0.0% of placebo-treated patients. PR Interval Prolongation and Adverse Reactions of First Degree Atrioventricular (AV) Block: A mean increase from baseline in PR interval of 2.3 milliseconds occurred in Trulicity-treated patients in contrast to a mean decrease of 0.9 millisecond in placebo-treated patients. Episodes of sinus tachycardia (ESRD), no clinically relevant change in dulaglutide PK was observed. There is limited systemic oral medication study in subjects with renal impairment including end-stage renal disease (ESRD) and varying degrees of hepatic impairment, no clinically relevant change in dulaglutide pharmacokinetics (PK) was observed. Renal Impairment: In the four Phase 2 and five Phase 3 randomized clinical studies, at baseline, 50 (1.2%) Trulicity-treated patients had mild renal impairment (eGFR ≥60 but <90 mL/min/1.73 m²), 171 (4.3%) Trulicity-treated patients had moderate renal impairment (GFR ≥30 but <60 mL/min/1.73 m²) and no Trulicity-treated patients had severe renal impairment (eGFR <30 mL/min/1.73 m²). No overall differences in safety or effectiveness were observed relative to patients with normal renal function, though conclusions are limited due to small numbers. In a clinical pharmacology study in subjects with renal impairment including end-stage renal disease (ESRD), no clinically relevant change in dulaglutide PK was observed. There is limited clinical experience in patients with severe renal impairment or ESRD. Trulicity should be used with caution, and if these patients experience adverse gastrointestinal side effects, renal function should be closely monitored. Gastrointestinal: Dulaglutide slows gastric emptying. Trulicity has not been studied in patients with pre-existing gastroesophageal reflux disease. Overdose: Overdoses have been reported in clinical studies. Effects associated with these overdoses were primarily mild or moderate gastrointestinal events (eg, nausea, vomiting) and non-severe hypoglycemia. In the event of overdose, appropriate supportive care (including frequent plasma glucose monitoring) should be initiated according to the patient’s clinical signs and symptoms.

PATIENT COUNSELING INFORMATION See FDA-approved Medication Guide

- Inform patients that Trulicity causes benign and malignant thyroid C-cell tumors in rats and that the human relevance of this finding has not been determined. Counsel patients to report symptoms of thyroid tumors (eg, a lump in the neck, persistent hoarseness, dysphagia, or dyspnea) to their physician. • Inform patients that persistent severe abdominal pain, that may radiate to the back and which may (or may not) be accompanied by vomiting, is the hallmark symptom of acute pancreatitis. Instruct patients to discontinue Trulicity promptly, and to contact their physician, if persistent severe abdominal pain occurs. • The risk of hypoglycemia may be increased when Trulicity is used in combination with a medicine that can cause hypoglycemia, such as a sulfonylurea or insulin. Review and reinforce instructions for hypoglycemia management when initiating Trulicity therapy, particularly when concomitantly administered with a sulfonylurea or insulin. • Patients treated with Trulicity should be advised of the potential risk of dehydration due to gastrointestinal adverse reactions and take precautions to avoid fluid depletion. Inform patients treated with Trulicity of the potential risk for worsening renal function and explain the associated signs and symptoms of renal impairment, as well as the possibility of dialysis as a medical intervention if renal failure occurs. • Inform patients that serious hypersensitivity reactions have been reported during postmarketing use of Trulicity and other GLP-1 receptor agonists. If symptoms of hypersensitivity reactions occur, patients must stop taking Trulicity and seek medical advice promptly. • Advise patients to inform their healthcare provider if they are pregnant or intend to become pregnant. • Prior to initiation of Trulicity, train patients on proper injection technique to ensure a full dose is delivered. Refer to the accompanying Instructions for Use for complete administration instructions with illustrations. • Inform patients of the potential risks and benefits of Trulicity and of alternative modes of therapy, such as diet, exercise, and oral medications. • Advise patients to take dietary instructions, regular physical activity, periodic blood glucose monitoring and HbA1c testing, recognition and management of hypoglycemia and hyperglycemia, and assessment for diabetes complications. During periods of stress such as fever, trauma, infection, or surgery, medication requirements may change and advise patients to seek medical advice promptly. • Each weekly dose of Trulicity can be administered at any time of day, with or without food. The day of once-weekly administration can be changed if necessary, as long as the last dose was administered 3 or more days before. If a dose is missed and there are at least 3 days (72 hours) until the next scheduled dose, it should be administered as soon as possible. Thereafter, patients can resume their usual once-weekly dosing schedule. If a dose is missed and the next regularly scheduled dose is due in 1 or 2 days, the patient should not administer the missed dose and instead resume Trulicity with the next regularly scheduled dose. • Advise patients treated with Trulicity of the potential risk of gastrointestinal side effects. • Instruct patients to read the Medication Guide and the Instructions for Use before starting Trulicity therapy and review them each time the prescription is refilled. • Instruct patients to inform their doctor or pharmacist if they develop new symptoms or a usual symptom, or if any known symptom persists or worsens. • Inform patients that response to all diabetic therapies should be monitored by periodic measurements of blood glucose and HbA1c levels, with a goal of decreasing these levels towards the normal range. HbA1c is especially useful for evaluating long-term glycemic control.

Eli Lilly and Company, Indianapolis, IN 46285, USA

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Additional information can be found at www.trulicity.com

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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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Amazon Making Moves To Disrupt Health Care Industry

By Frank Diamond

W ell, why shouldn’t the humongous e-commerce site turn its attention to health care? It’s affected practically every other industry.

Amazon made headlines in May when it hired Mark Lyons, whose background includes being a pharmacy services manager at Premera Blue Cross in Washington. Lyons’s mission, according to press reports: Investigate the feasibility of Amazon becoming a PBM. And last month, Amazon’s growing presence in the medical supply distribution industry made news.

Some experts believe that Amazon might get a bloody nose trying to make inroads into the PBM industry. “I would never underestimate Amazon,” says Adam J. Fein, pharmacy pundit and expert on the inside baseball of the industry’s inside baseball (check out his drugchannels.net website). “However, I believe that Amazon has limited feasible options for disrupting pharmacy and PBM markets.” That’s because our byzantine drug distribution and payment system resists disruptive innovation.

Here are the things that Fein believes Amazon will not be able to do: build or buy a PBM, become a central-fill mail pharmacy in a third-party payer’s network, or build or buy a specialty pharmacy.

Medical supply distribution is a different story. Amazon Business Platform, launched more than two years ago, is essentially a middleman for vendors. The platform offers services like business-to-business discounts and same-day shipping. Medical supply distributors want to sell to providers. And what do providers want? Things like IV bags, hospital beds, infusion pumps, scalpels, forceps, catheters—you name it.

MANAGED CARE takes no stand on whether this will eventually be good or bad for health care. We only note what usually happens when Amazon sticks its gargantuan toe in the waters of any industry: a tidal wave. Competitors find themselves in a price war that they have very little chance of winning.

Just one more thing to think about as change swirls about us.
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Former Pharma Sales Reps Enlisted To Fight Drug Costs

Capital District Physicians’ Health Plan (CDPHP), an Albany, N.Y., insurer, went over to the dark side and did some recruiting. The insurer hired former pharmaceutical salespeople to help it alert doctors about the price of some medications and how to adjust prescribing habits so that patients don’t get hit with exorbitant copayments, Kaiser Health News reports.

Take Mike Courtney, for instance. He’s a former salesman for Pfizer and Johnson & Johnson. Now, instead of visiting physicians to tout the latest, greatest, and most expensive, Courtney will tell them about cheaper alternatives.

Physician prescribing guides do not often contain specific information about drug costs. “Drug sales reps who visit their [doctor] offices don’t highlight high prices as they drop off free samples, and drugmakers can quietly but substantially hike the price of a drug from one year to the next,” Kaiser reports.

Two years ago, Valeant Pharmaceuticals raised the price of a dose of Glumetza, a drug used to lower blood sugar, to more than $80,000 a year, 20 times what it had been a few years earlier. Meanwhile, a generic version can be purchased for as little as a penny a pill.

This put CDPHP in a difficult position because Glumetza is on its formulary. Member copayments had to be a “nominal” amount of between $3 million and $4 million a year, he told Kaiser. “We get patient complaints saying, ‘Hey, I can’t afford this,’ and we say: ‘It’s cheap!’”

“When the products go generic, nobody’s promoting them anymore,” said Courtney, the former sales rep.

How To Improve Health Care IT

Fashioning health care IT so it protects patients against medical mistakes requires a sustained effort that should be funded by both the private and public sectors, according to a report by the Bipartisan Policy Center.

“This approach is practical, politically feasible, and can be implemented in the near-term to lay the foundation for improving safety,” according to the report, which was released in May.

The Bipartisan Policy Center is a think tank run by—as the name suggests—Democrats and Republicans.

And in the scheme of things, we aren’t talking major money. The cost would be a “nominal” amount of between $3 million and $4 million a year, the report says.

The report notes that more than 200,000 Americans die each year from preventable medical errors, the third-leading cause of death behind heart disease and cancer. Health IT has done much to reduce medication errors (and to lower cost and to improve the quality of care), the report says. “However,” it continues, “there are instances in which health IT has the potential to create harm if not effectively developed, implemented, or used.” Delays caused by, for instance lack of interoperability, can lead to medication errors and slow response to abnormal tests.

There’s also the issue of downtime when, because of some malfunction, providers don’t have access to electronic medical records. Anything from natural disasters to cybersecurity threats can cause downtime.

“There are a number of strategies and best practices that can be used to enable health care organizations to effectively carry out ongoing clinical and administrative processes in the event of unexpected downtime,” the report states. Foremost among these is the integration of health IT safety into a provider’s overall safety efforts.

The report argues for the dissemination of best practices to ensure health IT safety and for continuous refinement and adoption of those standards.

The authors also suggest that organizations tracking IT use should make it as easy as possible for institutions to report mistakes and not get punished for doing so.

Hospitals Lawyer Up To Boost Care Teams

The shift to value-based health care encourages hospitals to add lawyers to treatment teams, and often they are on hand to help patients at no additional cost.

Ellen Lawton, the codirector of the National Center for Medical–Legal Partnership at George Washington University, told Kaiser Health News that about 300 health care systems, children’s hospitals, and federally qualified health centers have placed lawyers on their health care teams. They help patients overcome myriad practical problems associated with illness and treatment.

“Lawyers might file for an order of
protection from a violent spouse, help appeal an insurance claim denial or get involved in child custody, guardianship, or power of attorney issues,” Kaiser reports.

The Kaiser article, published June 6, begins anecdotally with a story about Christine Crawford, a patient at Mount Sinai Health System in New York City.

She plans to have gender transition surgery later this year. The attorney on the care team helped Crawford with her name-change petition, but it didn’t stop there. She also notified Crawford’s former spouse and published the name change in the newspaper.

Lawyers on care teams can be particularly helpful when hospitals have to deal with poorer populations. Housing is often a problem for patients at Care Connections at Lancaster General Health/Penn Medicine in Lancaster, Pa., and lawyers can help fight eviction or track down federal housing subsidies.

Jeffrey Martin, MD, is the managing physician for the program. He tells Kaiser: “It’s hard to use inhalers and take 16 other medications if you’re living in the back of a car or on someone’s couch.”

Medicare Covering Exercise Sessions

Medicare has begun covering 36 sessions of supervised exercise for patients with symptomatic peripheral artery disease (PAD), CMS announced last month. The agency, citing guidelines by the American College of Cardiology Foundation and the American Heart Association, said that supervised exercise therapy (SET) alleviates common symptoms of cardiovascular disease, especially leg pain, and is more effective than unsupervised exercise and is at least comparable to more invasive revascularization treatments.

PAD, which occurs when plaque buildup narrows the arteries in the legs, affects 12% to 20% of Americans aged 60 or over. The incidence of PAD increases significantly with age. Medicare set some ground rules for the SET programs it will cover. The exercise therapy must be given over a 12-week period. Programs must consist of 30- to 60-minute sessions that include a therapeutic exercise training program for PAD in patients with leg pain, be conducted by people trained to conduct PAD exercise therapy, and take place in an outpatient setting.

In addition, beneficiaries must have a physician referral to begin the treatment, and the physician should educate the patient about cardiovascular disease and how to reduce the risks.

Medicare Administrative Contractors can decide to extend the SET program for an additional 36 sessions. A second physician referral is required for the additional sessions.

Bill Makes It Easier To Fire VA Employees

In the latest legislative push to refurbish the much-criticized VA health system, Congress last month passed a bill that would make it easier to fire employees for misconduct. The Senate and House passed the Department of Veterans Affairs Accountability and Whistleblower Protection Act of 2017, and President Trump was expected to sign the measure into law, the Los Angeles Times reports.

Civil servant unions are not thrilled, saying the measure erodes job protection for employees and makes it more onerous for whistleblowers to come forward.

J. David Cox Sr., president of the American Federation of Government

ACO growth expected to continue

The ACA’s emphasis on value-based care encouraged the growth of ACOs. Most experts agree that ACOs represent an opportunity to make health care more effective. They should stay with us no matter what happens to the ACA (which doesn’t look good as of this writing). MACRA and the 21st Century Cures Act both won broad bipartisan approval and both promise to continue to contribute to the growth of ACOs.

A white paper by Wellcentive, a vendor specializing in population health management, says that “the number of lives covered through ACOs is expected to grow exponentially, reaching more than 105 million patients by 2020 [baseline scenario], compared to just over 20 million today.” There are challenges: dialing back costs, dealing with a coming shortage of physicians, getting patients engaged, maximizing use of electronic health records.
Employees, told the Senate in a hearing in May: “This upends nearly 140 years of civil service law, and makes VA employees very close to ‘at will,’ which seems to be the real objective of the drafters of this provision. Although marketed as a bill to make it easier to fire bad employees, the proposals are designed to kill off and bury the apolitical Civil Service. It makes it just as easy to fire a good employee, an innocent employee, as it will be to fire a bad employee.”

The majority of lawmakers (the House passed the bill, 368 to 55) and many veteran advocacy groups disagree, saying the measure makes it easier to cut through bureaucracy to deal with employees guilty of misconduct.

Dan Caldwell, the director of policy for the advocacy group Concerned Veterans for America, tells the Los Angeles Times that the bill is a “key reform that needs to be implemented before you can start addressing … anything at all because if you don’t have accountability, then any type of future reforms will be undermined.”

The legislation mandates that a decision on whether to take disciplinary action must be taken within 15 business days. The employee has seven business days to respond to allegations. That’s a huge difference to the current situation, which now takes six months to a year to remove a permanent civil servant.

To address concerns that the legislation would make it easier to punish whistleblowers, the measure creates an Office of Accountability and Whistleblower Protection. Whistleblowers were crucial in exposing the wait times vets had to endure to get care—the issue that led to the ongoing scandals about VA care that continue to garner headlines.

**Briefly Noted**

The bleeding of the Obamacare exchanges continues, with the New York Times reporting that Anthem, one of the industry’s biggest players, will not participate in Ohio’s marketplace next year. “While Anthem had warned that it might leave some or all of the states where it offers individual plans, its exit from Ohio’s signals that even some of the market’s stalwarts are unnerved,” the newspaper reports. … Medicare Part D beneficiaries have been buffeted by the high cost of drugs, according to an analysis by the Wall Street Journal. The newspaper’s review found that the number of drugs with out-of-pocket costs of $1,000 or more rose by 86%, from 118 in 2011 to 220 in 2015. … Financial counseling offered as part of a worker’s wellness package can greatly reduce stress in the workplace, according to a survey by Money Management International, a not-for-profit credit counseling organization. The survey found that 86% of workers at Samaritan Health Services, a not-for-profit health organization in Corvallis, Ore., reported less stress after progressing on financial goals after counseling. … Will insurers have to cover healthy meals someday? Doctors in Boston are studying the benefits of medically tailored meals. The focus of their efforts is Community Servings, a not-for-profit organization that has been providing such sustenance for about 30 years by shopping for, preparing, or both, for people with chronic diseases. Seth Berkowitz, MD, a primary care physician at Massachusetts General Hospital, is doing research on the program. He told STAT: “We know lack of access to healthy food is associated with bad outcomes in virtually every area you look. What we don’t really know is how to intervene on the issue.” Some insurers cover what Community Servings does as a medical expense. Berkowitz wants to see if a case can be made for the entire health care system to follow suit. … In Colorado alone, there are about 17.5 tons of unused prescription drugs worth nearly $10 million that have to be thrown out when patients in long-term care facilities either move out, die, or no longer need the medication, ProPublica reports. Iowa is doing something about this, and its Safe-NetRx program looks to recover and redistribute about $5 million worth of drugs this year. … Blame the rise of drug-overdose deaths in Massachusetts on fentanyl, reports Kaiser Health News. In keeping with a pattern seen across New England, about 75% of the men and women in Massachusetts who died of an overdose last year had the substance in their system. That’s up from 57% in 2015. Fentanyl may be especially lethal because it’s potent and is mixed with other drugs in varying amounts unknown to the user, Kaiser reports. … Asian Americans are vulnerable to developing type 2 diabetes, yet are 34% less likely to be screened for the disease than non-Hispanic whites, according to a study published in the Journal of General Internal Medicine. University of Chicago researchers analyzed data from telephone surveys of more than 500,000 people. … Rather than tally environmental exposures individually, the Environmental Quality Index (EQI) combines them from five domains (air, water, land, built environment, and sociodemographic environment). Comparing the EQI with the incidence of cancer at the county level, researchers found that poor environmental quality was associated with cancer and that the relationship was strongest for prostate and breast cancer. … There’s a greater risk of longer length of stay, readmissions, and death if a patient gets a preventable hospital-acquired complication—and that’s especially true for patients who have kidney disease, according to a study in the Clinical Journal of the American Society of Nephrology. The researchers used data on all the adults hospitalized in the province of Alberta from 2003 to 2008 to conduct their study. …
California's legislators are considering a single-payer health care system in the state, but the cost is giving some lawmakers pause, reports Kaiser Health News. It would come to about $400 billion annually, with half of that money coming from a 15% payroll tax and the other half from all of the public funds already allotted for health care. Fewer skilled nursing home admissions and shorter lengths of stay helped ACOs in the Medicare Shared Savings Program bring about a 9% decrease in postacute spending, according to a study in *JAMA Internal Medicine*. Reductions in use of nursing homes and length of stay were mainly because of within-hospital or within-nursing home changes in care specifically for ACO patients, the researchers found. The main caregiver for someone with Alzheimer's or another form of dementia is usually a family member, and that person often feels overwhelmed. A new “boot camp,” sponsored in part by the Archstone Foundation, gives caregivers tips and advice. Efforts to subsidize premiums for private health insurance for low-income people may not work as well as policymakers had hoped, according to a study by economists at MIT and Harvard. Looking at data from CommCare, Massachusetts’ subsidized insurance exchange, researchers found that people’s “willingness to pay” is three to four times below their expected medical costs. “As a result,” the abstract says, “we estimate that take-up will be highly incomplete even with generous subsidies: If enrollee premiums were 25% of insurers’ average costs, at most half of potential enrollees would buy insurance, and even premiums subsidized down to 10% of average costs would still leave at least 20% uninsured.”

Listen to your doctor, patients have always been told and there was always an "or else" implied. Usually it was "or else, you won't get better." Now, it’s “or else he or she will tell you not to come back,” according to a research letter in *JAMA Internal Medicine*. The authors, from Mathematica Policy Research and CMS, say patient dismissal could be an unintended consequence of the shift to value-based care as clinicians face pressure to limit their panel to patients for whom they can readily demonstrate value in order to maximize revenue. Only half of employers offer vision benefits, according to MetLife’s 2017 Employee Benefit Trends Study, even though more than half of employees rate vision care as an essential benefit, right behind medical and dental benefits. Yet more data suggesting that too much imaging can be a bad thing. A study in the May issue of the *Journal of Hospital Medicine* included 376 patients who were hospitalized because of chest pains at an academic medical center. Of these, 197 (52%) had new radiologic findings, and those findings were associated with a 26% increase in length of stay yet only 7% of the findings were clinically significant. Sexual abuse in nursing homes is underreported, and often the perpetrators go unpunished, reports the *Kansas City Star*. It will take a lot to fix the problem, including soul-searching, because the abuse “hides behind reporting systems that fail to catalog such complaints separately from other forms of abuse that afflict the elderly and disabled.” The Administration for Community Living, which collects data from state-level ombudsmen, has cataloged more than 20,000 complaints of sexual abuse at long-term care facilities over 20 years, which works out to nearly three such complaints a day, the newspaper reported. And the newspaper says that tally is incomplete and does not include resident-on-resident sexual assaults. The number of children and adolescents admitted to children’s hospitals because of suicidal thoughts or self-harm more than doubled from 2008 to 2015, according to research presented at a recent meeting of the Pediatric Academic Societies. Significant increases were seen in all age groups but were higher among the older children, according to a press release about the findings presented by Gregory Plemmons, MD, an associate professor of pediatrics at Monroe Carell Jr. Children’s Hospital at Vanderbilt. Even drugs not on the DEA’s schedules have high abuse potential in prisons, reports Jeffrey E. Keller in his blog, *Jailmedicine*. Keller is the medical director of Badger Medical, which provides medical services to several jails and juvenile facilities in Idaho. Drugs on Keller’s list include trazodone, albuterol, and first-generation antihistamines like Benadryl. There is an active market for drugs among inmates, Keller writes, so even if an inmate has no interest in abusing the drugs himself, he may want to sell the drugs. There’s no definitive way yet for physicians to determine which prostate cancer cells will become aggressive and which a man can live with. But methods that can do just that appear to be in the works, according to *STAT*. One, called multiparametric MRI, shows the size and density of prostate cancer and connections to the blood supply.

Dutch researchers reported at a European meeting earlier this year that multiparametric MRI reduced unnecessary biopsies by 70%, according to *STAT*. The health situation in America for black men is so bad that they often live longer in prison than out, according to a study in *Lancet*. “Black male prisoners, for instance, have far lower mortality than similarly aged black men in the general population,” the study states. Why? It’s not exactly clear, but decreased risk of death by violence or accidents, reduced access to illicit drugs and alcohol, and improved access to health care possibilities.

—Frank Diamond

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Trying for Association Health Plans Again and Again and Again

House salvages 2005 bill that’s gone nowhere three times in 12 years.

By Richard Mark Kirkner, Contributing Editor

If there’s a salvage yard for ideas for fixing the country’s health care system, Republicans are picking it pretty clean. First Donald Trump during his campaign talked up the idea of letting plans sell products across state lines. Then high-risk pools became a centerpiece of the House-passed American Health Care Act.

Another idea plucked off the scrapheap has gained less attention: letting small employers join forces to form association health plans.

This is such a recycle job that the legislation the House passed in March, the Small Business Health Fairness Act of 2017, reads almost word-for-word the same as a 2005 version under the same title. The House passed that legislation in 2005—and again in 2009 and 2011—but the Senate never took it up.

AHPs and MEWAs

Self-insured association health plans, or AHPs, have been around, and actually exist today as state-regulated, multiple-employer welfare arrangements, or MEWAs (pronounced mee-wahs). An AHP is a MEWA that’s tied into a trade association or similar group, like a Chamber of Commerce. States typically require MEWAs to have a minimum number of employers and covered employees to qualify, and some kind of commonality among employer members; that is, they should all be in the same region or a similar industry. There aren’t many MEWAs. In the two biggest states, California and Texas, 10 MEWAs are functioning today.

The House legislation uses the term AHP. In 1983, Congress changed the Employee Retirement Income Security Act to allow states to regulate AHPs while preserving the state regulatory exemption for self-insured, single-employer plans. The House legislation would actually undo that 1983 ERISA change and exempt AHPs from state oversight, provided they get certification. MEWAs that don’t get that certification would continue to function under state rules. The bill would empower the Department of Labor to be the sole regulator of such plans.

Business groups in favor

Business groups like the U.S. Chamber of Commerce and the National Federation of Independent Business (NFIB) endorse AHPs as a way to give employers more options beyond the strictures of the ACA. “Our members are clamoring for more affordable options for offering their employees health insurance,” says Kevin Kuhlman, government relations director for NFIB, a trade association for small businesses.

The National Association of Insurance Commissioners has come out against the legislation, claiming states need to regulate these plans to avoid their sins of the past, which, critics point out, include fraud and poor management. In the states, MEWAs are subject to some robust regulations. Texas is known to have extensive MEWA regulations. MEWAs there must have at least five separate employers, cover at least 200 employees, maintain stop-loss coverage, and have cash reserves of 20% of the total estimated contributions for the current plan year.

One of the largest MEWAs is Western Growers Assurance Trust, a health plan based in California that covers 70,000 enrolled lives and has $225 million in annual revenue. It offers health benefits to members of the Western Growers Association, an association of farmers and agriculture-related industries that covers four states. It is subjected to California regulation.

Despite the ERISA changes in the 1980s, confusion over regulation of MEWAs was rampant. A 2005 Georgetown University report—compiled in response to the 2005 legislative effort to exempt these entities from state oversight—noted that state regulators shut down 41 illegal entities selling coverage through phony and real associations, and the Department of Labor shut down three others. “During a recent cycle of
scams, 144 operators left over 200,000 policyholders with over $252 million in medical bills,” the report states.

**Cherry picking history**
Mila Kofman, the author of that 2005 Georgetown report and now executive director of the DC Health Benefit Exchange Authority, the district’s ACA exchange, says AHPs have a history of luring healthy individuals out of the insurance pool. The legislation could be another nail in the coffin of the state and federal exchanges. “The cherry picking by itself will destroy our individual side and potentially destroy our small group side as well,” she says, explaining that the D.C. exchange has two carriers now offering 20 different products signed up for its individual exchange next year and has a “very robust SHOP”—or Small Business Health Options Program—for its small-group business.

Kofman, who’d been superintendent of insurance in Maine before taking the D.C. job, wrote another report about Kentucky’s experience in the 1990s when it exempted association health plans from community rating and guaranteed issue requirements. That led to an exodus of 21 of 23 insurers from the state’s individual nongroup market. Wrote one scholar, “the association exemption provided a haven for healthy risks in the associations,” and Kofman says, “There’s no reason to believe the experience anywhere would be different from what Kentucky saw and what states have been saying they’re afraid of happening to regulated markets.”

In their letter to committee leadership stating their opposition to the legislation, National Association of Insurance Commissioners picked up on the themes that Kofman voices, saying the legislation would eliminate all state consumer protections and solvency standards and actually drive up insurance costs for small businesses that do not participate in an AHP.

In backing the legislation, NFIB’s Kuhlman notes the legislation provides protections to avoid a replay of history. “I do think they have learned the lessons from the past,” he says. “With the exception of ERISA, the federal government basically stayed out of regulating health insurance. It’s only in the past five years or so that the regulations have expanded.” That expansion, of course, is courtesy of the ACA. To be fair, while the 2017 bill is a virtual mirror image of the 2005 legislation, the latter was drafted in the wake of the scams Kofman documented. The 2005 bill was crafted to address those problems.

The protections in the latest bill are unchanged from the 2005 version. It prohibits rate discrimination based on health status and requires a minimum of 1,000 participants. Reserve requirements depend on liabilities, obligations, and excess stop-loss insurance, but mandate a minimum surplus above claims of $500,000 or up to $2 million based on projections. Plan sponsors can be trade, industry, or professional associations or chambers of commerce, and the Labor Department would credential and oversee AHPs.

Don’t wager on the upper chamber voting on the 2017 edition anytime soon. “Nobody really looked at this legislation seriously to see whether it made sense in today’s market,” says Health Affairs blog contributor Timothy Jost. “The last time, it passed in the House and died in the Senate, and that’s likely this time around.”

**Will SHOP changes mean more takers?**
Regardless of what happens with the Small Business Health Fairness Act of 2017, CMS is making another move to change the way small businesses can purchase health insurance. Beginning in 2018, instead of having to purchase coverage on HealthCare.gov, small business will be able to sign up through an agent or broker instead while still using HealthCare.gov to determine their eligibility. In the 17 states that run their own exchanges, small businesses will still be able to enroll through the Small Business Health Options Program, or SHOP, marketplaces.

The ACA set up the SHOP marketplaces to cater to small businesses, but they haven’t exactly been a hit. The Congressional Budget Office initially projected that 4 million people would enroll through the SHOP marketplaces by 2017, but only 230,000 individuals covered by 27,000 participating employers have done so. CMS said it intends to propose rulemaking to change SHOP enrollment. The rule would let businesses sign up outside the SHOP marketplace and still claim the tax credit.

The D.C. Health Benefit Exchange Authority, the exchange marketplace for Washington, D.C., runs its own SHOP. Mila Kofman, the exchange’s executive director, doesn’t expect much impact from the proposed rule because so few businesses claim the tax credit. “I’d be surprised if even one small business qualified for the tax credits in our exchange,” she says. “That’s why the tax credits for small business need to be expanded so more small businesses could qualify.”
IMPORTANT SAFETY INFORMATION

WARNING: RISK OF SERIOUS DEHYDRATION IN PEDIATRIC PATIENTS
Trulance™ is contraindicated in patients less than 6 years of age; in nonclinical studies in young juvenile mice administration of a single oral dose of plecanatide caused deaths due to dehydration. Use of Trulance should be avoided in patients 6 years to less than 18 years of age. The safety and efficacy of Trulance have not been established in pediatric patients less than 18 years of age.

Contraindications
• Trulance is contraindicated in patients less than 6 years of age due to the risk of serious dehydration.
• Trulance is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.

Warnings and Precautions
Risk of Serious Dehydration in Pediatric Patients
• Trulance is contraindicated in patients less than 6 years of age. The safety and effectiveness of Trulance in patients less than 18 years of age have not been established. In young juvenile mice (human age equivalent of approximately 1 month to less than 2 years), plecanatide increased fluid secretion as a consequence of stimulation of guanylate cyclase-C (GC-C), resulting in mortality in some mice within the first 24 hours, apparently due to dehydration. Due to increased intestinal expression of GC-C, patients less than 6 years of age may be more likely than older patients to develop severe diarrhea and its potentially serious consequences.
• Use of Trulance should be avoided in patients 6 years to less than 18 years of age. Although there were no deaths in older juvenile mice, given the deaths in young mice and the lack of clinical safety and efficacy data in pediatric patients, use of Trulance should be avoided in patients 6 years to less than 18 years of age.

Diarrhea
• Diarrhea was the most common adverse reaction in the two placebo-controlled clinical trials. Severe diarrhea was reported in 0.6% of patients.
• If severe diarrhea occurs, the health care provider should suspend dosing and rehydrate the patient.

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• In the two combined CIC clinical trials, the most common adverse reaction in Trulance-treated patients (incidence ≥2% and greater than in the placebo group) was diarrhea (5% vs 1% placebo).
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• Avoid use of Trulance in patients 6 years to less than 18 years of age [see Warnings and Precautions, Use in Specific Populations]

• The safety and effectiveness of Trulance have not been established in patients less than 18 years of age [see Use in Specific Populations]

INDICATIONS AND USAGE: Trulance is indicated in adults for the treatment of chronic idiopathic constipation (CIC).

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• Patients less than 6 years of age due to the risk of serious dehydration [see Warnings and Precautions, Use in Specific Populations]

• Patients with known or suspected mechanical gastrointesinal obstruction.

WARNINGS AND PRECAUTIONS: Risk of Serious Dehydration in Pediatric Patients — Trulance is contraindicated in patients less than 6 years of age. The safety and effectiveness of Trulance in patients less than 18 years of age have not been established. In young juvenile mice (human age equivalent of approximately 1 month to less than 2 years), plecanatide increased fluid-secretion into the intestines as a consequence of stimulation of guanylate cyclase-C (GC-C), resulting in mortality in some mice within the first 24 hours, apparently due to dehydration. Due to increased intestinal expression of GC-C, patients less than 6 years of age may be more likely than patients 6 years of age and older to develop severe diarrhea and its potentially serious consequences.

Avoid the use of Trulance in patients 6 years to less than 18 years of age. Although there were no deaths in older juvenile mice, given the deaths in younger mice and the lack of clinical safety and efficacy data in pediatric patients, avoidance of use of Trulance in patients 6 years to less than 18 years of age [see Contraindications, Warnings and Precautions, Use in Specific Populations].

Diarrhea
Diarrhea was the most common adverse reaction in the two placebo-controlled clinical trials. Severe diarrhea was reported in 0.6% of patients [see Adverse Reactions]. If severe diarrhea occurs, suspend dosing and rehydrate the patient.

ADVERSE REACTIONS: Clinical Trials Experience — Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared with rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety data described below reflect data from 1733 adult patients with CIC randomized in two double-blind, placebo-controlled clinical trials (Study 1 and Study 2) to receive placebo or 3 mg of Trulance once daily for 12 weeks. Demographic characteristics were comparable between the Trulance and placebo groups [see Clinical Studies in the full Prescribing Information].

Most Common Adverse Reactions

Table 1: Most Common Adverse Reactions in Two Placebo-Controlled Trials of Trulance (Study 1 and Study 2) in Patients with CIC

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Trulance (N = 865)</th>
<th>Placebo (N = 870)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diarrhea</td>
<td>5</td>
<td>1</td>
</tr>
</tbody>
</table>

*reported in at least 2% of Trulance-treated patients and at an incidence greater than placebo

Diarrhea

The majority of reported cases of diarrhea occurred within 4 weeks of treatment initiation. Severe diarrhea was reported in 0.6% of Trulance-treated patients compared to 0.3% of placebo-treated patients. Severe diarrhea was reported to occur within the first 3 days of treatment [see Warnings and Precautions].

Adverse Reactions Leading to Discontinuation

Discontinuations due to adverse reactions occurred in 4% of Trulance-treated patients and 2% of placebo-treated patients. The most common adverse reaction leading to discontinuation was diarrhea: 2% of Trulance-treated patients and 0.5% of placebo-treated patients withdrew due to diarrhea.

Less Common Adverse Reactions

Adverse reactions reported in less than 2% of Trulance-treated patients and at an incidence greater than placebo were:

- sinusitis, upper abdominal pain, upper respiratory tract infection, abdominal distension, abdominal tenderness, and increased liver biochemical tests (2 patients with alanine aminotransferase [ALT] greater than 5 to 15 times the upper limit of normal and 5 patients with aspartate aminotransferase [AST] greater than 5 times the upper limit of normal).

USE IN SPECIFIC POPULATIONS: Pregnancy — Risk Summary

Plecanatide and its active metabolite are negligibly absorbed systemically following oral administration [see Clinical Pharmacology in the full Prescribing Information] and maternal use is not expected to result in fetal exposure to the drug.

The available data on Trulance use in pregnant women are not sufficient to inform any drug-associated risks for major birth defects and miscarriage. In animal developmental studies, no effects on embryofetal development were observed with oral administration of plecanatide in mice and rabbits during organogenesis at doses much higher than the recommended human dosage.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the United States general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Data
Animal Data

Pregnant mice and rabbits were administered plecanatide during the period of organogenesis. There was no evidence of harm to embryo-fetal development at oral doses up to 800 mg/kg/day in mice and 250 mg/kg/day in rabbits. Oral administration of up to 600 mg/kg/day in mice during organogenesis through lactation produced no developmental abnormalities or effects on growth, learning and memory, or fertility in the offspring through maturation.

The maximum recommended human dose is approximately 0.05 mg/kg/day, based on a 60-kg body weight. Limited systemic exposure to plecanatide was achieved in animals during organogenesis (area under the plasma concentration-time curve [AUC] = 489 ng·h/mL in rabbits given 250 mg/kg/day). Plecanatide and its active metabolite are not measurable in human plasma following administration of the recommended clinical dosage. Therefore, animal and human doses should not be compared directly for evaluating relative exposure.

Lactation

Risk Summary

There is no information regarding the presence of plecanatide in human milk, or its effects on milk production or the breastfed infant. No lactation studies in animals have been conducted. Plecanatide and its active metabolite are negligibly absorbed systemically following oral administration [see Clinical Pharmacology in the full Prescribing Information]. It is unknown whether the negligible systemic absorption of plecanatide by adults will result in a clinically relevant exposure to breastfed infants. Exposure to plecanatide in breastfed infants has the potential for serious adverse effects [see Use in Special Populations]. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Trulance and any potential adverse effects on the breastfed infant from Trulance or from the underlying maternal condition.

Pediatric Use

Trulance is contraindicated in pediatric patients less than 6 years of age. Avoid use of Trulance in patients 6 years to less than 18 years of age [see Contraindications, Warnings and Precautions]. The safety and effectiveness of Trulance in patients less than 18 years of age have not been established.

In nonclinical studies, deaths occurred within 24 hours in young juvenile mice (human age equivalent of approximately 1 month to less than 2 years) following oral administration of plecanatide, as described below in Juvenile Animal Toxicity Data. Because of increased intestinal expression of GC-C, patients less than 6 years of age may be more likely than patients 6 years of age and older to develop diarrhea and its potentially serious consequences. Trulance is contraindicated in patients less than 6 years of age. Given the deaths in young juvenile mice and the lack of clinical safety and efficacy data in pediatric patients, avoid the use of Trulance in patients 6 years to less than 18 years of age.

Juvenile Animal Toxicity Data

Single oral doses of plecanatide at 0.5 mg/kg and 10 mg/kg caused mortality in young juvenile mice on postnatal days 7 and 14, respectively (human age equivalent of approximately 1 month to less than 2 years). Treatment-related increases in the weight of intestinal contents were observed in juvenile mice following single doses of plecanatide on postnatal day 14 (human age equivalent of approximately less than 2 years), consistent with increased fluid in the intestinal lumen. Although the recommended human dose is approximately 0.05 mg/kg/day, based on a 60-kg body weight, plecanatide and its active metabolite are not measurable in adult human plasma, whereas systemic absorption was demonstrated in the juvenile animal toxicity studies. Animal and human doses should not be compared directly for evaluating relative exposure.

Geriatric Use

Clinical studies of Trulance did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from patients 18 years to less than 65 years of age. Of 2601 subjects in clinical trials of Trulance, 273 (10%) were 65 years of age and over, and 47 (2%) were 75 years and over. In general, dose selection in the elderly should be based on clinical judgement and should take account of the age-related decreases in hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

DOSEAGE AND ADMINISTRATION: Recommended Dosage — The recommended adult dosage of Trulance is 3 mg taken orally once daily, with or without food. [See Preparation and Administration Instructions in the full Prescribing Information].

Date of Issue: 07/17
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PP-PLE-US-0089
Novartis’s Entresto came to market in 2015 in a blaze of glory. A combination of valsartan, an angiotensin receptor blocker, and sacubitril, a neprilysin inhibitor, Entresto’s rise to stardom started when its pivotal phase 3 study, the PARADIGM–HF trial, was stopped early. Interim results showed it crushing its comparator, enalapril, a leading light in the ACE inhibitor class. Relative to enalapril, Entresto reduced cardiovascular death and heart failure hospitalization by 20% and all-cause mortality by 16%.

There was more good news for Novartis and its budding heart failure rock star last year. Updated heart failure guidelines from the American College of Cardiology, the American Heart Association, and the Heart Failure Society of America recommended replacing ACE inhibitors and ARBs with Entresto.

Now, though, some experts and industry observers are wondering why the wunderkind hasn’t done more wonderfully on the market.

A November 2016 letter in the Annals of Internal Medicine written by one of PARADIGM–HF’s lead investigators noted that the “plethora of articles and P values concerning sacubitril/valsartan published over the past 3 years [since PARADIGM–HF ended] have had minimal impact on prescribing behaviors.” In May of this year, three other Annals letter writers zeroed in on the main issue with most drugs these days—price. As a brand name drug, Entresto costs substantially more than the generic ACE inhibitors and ARBs. GoodRx reports the average cash price for uninsured patients for Entresto is $504 per month, compared with $44 for enalapril.

Out-of-pocket costs may be an issue for elderly patients, the population most likely to have heart failure. Entresto is not out of line with other brand drugs covered by Part D plans. GoodRx reports that about two thirds of Part D plans cover Entresto, and the copayments range from $18 to $30. Still, that is more than the copayment for enalapril, which in many Part D plans is $2.

Novartis has showed some flexibility by entering into performance contracts with Aetna, Cigna, and Harvard Pilgrim. The drugmaker has agreed to a reduced price for Entresto if the drug doesn’t reduce hospital admissions.

Physicians are wary
In the May issue of Barron’s, CEO Joseph Jimenez acknowledged that the company had underestimated doctors’ reluctance to prescribe Entresto.

William Chavey, MD, lead author on a comprehensive heart failure management article in American Family Physician and service chief of family medicine at the University of Michigan, says that “if Entresto had been released without the 30 years’ experience for ACE inhibitors, it might be a different story.”

“You have a generation of physicians who were raised on the idea that ACE inhibitors are the cornerstone of therapy,” Chavey explains. “They produce good outcomes and people know how to use them.”

Another factor in Entresto’s market struggles is that heart failure patients often take many medications in addition to an ACE inhibitor or an ARB. A regimen may include a beta blocker, an aldosterone antagonist, a vasodilator, a diuretic, and digoxin. It may take multiple visits to find the right mix, says Chavey: “Optimizing therapy is not necessarily a knowledge problem. It’s an operational problem.”

So while Entresto may have great clinical trial results, physicians don’t know yet how it will interact with all the other medications their patients are taking. “It is such a paradigm-changing drug that physicians want to be confident they are doing the right thing before they start prescribing it widely,” says Chavey.
New Caution About Risk Adjustment After United Whistleblower Lawsuit

UnitedHealthcare has denied allegations that it gamed Medicare Advantage risk adjustment, but other insurers are taking note and might be more cautious.

By Joseph Burns
Contributing Editor

Here’s the $1 billion question hanging over Medicare Advantage plans: Did UnitedHealthcare’s risk adjustment department actually “turn on the gas,” as one executive put it, in an illegal effort to increase revenue?

That’s the claim at the heart of two cases the federal Department of Justice brought this spring against UnitedHealthcare, the nation’s largest health insurer. In May, the DOJ intervened in two cases brought by whistleblowers against UnitedHealth Group. Taken together, damages in the two cases could total more than $1 billion, Kaiser Health News reported.

Following the government’s intervention in the second case, the New York Times published a must-read story, quoting from an interview it had with Benjamin Poehling, a former UHC finance director turned whistleblower. Poehling told the Times’s reporter that Jerry J. Knutson, the CFO in Poehling’s division, advised Poehling and colleagues, “to really go after the potential risk scoring you have consistently indicated is out there.” Poehling quoted Knutson as writing in an email, “Let’s turn on the gas!”

It could be several years before these cases emerge from the court system, and settlements with no admission of guilt are fairly common. So far, United has adamantly denied it did anything wrong.

Payment for diabetes
For several years now, Kaiser and the Center for Public Integrity, a not-for-profit investigative journalism organization, have been reporting on how Medicare Advantage plans manipulate risk adjustment to their advantage. The Government Accountability Office has investigated inflated risk scores.

The DOJ alleges that United made patients appear sicker than they were in an effort to collect higher payments than deserved and then avoided repaying Medicare for those payments for more than a decade. The Times reported that United allegedly gave patients with diabetes extra scrutiny to see if their diabetes caused other conditions as a way of bumping up Medicare payments. For example, Medicare would pay $9,580 per year for a 76-year-old woman who has diabetes and kidney failure. But if the company claimed the diabetes caused the kidney failure, the payment would rise to $12,902, the newspaper reported. United wouldn’t look for members who had high blood pressure because such a diagnosis does not raise risk scores, the Times added.

All of this attention on United’s risk-adjustment practices could cause health insurers to rethink their approach to risk scoring.

“Any plans that are playing on the edge are likely to pull back,” says Paul von Ebers, the founder of Prospective Health, a consulting firm in Fargo, N.D. “There’s a lot of discussion about these cases in the health insurance industry, and health plans are taking the issue very seriously.”

A former CEO of Blue Cross Blue Shield of North Dakota, von Ebers has extensive experience working in and managing risk adjustment departments. Most health plans that have high star ratings tend to comply with CMS’s risk-adjustment rules, he says.

To demonstrate a high level of compliance, the best Medicare Advantage plans pay as much attention to adjusting patients’ risk scores down as up, he says. “They have to adjust their risk scores both ways to make sure that they remain compliant.”

The problem for many insurers is that physicians often don’t document all of the illnesses of every patient, said a case manager for a national health insurer. The case manager asked not to be named.

Von Ebers agrees that recording information accurately on each patient’s illness is a challenge. What’s more, risk adjustment itself is full of gray areas, he says. “There’s a debate about whether the risk-adjustment process appropriately accounts for a patient’s level of illness,” he adds. “Some people feel the CMS process overadjusts for disease, and some people feel it’s not capturing everything. It’s probably a little of both.”

In court, United is likely to argue that the risk adjustment system is fundamentally flawed. In news reports, the company has said the justice department misunderstands or is ignoring how the Medicare Advantage program works. NG
n the world of health care quality measurement, perhaps nothing these days is more unloved than process measures. Providers are frustrated by the documentation these measures require, while payment models increasingly drive accountability for outcomes over process.

So you might be surprised to learn that process measures have their defenders in large health systems. But they’re not necessarily the same measures CMS wraps into payment programs. Take joint replacement procedures, which tether providers to Surgical Care Improvement Project (SCIP) process measures like timeliness of antibiotic administration or removal of urinary catheters.

Robert Pendleton, MD, chief medical quality officer at University of Utah Health Care, an integrated health system serving patients in six Western states, says the evidence correlating several SCIP measures with outcomes is relatively weak. “We challenged our providers and said, ‘We may want you to include one or two SCIP measures because we have to, but let’s walk through care delivery. What, in your mind, has the biggest impact on outcomes?’ And they came up with a different list than SCIP. They came up with things like patient engagement and getting the patient out of bed immediately after surgery.”

Those are process measures, but two that made a difference—and two that proved the treatment team right. Their implementation led to lower rates of readmission and surgical site infections.

Choosing the right blend of quality metrics for each DRG is one of the many intricacies of Value-Driven Outcomes (VDO), Utah’s answer to the challenge of how to “do” value-based care. An initiative five years in the making, VDO matches indicators of quality to DRGs with substantial variation in cost within Utah’s own system. Those indicators are a combination of process and outcomes measures—some defined by CMS and some developed internally by care teams.

The results, which Vivian Lee, MD, and her colleagues at Utah published in JAMA last fall, have been impressive: an 11% reduction in direct costs for total joint replacement after two years—one of three VDO pilots reported in JAMA.

“This is not incremental. It’s a big deal,” Michael Porter, the Harvard Business School professor who is credited with developing the idea of value-based care, said in a JAMA podcast after publication of the study. “I hope this will be the shot heard ‘round the world. Now that we have these results, there are no more excuses. Everyone needs to get on the bus.”

The other two pilots were also encouraging. One was an effort to reduce unnecessary hospitalist use of lab tests; average lab test costs per person per day fell 12% in 4,276 patient encounters. The other was aimed at reducing mean time to anti-infective delivery after signs of sepsis; time was cut almost in half over 76 encounters. Results from all three pilots were statistically significant.

Pinning responsibility

VDO is complex, with multiple operational variables. Its “opportunity index,” which measures cost variability among DRGs, helps to prioritize areas for improvement. For each DRG, six to eight national and locally developed process and outcomes metrics compose a “perfect care index,” adherence to which is measured to gauge effects on outcomes. VDO also tracks costs per patient and care team, all the way down to each bandage and minutes of nursing time. Data
The right processes matter, says Yoshimi Anzai, MD, the associated chief medical officer at University of Utah Health Care. It could be something simple like saying “your mother is going home today after surgery.”

Generated from these variables feed an analytics system that creates tools for providers to see their performance in real time.

One of those tools is a scorecard for each admission, showing component costs of care (e.g., pharmacy, labs, or facility use) and whether each measure in the perfect care index was met. Utah has developed scorecard templates for about 30 DRGs and intends to create 50, but none is cast in stone.

That’s because the measures in the perfect care index for each DRG change periodically. “Once we reach close to 100% [performance], we take that metric out and add something new,” says Yoshimi Anzai, MD, MPH, associate chief medical quality officer at Utah. “It’s always continuous quality improvement for every scorecard.”

Often, the focus of perfect care index measure development and refinement comes back to processes. When care teams were not consistently hitting the “early mobility” measure for joint replacement patients, the root cause turned out to do with in-house physical therapist scheduling. Adjusting physical therapists’ work hours to get more patients out of bed on Day 1 led to lower lengths of stay and costs. Engaging the care team in troubleshooting and refining the measure created champions for it.

A second VDO engagement tool is an online “value explorer,” which allows each provider to see his own costs of care, lengths of stay, and other metrics compared with peers in real time. “The immediacy of VDO allows us to tap into behavioral economics principles,” says Pendleton. “If we can show within my peer group of 20 hospitalists that two take better care of patients with pneumonia than the rest of us, that is a powerful way to get the other 18 to question [why] and learn from the best.”

Yet a third analytic tool within VDO calculates supply costs at the team and provider levels. This tool untangles the complexity of accurately assigning costs to, say, a specific surgeon. For some diagnoses, like joint replacement, costs are easy enough to isolate, but for a complicated condition like heart failure, cost granularity can be difficult but is essential for driving change.

“The data have to be actionable, or you get into this notion of ‘I didn’t order that. That’s not my responsibility,’” says Anzai.

Utah applies the same thinking to lab and imaging tests to curb waste and help physicians understand what they can control. “If you attribute all the lab tests for the entire admission to one discharge provider, they’ll say ‘Well, I wasn’t caring for that patient on those days,’” says Anzai. “So we took one more step to say ‘when you are the attending for these service dates, that order is attributed to you. You have to own the data.’”

The intent, she says, is not to chasten physicians; rather, Utah depends on them to standardize care practices and drive culture change. Physicians often know which process, imaging study, or instrument will lead to better outcomes. “Go to the people who provide patient care every day and ask,” says Anzai. “We have to be open to listening to them.”

Small changes, big improvements

The execution of VDO has yielded a few lessons. One pleasant surprise has been the degree to which physicians have been willing to explore new ways of doing things when presented with real-time data. “That
has exceeded our expectations,” Lee told JAMA after publication of her team’s article.

Pendleton believes the real-time approach is more effective than many CMS value-based programs, however well intentioned they may be. The two- and sometimes three-year-old data those programs use to spur behavior change, he says, “is distant enough for providers that it’s not nearly as motivating.”

Another lesson is that cost variations within a DRG aren’t always what they seem. The challenge lies in identifying patient subpopulations. For patients receiving hip and knee replacements—a seemingly homogeneous group—the outliers turned out to be joint replacements done on patients with bone cancer in Utah’s cancer hospital. “Those patients are a very different group,” says Pendleton. “The supplies they need are completely different. The complexity of the surgery is different.” Once they were carved out of the index, there was far less variation.

A final lesson is that care redesign does not have to be a major breakthrough; processes that may seem trivial could improve outcomes. A clinical pathway team at Johns Hopkins demonstrated last year when it reported that setting the bed angle in the ICU to 30 degrees reduced the risk of ventilator-associated pneumonia in patients undergoing CABG.

The same is true at University of Utah: The right processes matter. Like adjusting PT schedules. Or in how surgeons talk with family members. Saying “your mother is going home today after surgery” gets the family thinking about what needs to be done to improve post-op outcomes, says Anzai.

And therein lies the difference between how CMS imposes process and how Utah uses it to its advantage.

“The history of process measures has been a somewhat disappointing story,” says Pendleton, who thinks that by the time process measures from on high are scaled up, they have less impact than organically grown measures that encourage providers to think about how to deliver better care. “When you have 2,000 payer-mandated process measures, then health care systems are really stymied. All they can do is keep up rather than innovate.”

The perfect care index, by contrast, “becomes an intrinsically motivating tool to engage our providers in defining the processes in our own culture that we believe will deliver on health outcomes,” he says. “The data don’t have to be perfect because you’re not worried about reporting it to some public entity. You’re using it for the sole purpose of improvement and learning and driving toward better outcomes for patients.”

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We started out in California and with an ACA success story (so far). But better figure on spending a lot on marketing and outreach.

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It’s a big country. We only wish we could have seen more of it.
California Dreamin’,
But Will It Stay That Way?

Medicaid expansion and Covered California’s $100 million-a-year marketing budget have pushed the uninsured rate into the single digits, but enrollment has plateaued.

By Jan Greene

While federal health policy roils in chaos, and the individual nongroup markets in many states have been destabilized by bailing insurers, California basks in a never-ending sunny day of coverage. Since expanding Medicaid and launching its own ACA exchange in 2014, California has slashed its uninsured rate from 17% to 7.1% (7.1 million to 2.9 million uninsured). There is no mass exodus of insurers from the Golden State’s exchange, no sudden loss of counties that offer subsidy-eligible health plans. Buying individual insurance is no bargain without a tax credit, but by comparison, California’s individual insurance market is thriving.

The first year or two of the exchange involved some growing pains and the usual technical difficulties with the exchange website and accessing an accurate list of in-network doctors. But now many consumers use the Covered California website to do their research even if they end up purchasing directly from an insurer, as about half of individually insured Californians do. Most of those buying from the exchange (90%) get a subsidy. There’s not much difference in plan design or premium on-exchange or off, since California put all its individual market in the same big risk pool as part of a strategy to spread risk among as large a group of people as possible.

That choice—to maximize the risk pool—is one reason for the relatively calm state of the individual insurance market in California. Simple demographics help—the population is big enough to spread the risk widely, which allows insurers to relax.

Smart moves

But the people who developed Covered California are also getting kudos for making some key policy choices:

• When given the choice by federal authorities, not allowing “grandmothered” plans (those purchased in the period after the ACA’s passage and before the exchange went live) to continue when the exchange went online in 2014. It was a controversial move at the time but one that helped to stabilize the risk pool, because those plans tended to cover healthier people.
• Investing heavily in marketing—a storied average of $100 million or more per year, for billboards, television ads, and legions of helpers hired to find and assist buyers.
• Having Covered California be an “active purchaser” so that it can choose which insurers can participate on the exchange and negotiate with insurers over plan design and rates.
• Choosing “patient-centered” plan designs by limiting copays and deductibles and negotiating each year to reduce them further.

“California has a lot of built-in advantages, but Covered California made a number of policy choices that improved the market,” says Larry Levitt, senior vice president for special initiatives for the Kaiser Family Foundation. California also started out with a number of large, brand-name insurers that were generally enthusiastic about participating under the ACA, such as Kaiser Permanente and Blue Shield of California, which has been active in state-level health policy efforts to expanding coverage. California may

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STAT BOX

% in the individual market: 9%
% uninsured: 8%
Per capita health expenditures (rank): $6,238 (43)

Rankings include the District of Columbia
Source for all data: Kaiser Family Foundation
have also benefited from not having an ACA co-op, which might have drained away healthy enrollees with its artificially low initial premiums.

Risk mix is right
Three years in, Levitt notes, market share on the individual market is well distributed among insurers, and a few smaller regional insurers—such as Chinese Community Health Plan in San Francisco, which caters to the local Asian community—have been able to get a toehold in the market. “That’s definitely a sign of a healthy market,” Levitt says. Eleven plans participated in 2017, and there were indications as we went to press that same number would participate next year. At the same time, Levitt notes, it’s a tight market for any new big players to join, as Oscar has found to its consternation, signing up just a handful of people in southern California in its 2015 entry to that market; Oscar is still hanging in there with first quarter 2017 losses of $25 million, which is less than the previous year’s first-quarter loss of $48 million. UnitedHealthcare stepped into the exchange market for just one year in 2016 and pulled out again after signing up a tiny number of enrollees.

The risk mix among enrollees has stayed in the healthy range, according to a Covered California analysis published on the Health Affairs blog in mid-May. The analysis looked at data on exchange members’ health status, along with emergency department inpatient visits to come up with health risk factors for exchange enrollees; this is information Covered California shares with its insurers. They found that between 2016 and 2017, health risk scores adjusted slightly up and down for various insurers, but all remained reasonably stable, suggesting that all the sicker people remained distributed among health plans, a sign of the market’s health.

Premiums have gone up in the past few years (4.2% in 2015, 4% in 2016, 13.2% in 2017), but not enough to stop the continued growth of the individual market. Covered California officials chose to take advantage of a provision in the ACA allowing them to negotiate rates with participating insurers, giving the exchange more influence on prices than state insurance regulators, who have no authority to approve rates but only to review them and shame health plans if they propose increases that aren’t supported by data.

California’s health care community, including some of its major insurers and employers, have long worked together to improve the market, which culminated in a 2005 effort at health reform that came very close to creating a mini-ACA in the state. It fell short of the votes it needed in the state Senate, despite endorsements from an unusually wide array of players. “There is a high degree of knowledge and sophistication among all the players involved” in the California marketplace, Levitt says, and that has helped to create “an atmosphere of cooperation.”

Covered California’s leader, Peter Lee, is a veteran of California health reform efforts from his years leading a sophisticated employer group, the Pacific Business Group on Health, and several years at CMS working on delivery-system innovation. So it made sense that California’s exchange would be more than just a clearinghouse for selling health plans and would incorporate market reforms and delivery system improvements as well. For instance, its latest contracts with insurers require them to adopt payment strategies based on quality performance, support integrated

It makes sense for California’s exchange to incorporate market reforms and delivery system improvements, says Peter Lee of Covered California. It shouldn’t just be a clearinghouse for health plans.
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Leveraging touchpoints like pharmacist counseling and mobile and digital adherence tools, Walgreens new-to-therapy patients had higher adherence and lower overall costs compared to other pharmacies. That leads to healthier members, while saving money—which means better outcomes for everybody.

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delivery models, and encourage the use of patient-centered medical homes.

Enrollment plateaus
Enrollment in the individual market took off between 2013 and 2015—growing from 1.5 million to 2.3 million—but plateaued in 2016. Levitt notes that more progress could have been made to bring down the uninsured rate if Covered California, along with others carrying out the ACA, had emphasized the requirement to buy insurance. But the individual mandate was politically unpopular, leaving advocates reluctant to press consumers to comply.

Much of California’s ability to reduce its uninsured rate came from expanding Medicaid—known as Medi-Cal in California—which signed up 3.8 million people through the exchange website, their county Medi-Cal office, or an agent. Many states got extra money from CMS to build exchange websites that could accommodate Medicaid enrollment along with private insurance enrollment. It wasn’t always technologically successful, but eventually Covered California made it work for Californians.

The enrollment plateau during the 2017 signup season is being seen across the country and won’t likely be re-accelerated without a bigger marketing effort, an increase in subsidies, or higher penalties for those who don’t buy insurance, Levitt says.

Brokers happy
Health insurance brokers have embraced the exchange and the private market for individual insurance, says Stephanie Berger, president-elect of the California Association of Health Underwriters and a broker in Ventura County. “We’ve helped a lot with Medi-Cal enrollments and we don’t get compensated for that, so that’s been really positive,” says Berger.

Brokers and agents are working much harder than they used to pre-exchange, she says, because they are functioning as navigators for many people who are new to insurance and need to understand their options and how insurance works. “The amount of work it takes to help people get enrolled and provide them with service is tenfold what it was, and the compensation continues to shrink,” she said. “That is an issue and we’re getting less than half of what we got pre-ACA on these policies.”

Still, agents remain in the mix with the enrollers who were hired as part of the big marketing push, despite worries that the agents would lose their place in the market. Consumers need plenty of help with signups, and brokers still get commissions on both exchange and non-exchange policies; brokers get paid the same commission for plans with the same design on- and off-exchange, but insurers can pay different fees for off-exchange plans with different designs. Because the plans within each of the four levels are quite similar, agents help enrollees understand the differences in provider networks and formularies.

In Ventura County, Berger’s brokerage serves an unending stream of people new to insurance, many of them Spanish speaking and in need of some help to get up to speed on the complexities of copays and deductibles. Her bilingual agents are happy to help, Berger says. “The role of everyone in this project is to lower the uninsured rate,” she says.

While nobody knows what might happen in Washington, the working assumption is that the 2018 plan year will go as planned, and all of California’s insurers are on board with selling on the exchange.

The other wrinkle in California is an effort to pass a single-payer plan that would blow up private insurance in the state. It’s been approved by the state Senate, but it is opposed by insurers and business. It carries a $400 billion yearly price tag, making it a tough sell. Insurance brokers, not surprisingly, oppose a single-payer system. “That’s our biggest challenge right now. It would wipe out the entire system,” says Berger.

Instead, they’d like to see continued work to make the insurance market viable for insurers and get more Californians covered. “The uninsured rate in California is at an all-time low,” she said. “That means this program has been a success.”

Jan Greene is a veteran health care journalist based in Northern California. Her work has appeared in the Los Angeles Times, Health magazine, Hospitals & Health Networks, and many other publications.
Texas: A Health Insurance Two-Step
The ACA made a dent, but Texas continues to lead the country in the percentage of people without insurance. Now it has also grabbed the top spot in high-deductible insurance.

By Charlotte Huff

As other states have expanded Medicaid coverage and promoted ACA-related exchange options, the Republican-led legislature in Texas pursued a more minimalist approach.

As a result, the Lone Star State continues to lead the country in the percentage of its residents without health insurance, although a dent has been made. As of 2015, 17% of Texans were uninsured, compared with 22% two years before, according to the most recent census bureau data.

Some of the newly insured are getting coverage through Medicaid. Enrollment has increased by 7% in Texas, and 30% nationally, compared with pre-ACA levels, according to Kaiser Family Foundation data. Even though state legislators balked at expanding Medicaid, some Texans discovered that they already qualified when enrollment drives and ACA-related publicity enticed them into looking into coverage, says Tom Banning, CEO of the Texas Academy of Family Physicians.

Meanwhile, those residents relying on ACA exchange plans have been sorting through increasingly slim pickings. By the 2017 enrollment period, only 10 insurers participated compared with 16 in 2016, according to an analysis published in February by the Brookings Institution and the Rockefeller Institute. Of the 10, six offered policies in 11 or fewer of the state’s 254 counties, and no PPO policies were available.

Along with strict limits on financial eligibility for Medicaid, the uninsured rate in Texas can be tied to several other factors, including a relatively high number of undocumented residents and a lower rate of job-provided insurance compared with many other states, according to the Texas Medical Association. With so many uninsured, there was pent-up demand for medical care, the extent of which caught insurers off guard, says Michael Morrisey, a health economist at Texas A&M University and a coauthor on the Brookings and Rockefeller analysis.

When more reliable usage data rolled in last year, insurers realized that “they got the pricing wrong,” Morrisey says. “People were much higher utilizers of [medical] services then they had anticipated.”

There have been a few health insurance-related silver linings in recent years. Texas continues to attract large employers, particularly in growing regions such as suburban Dallas, Banning notes. Toyota and JPMorgan Chase are among those who have recently expanded their Dallas footprint, with jobs and health benefits attached.

Still, the proliferation of high-deductible health plans—both through employers and on the individual market—has created its own set of challenges, Banning says. More Texans are enrolled in the plans—1.7 million as of 2016—than in any other state, according to a survey by America’s Health Insurance Plans, which studied plans paired with health savings accounts.

Sometimes physician practices may not know how much of the deductible a patient has met until they submit the bill, and then have to chase down payment after the fact, Banning says. “We’ve seen accounts receivables increase and bad debt write-offs increase as a result of not being able to collect those dollars.”

As for participation in the ACA exchanges, insurers may stall on reaching a decision for 2018 until late summer, if last year’s pattern is any guide, says Morrisey, who heads up the health policy and management department at Texas A&M. All eyes will be trained on Blue Cross and Blue Shield, which now offers coverage in all 254 counties, he says.

If the Medicaid caps proposed in the House legislation to repeal and replace the ACA do become law, the resulting cuts could reverberate throughout the state’s health system, according to an analysis published this spring by Avalere. It projected that Texas could lose $5.1 billion in funding for children covered by Medicaid from 2020 to 2026, more than any other state.

Charlotte Huff is a freelance health and business journalist in Fort Worth, Texas.
Since the ACA took effect, Florida has led the pack when it comes to individual health insurance enrollment. More than 1.76 million Floridians signed up for coverage in 2017, which is higher than any other state, and the ACA has made a major dent in the number of residents who are uninsured. “It’s serving a huge population of people who didn’t have health insurance before” because they couldn’t afford to pay for coverage, says Patricia Born, who teaches about insurance and risk management at Florida State University (FSU) and authored a report on Florida’s insurance market for the Brookings Institution. “People were just so happy to be able to get coverage. They had unmet [health care] needs to get addressed.”

Despite Floridians’ embrace of individual health insurance, the state still has one of the highest uninsured rates in the nation. In 2015, 15% of the state’s residents—2.8 million people—remained uninsured, compared with the national average of 10%, according to the Kaiser Family Foundation. Florida, as well as the four other states with an uninsured rate of 15% or more, all failed to expand Medicaid. Yet Florida’s uninsured rate is still a steep drop from the time before the ACA took effect. In 2013, 22% of Floridians didn’t have insurance.

Florida, which is the third most populous state in the country, has a unique health insurance profile. It still attracts retirees in droves and because of the state’s large senior population, its Medicare enrollment of 4 million is second largest in the country, behind California. Though Florida is not a Medicaid expansion state, its high poverty rate and large population have led to a large number of people being covered by Medicaid and the CHIP program; enrollment totaled 4.36 million in March. Meanwhile, it has the second-lowest percentage of residents covered by employer-based health insurance, at 39%. The national average is 49%. Many Floridians work in the construction and hospitality industries, where employers often don’t offer health insurance. The flip side to the lack of employer-provided insurance is a large individual market; in 2015, 10% of the state’s residents had purchased coverage in the nongroup market, the highest percentage in the nation. The national average is 7%.

Currently, only five insurers offer policies on the state’s ACA exchanges. That’s down from eight when the exchanges were launched in 2014, according to Born’s report. Florida Blue, the Blue Cross Blue Shield plan in the state, has been the dominant player in the Florida individual market, and in 2015 had a 41% market share, based on premiums written. Humana ranked second, with 15% of the premiums written.

While other major carriers have either pulled out of the Florida individual market or only offer policies outside the exchange, Coventry Health Care, Molina Healthcare, and Ambetter/Sunshine Health have entered the market, Born’s report found. Ambetter is offered on the individual market in 12 states by Centene. “Insurers that are more familiar with the Medicaid individual market, like Molina, have done quite well,” Born says.

Both Cigna and Aetna no longer offered policies on the exchange in 2017, but sell policies outside the exchange, while UnitedHealthcare no longer sells any policies, either on the exchanges or off them. In 2015, the vast majority of individual policies were purchased on the exchange. Less than 215,000 were bought outside the exchange.

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**STAT BOX**

- % in the individual market: 10%
- % uninsured: 15%
- Per capita health expenditures (rank): $7,156 (18)
Florida Blue dominates the individual market, with nearly a 50% market share in 2017. Joseph C. Gregor, the vice president of commercial segments, attributes Florida Blue’s success in the individual market to the company’s “deep knowledge” of how that part of the insurance market works in the state and its history: “We have been providing health care coverage to Florida residents for nearly 75 years.” Florida Blue will continue to offer policies on the exchange in all 67 Florida counties in 2018. Already, in many rural areas it is the only game in town as far as health insurance goes. “When pricing our plans, we did so in a way to ensure long-term growth and stability, as opposed to pricing cheaply to quickly gain market share,” Gregor says. Nationally, enrollment in the individual market fell an average of about 5% in 2017, Gregor points out, while in Florida it ticked up 1%.

Florida Blue also made the unusual decision to invest in 20 brick-and-mortar retail centers, where consumers can physically walk in and get help buying a Florida Blue policy. Since the ACA took effect, more than a half-million consumers have visited a Florida Blue Center, according to Gregor.

Still, partly because Medicaid wasn’t expanded, many Floridians earn too little to be eligible for a subsidy to purchase insurance on the ACA exchange but too much to be eligible for Medicaid. Any hope of expanding Medicaid in the state is currently “DOA,” says Steven Ullmann, director of the University of Miami’s Center for Health Sector Management and Policy. State lawmakers and Republican Gov. Rick Scott have argued that expansion would be a taxpayer-funded entitlement that would be difficult to repeal.

“It’s a perverse situation. Low-income people are unable to get any kind of coverage,” says Leslie Beitsch, the chair of behavioral sciences and social medicine at FSU and a former commissioner of health in Oklahoma. Because of that, says Beitsch, “I think people are actually dying.”

No newcomers
While the individual mandate pushed more healthy people to sign up for health insurance, Born says, medical costs were higher than expected, and “plans raised rates to be sustainable.”

“No new carriers entered the marketplace for the 2017 plan year,” Born wrote. “Regulators have spoken with all health carriers in the state to encourage participation, but carriers report an inability to encourage plans to raise rates on exchange business and their opportunities to innovate are limited. Florida Blue experimented with offering a low-cost, highly managed HMO plan, ‘MyBlue,’ but customers complained that they could not find participating doctors.”

In many states and in many markets, people want insurance with a network that includes big-name physicians and prestigious hospitals. But in Florida, many consumers simply pick the lowest-cost plan available in their market, Born says. “They’re not too concerned about which doctors they get.”

“When customers are able to compare a lower cost, narrow network to a more expensive broader network, they begin to question the need to be able to go to every single hospital and physician in a given region,” says Mark Cherry, principal analyst with Decision Resources Group, a health care consultancy.

Some Florida markets have more than one large health care system, so an insurer might drop one system from its network but still have an ample number of providers for consumers to choose among, Cherry says. “The acceptance [by consumers] of narrow networks gives leverage to large insurers and large health systems to walk away from negotiations.

“Insurers want to offer a narrow network at a low premium, and a lot of large health systems don’t want to make any reimbursement concessions to get on that narrow network,” he says.

It’s still too early to tell what will happen to the Florida market, given the uncertainty around the ACA. Beitsch says, “Uncertainty unravels the market. This is so uncertain, it makes it less likely that others [insurers] will enter the market and more likely that those in the market will exit. In some ways, it’s becoming a self-fulfilling prophecy that the ACA won’t work.”

Susan Ladika is a freelance writer in Tampa, Fla., with 30 years of experience covering health care and other issues.
Tennessee: Individual Market Just Barely Viable—For Now

Conservatives say Tennessee’s experience shows the ACA’s fatal weaknesses. But one expert believes that, properly nurtured, the state’s individual market could thrive.

By Timothy Kelley
Senior Contributing Editor

Tennessee’s ailing individual insurance market got good news in May, but you couldn’t call it a clean bill of health.

After several insurers exited, it had looked for a while as if 16 eastern counties around Knoxville would have no ACA coverage option at all on the state’s federally run exchange for 2018. Then, in early May, Tennessee Blue Cross Blue Shield’s president and CEO, J.D. Hickey, wrote the state insurance commissioner saying it was willing to offer a plan there—but with qualifiers aplenty. Having lost more than $400 million on the business over three years, he said, the company would have to raise rates to price in downside risks—“even at the prospect of a higher-than-average margin for the short term.” He said the Tennessee Blues reserved the right not to sign its qualified health plan agreement at the September 2017 deadline if “post-bid” changes further destabilized the market. Although the Blues’ financial performance had improved, he added, the return to Knoxville didn’t mean all was well.

“This is in no way a political decision,” wrote Hickey. “Nor is it a reflection of our perspective on the stability of the individual marketplace overall.”

Politics does matter. If Tennessee weren’t so red, its own former Senator Al Gore might have snagged its 11 electoral votes in 2000, votes that would have given him the White House. But shades of red vary. Republicans Gov. Bill Haslam and Sens. Lamar Alexander and Bob Corker are seen as fairly moderate—not so the state legislature, which in 2015 rejected Insure Tennessee, a plan backed by Haslam that would have expanded Medicaid.

Nationally, those who say the ACA is collapsing often point to Tennessee as evidence. And Gov. Haslam has called it “ground zero” for plans pulling out of the ACA marketplaces:

- In October 2015, Community Health Alliance, like many of the ACA-created co-op plans, folded.
- UnitedHealthcare left the individual market in Tennessee at the end of 2016.
- Also at 2016’s close, Tennessee Blues withdrew from the state’s big metropolitan areas—Memphis, Nashville, and Knoxville—while continuing to offer coverage in rural areas of the state.
- Humana, which offers exchange plans in 11 states this year, has announced that for next year it will no longer provide individual-market plans at all. The company reportedly insures some 40,000 Knoxville-area residents. (Cigna still serves two of the three big cities, but not Knoxville.)

Still, ideology isn’t everything. “The state has a history of being very pragmatic about things,” says John Graves, assistant professor of health policy and medicine at the Vanderbilt University School of Medicine in Nashville. By and large, he says, that has been its approach to health insurance. He believes a combination of factors produced Tennessee’s current problems. Many of these factors didn’t arise from deliberate obstruction of the ACA by its foes, and in one that did, the shiv was inserted in Washington, not Nashville.

Unhealthy folks

Between Graceland and Lookout Mountain there are a lot of struggling Tennesseans. The state’s median household income ranks 43rd in the nation. Still, the state’s economy has been perking up. A booming health care industry has helped make Nashville one of the nation’s fastest-growing metro areas. This January, the University of Tennessee’s Boyd Center for Business and Economic Research projected that the unemploy-
ment rate would remain below 5% through 2018, with baby boomer retirements helping to fuel a tightening labor market. But the health of its residents remains a challenge. For example, Tennessee seniors placed 44th in this year’s rankings from the American Public Health Association and the United Health Foundation, based on a mix of socioeconomic determinants and health status stats. And the Commonwealth Fund’s 2017 scorecard puts the state at 43rd in “adults who went without care because of cost in the past year.” (It does better with kids.)

As for the state’s recent insurance history, it’s been a bit quirky. Blue Cross Blue Shield once dominated the employer-paid group insurance market, says Graves, “but that isn’t really the case today.” The individual-market ACA plans debuted in 2014 with some of the nation’s lowest premiums. One reason, Graves believes, may have been deliberate loss-leader pricing to attract enrollees in the confidence that “people are inertial in terms of their health insurance—they don’t want to change all the time.”

If that was indeed a factor, Tennessee insurers were like a prison inmate who aims an axe at his little toe to get off work detail and ends up slicing off a leg. “They missed by so much that they lost a ton of money,” says Graves. “There’s only so many years of that you can handle before it’s no longer a viable business for you.”

Kevin Walters, the spokesman for the state’s Department of Commerce and Insurance, noted that “unfortunately, the Tennessee population is not among the healthiest.” That factor, he contends, “compounded with policies that required benefits that more closely matched robust small-group plans than available individual market plans led to significant rate increases.”

The difficulties weren’t all local in the making by any means. Walters stresses that the departure decisions of UnitedHealthcare and Humana were “made on the national level and were not Tennessee-specific.” Indeed, says Graves, three temporary ACA provisions intended to stabilize premiums and protect insurers against adverse selection in the early going—national factors all—didn’t work in the state as ACA backers had hoped:

• A partial reinsurance program had limited effect because it kicked in at a relatively high threshold (for 2014 and 2015 it was $45,000), covered just 50% of claims (starting in 2015), and ended once claims reached $250,000.
• A risk adjustment fund, intended to be revenue-neutral at the state level, was meant to compensate plans that drew sicker-than-average enrollees from payments by plans with a healthier selection. “In Tennessee,” says Graves, “everybody got sicker-than-expected folks, and the risk-adjustment program was not designed to mitigate systematic mispricing like that.”
• The risk corridor program that was underfunded. Critics called risk corridors an insurers’ bailout, and in 2015, Republican Sen. Marco Rubio of Florida got legislation passed forbidding the use of federal funds to make up for any shortfall.

“Tennessee’s position was is in some ways unique given all of these factors working in concert, contributing to heavy insurer losses with very few stabilization funds flowing in,” says Graves. “But generally speaking, these are factors that could affect any state.”

Playing by different rules
But there is one factor that is particular to Tennessee. Since 1948, the Tennessee Farm Bureau, an almost century-old state farmers’ group that is the nation’s largest of its kind, has been permitted as a “not-for-profit membership services organization” to offer medically underwritten plans that state law doesn’t officially consider health insurance. These plans risk-rate consumers and can reject them for potentially costly pre-existing conditions. People who choose them are noncompliant with the ACA’s individual mandate and thus must pay a penalty, but the plans are so cheap they can still be net money-savers.

Kevin Lucia and Sabrina Corlette of the Center on Health Insurance Reforms at Georgetown University’s Health Policy Institute wrote in an April blog that “state policymakers could have, but did not” require those Farm Bureau plans to “live by the same rules as other insurers in the state.”

Farm Bureau plans have shown rapid growth in the
years since the ACA's enactment, with an estimated 73,000 Tennesseans now signed up. One needn't be an insurance nerd to grasp the likely effect on the exchange's market selection caused by cheaper competitors with special access to an elevated section of the playing field.

"It's impossible to say for certain," wrote Lucia and Corlette, "whether, by siphoning healthy enrollees away from the ACA's marketplace, the Tennessee Farm Bureau plans have contributed to the poor risk score of Tennessee's marketplace and the financial struggles of insurers selling ACA-compliant plans." But the analysts didn't exclude the possibility that having those missing 73,000 people on board might "improve the overall balance of healthy and sick." According to healthinsurance.org, 234,125 people signed up for individual insurance on Tennessee's exchange for 2017, almost 13% fewer than last year.

Looking back, Graves believes part of Tennessee's problem was passivity. "The state could have been more active in seeking out insurers and making sure they were setting rates appropriately," he says. "The moment we went federal—that is, the moment when early efforts to set up a state-run exchange were abandoned in favor of one run by Uncle Sam—"we took more of a passive approach."

Walters is less inclined to fault Nashville. "Blaming the Farm Bureau in Tennessee for marketplace conditions that are not unique to Tennessee does not seem entirely appropriate," he says. "The Tennessee ACA experience has seen fewer carriers, narrower networks, and higher-priced premiums. This is a result shared by many other states."

Make it like Medicaid

So what other national lessons can be learned from Tennessee's experience? "The approach that seems to have worked here," says Graves, "is handling the exchange population much as you would a Medicaid managed care population rather than an employer plan in terms of structuring networks." He points out that the state was one of the first to embrace Medicaid managed care, and the state's program, TennCare, has been "pretty forward thinking in its approach—right now they are in the midst of a massive demonstration project on bundled payment." He says exchange plans might thrive by emulating TennCare's emphasis on narrower provider networks, along with making sure there are enough behavioral health specialists—and other details his team at Vanderbilt is still in the process of pinning down.

Graves still sees hope for the individual market. "The fact that an insurer came back into the market—and that many other markets have actually seen net inflows of insurers—suggests that these marketplaces can work," he says. "But it's going to take active management across multiple levels—federal, state, all the way down to the issuer."

Pennsylvania's Individual Market Seems To Be Slowly Stabilizing

Put the emphasis on 'slowly.' Still, those who make policy and those who sell policies will take any sign of hope they can get.

By Robert Calandra

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ometime in the waning months of 2013, the notoriously kludgy ACA website began to find its footing in Pennsylvania—and beyond.

But medical economists, insurance commissioners, and academics warned that it would take at least five years for the ACA exchanges to shake all the bugs out. If the rate filings for 2018 in Pennsylvania are any indication, then the shakeout has occurred—and hello, stabilization. After premiums for 2017 increased, on average, by 32.5% over premiums for coverage in 2016, rate filings by insurers for 2018 show rates going up by only 8.8% over 2017 rates.

"I think our individual market is really on the path into stabilizing," says Teresa Miller, Pennsylvania's insurance commissioner, who was appointed by Democratic Gov. Tom Wolf. "It shows our insurers are better understanding the market. We always knew there would be a transition."

ACA enrollment has been fairly stable in Pennsylvania, showing none of the death spiral dynamics

STAT BOX

| % in the individual market: | 5% |
| % uninsured: | 6% |
| Per capita health expenditures: | $7,730 (11) |
that President Trump and other ACA critics have talked about. In July 2014, a little more than 318,000 Pennsylvanians had purchased coverage through the ACA exchanges. This year, enrollment was 426,000, a 33% increase.

The state did not expand Medicaid until April 2015. Since then, the number of Pennsylvanians covered by Medicaid has increased from 2.4 million to almost 3 million, which has boosted Medicaid costs by about $5 billion per year.

Familiar dynamic
Like many states, Pennsylvania has seen the number of insurers selling policies on the exchanges shrink and, in large parts of the state, there’s only one insurer doing business. UnitedHealthcare and Aetna jumped ship last year. The five remaining companies are losing money in the nongroup ACA market, but they are long-standing, community-based carriers with deep roots, she says.

The remaining insurers—Independence Blue Cross, Highmark Blue Cross, Geisinger Health Plan, UPMC Health Plan, and Capital Blue Cross—are spread across the state’s nine rating areas and none offers plans in all nine regions. In the Philadelphia market, which includes the city and four surrounding suburban counties, Independence Blue Cross is the only ACA exchange insurer. Out west, Pittsburgh and Allegheny County are serviced by UPMC and Highmark, while Geisinger and Capital offer plans for the middle and northern parts of the state.

Miller says premium rates may have more to do with the provider market and what insurers must pay than with competition—or lack thereof—among insurers. In Philadelphia, the provider side of the street is dominated by the University of Pennsylvania Health System, although it does have some stiff competition from the Temple and Jefferson University health systems and the Einstein Healthcare System.

Not so in Pittsburgh. The University of Pittsburgh Medical Center, with operating revenue of $12.8 billion in 2016, is the largest provider organization by far and also has its own health insurance plan. But partly because it is an integrated system, the UPMC insurance plan has some of the lowest rates in the state.

Burden on states
The one thing that would keep rates on an even keel in Pennsylvania would be a crystal ball about the ACA–AHCA future. None of those were available as we went to press. But as part of its rate-review process, Miller says the state asked insurers what their rate increase would be if the individual mandate was repealed or cost-sharing reductions were not paid. If both were to happen, Miller says the filings show rates will go up 36%.

“My only fear now, and I think the concern of all of our companies remaining have expressed, is the concern about what is coming from Washington,” she says. Over the past several months, Miller and several members of the Wolf administration have been working on proposals to present to the state legislature should a repeal-and-replace law reach President Trump’s desk.

“The concern we have with the American Health Care Act is it certainly seems to be trying to put the financial burden back on the states,” Miller says. “We could put things in place, but at the end of the day I just don’t know where we would find the funding to really truly create what the ACA has done in Pennsylvania.”

Robert Calandra is an independent journalist in Philadelphia with more than 20 years experience writing about health care.

Massachusetts: What Universal Coverage Could Look Like

The Bay State can boast of the lowest uninsured rate, but the high costs give even proponents pause.

By Joseph Burns
Contributing Editor

These details will seem familiar: an individual and employer mandate, guaranteed issue, community rating, a health insurance marketplace, and government subsidies for those who can’t afford coverage. They were the ingredients of Massachusetts health
care reform legislation that former Gov. Mitt Romney signed into law in 2006. Romney, working closely with the leaders of a state legislature firmly in the control of Democrats, crafted a scheme that hewed to market-based ideas that the conservative Heritage Foundation had long espoused. And the Massachusetts law was, of course, the mini-me of the ACA that passed four years later.

**AHCA consequences**

Politically, “Romneycare” turned out not to be such a good thing for Romney and may have helped doom his 2012 presidential bid. But from a policy perspective, it was effective in reducing the percentage of Massachusetts residents without health insurance from 11% in 2006 to 2.8% today, the lowest rate in the nation. Jonathan Gruber, an MIT economist and one of the architects of the Massachusetts law and the ACA, notes that an uninsured rate of 3% is close to what you’ll see in countries with universal health coverage.

Premium prices and the individual mandate have fueled some of the animus toward the ACA. But in Massachusetts, among the bluest of the blue states, there have been few complaints about these issues, particularly the mandate, according to Gruber, one of the ACA's stoutest defenders. “The mandate is accepted widely as an element of the social contract,” he says.

Massachusetts also expanded its Medicaid program, called MassHealth, under the ACA. Today, almost 400,000 state residents have health insurance under the Medicaid expansion, according to Families USA.

**Big spenders**

But the state's health care reform law—like the ACA—did not fix the problem of rising health care costs—and Massachusetts health care spending and prices are among the highest in the country. The high cost of living is a factor in the price of health care. So is the clout of the state’s large prestigious health care systems, especially Partners Healthcare in Boston, which includes Harvard-affiliated Massachusetts General Hospital, and Brigham and Women's hospitals. In negotiations with the state's not-for-profit health insurers—Tufts Health Plan, Harvard Pilgrim, and Blue Cross Blue Shield of Massachusetts—the health care systems can, and have, driven a hard bargain.

“In Massachusetts and elsewhere, the intense market concentration is widely considered to have more of an impact on health care costs rising above the rate of economic growth,” notes John E. McDonough, a health policy professor at the Harvard T. H. Chan School of Public Health, who, like Gruber, had a hand in crafting the Massachusetts law and the ACA. McDonough was head of a group that pushed for passage of the Massachusetts law and was an adviser to the U.S. Senate's health, education, labor and pensions committee during the drafting of the ACA.

Six years after the initial law went into effect, the Massachusetts state legislature passed a law that is supposed to tie health care cost increases to the state's economic growth, which has been robust partly because these are boom times for the state's biotech and pharmaceutical industries. In response, the Health Policy Commission set a health care cost growth benchmark of 3.6% annually, and then this year lowered that rate to 3.1%. To date, however, the commission has taken no enforcement action.

**AHCA consequences**

So what would happen in Massachusetts if Congress passes a law similar to the AHCA? About 450,000 Massachusetts residents—90,000 covered through policies purchased through the ACA exchange and 355,000 covered by Medicaid—would lose coverage in about five years, according to an analysis by the Urban Institute and Blue Cross Foundation of Massachusetts. McDonough predicts that the uninsured rate would return to a level of more than 10%.

Massachusetts has more generous premium subsidies than what the ACA provides, notes Gruber. If the AHCA passes, then low-income residents would get much smaller tax credits, forcing the state to make up the difference and perhaps make other changes in the health care law. Can a Republican governor—this time, it would be Charlie Baker—and the state's Democratic legislature catch health care reform lightning in a bottle as Romney and the legislators did in 2006?
Healthcare cost reduction realized through 12-month matched cohort study comparing claims and survey data between a study group and a historical control group. Enrolled members saw an average $687 PMPM cost reduction, including a 67% reduction in long-term care costs, a 32% reduction in acute hospitalizations and a 29% reduction in ED fees. Financial savings may vary by organization and are not guaranteed. Copyright ©2017 GreatCall, Inc.

Small changes in the daily activity of seniors can signal health concerns. Healthsense uses unique remote monitoring technology to collect and analyze this information and initiate action to help you ensure a higher quality of care, with a reduced total expense.

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Demographics, Geography Make for an Uphill Battle

Maine has a rich history of health care policy innovation, although it was the ACA that finally brought down the uninsured rate. An older, rural population means no guarantees.

By Joseph Burns
Contributing Editor

Massachusetts gets credit—or blame, depending on your point of view—for developing the health insurance reform law that became the template for the ACA. But three years before, Maine had a law that many see as a forerunner of the Massachusetts scheme and as one of the first attempts in this country at making health insurance available to all.

With the ungainly name of Dirigo Health Reform (dirigo is Latin for I lead), the health insurance program sought to reduce cost shifting from hospitals, health systems, and physicians. And like the ACA, it also subsidized health insurance for individuals buying coverage from commercial insurers, called for expanding Medicaid, and included strategies to improve quality and cut costs. Other provisions regulated premiums in the small-group market, pushed for price transparency, standardized reporting for how health insurers set premiums and hospitals set prices. While the Dirigo Health Reform law helped to expand insurance coverage, the lack of an insurance mandate combined with guaranteed issue caused premiums to rise.

Maine was also a pioneer in developing the “invisible” high-risk pool, a version of which was a last-minute addition to the House version of the AHCA.

But these state-level efforts did little to lower the uninsured rate. In fact, the rate rose from 8.8% in 2007 to 11.2% in 2013, according to data from the Maine Center for Economic Policy (MCEP), a nonpartisan research organization that focuses on low- and moderate-income Mainers.

After the ACA—including an ACA co-op, Community Health Options (one of only five remaining nationwide)—became effective in 2014, the uninsured rate went down to 8.4% in 2015, an all-time low for Maine, MCEP data show.

Maine is in an uphill battle when it comes to insurance coverage and health care costs because it’s both the most rural state in the country and the one with the highest median age, two factors that drive up health spending. “Maine has good quality of care and relatively conservative utilization, but we have high health care costs,” notes Elizabeth Mitchell, president and CEO of the Network for Regional Healthcare Improvement in Portland, Maine.

As in many states, some of the cost woes stem from health systems that are large enough to dominate the market and set high prices. In Maine they include Eastern Maine Health and MaineHealth. “The key driver is we have concentrated health systems with a lot of market leverage,” says Mitchell. “Also, we subsidize the care of those no one pays for, such as those who need behavioral health care or those who need access in small, rural areas.” For these and other reasons health insurance is expensive, she adds, “because we haven’t addressed the underlying drivers of health care costs.”

One lesson observers can take from Maine’s experience is that tinkering with any health reform program is necessary to make it sustainable, says Garrett Martin, MCEP’s executive director. “Unless everyone is willing to tweak it and improve it, then any problems you have will be magnified over time and become a series of Achilles’ heels that opponents can harp on to drag the thing down.”

Predicting what happens next in Maine is difficult, partly because the state, while politically bluish, marches to its own drummer. Trump and Clinton split its four electoral votes; the junior senator, Angus King, is an independent; and the governor, Paul LePage, is a Tea Party Republican who opposed the ACA. LePage has vetoed multiple Medicaid expansion bills but proponents managed to get an initiative on the ballot this November, which, if it passes, would expand the program.

STAT BOX

| % in the individual market: | 5% |
| % uninsured: | 5% |
| Per capita health expenditures: | $8,521 (S) |
Minnesota: A Health Care Island Scrambles To Stay Afloat

The Democratic governor and the Republican legislature have moved to shore up the individual market, but Minnesotans are leaving it in droves.

By Peter Wehrwein
Editor

This state is known for its 10,000 lakes (and hockey and the accents on Fargo). But when it comes to health care, Minnesota is more insular than limnic.

“We’re not an island,” says Jim Schowalter, president of the Minnesota Council of Health Plans. “But from a health care perspective we are kind of like one.”

Prosperous (the seasonally adjusted unemployment rate is 3.7%) and socially cohesive (at least on the surface; google “Minnesota nice”), Minnesota has a sui generis health care landscape.

The state has had a subsidized insurance program for low-income residents who don’t qualify for Medicaid since the ’90s; this year, about 89,000 Minnesotans are getting health insurance through MinnesotaCare, as the program is called. HealthPartners, Medica, and other not-for-profit HMOs have large roles, partly because of a 40-year-old law that requires insurers licensed as HMOs to be not-for-profits. Other states had such prohibitions but got rid of them years ago.

Under the ACA, Minnesota health care continued to evolve in its own niche in a (relatively) singular way. MinnesotaCare was recast as a Basic Health Program for people with incomes between 133% and 200% of the federal poverty level. Only Minnesota and New York have taken advantage of the Basic Health Program provision of the ACA. The ACA exchange plans, MinnesotaCare, and the state’s Medicaid program combined to bring the uninsured rate down to 6%.

Earlier this year, Gov. Mark Dayton, a Democrat, proposed letting residents buy into MinnesotaCare, which would have put Minnesota on the map as one of the states experimenting with a state-level version of the public option. The legislature nixed that idea.

Instead of MinnesotaCare-for-all, Dayton and the Republican-controlled legislature ended up negotiating a deal that allocated $326 million in state funds for “premium relief”—in the form of a 25% rebate on premiums—for Minnesotans in the individual market who are not eligible for receiving ACA premium subsidies because their income is too high.

The legislature also created a $540 million reinsurance program to prop up the shaky individual market, although the program is contingent upon the state getting a 1332 Medicaid waiver.

In other ways, Minnesota is not so distinctive. After setting their premium prices low—in fact, the lowest in the country in 2014 by some tallies—health plans in the state have dialed up premiums as the claims exceeded the money they were taking in. “The ACA did not reduce the cost of care,” notes Schowalter a little ruefully.

One of the consequences of the premium hikes is that the number of Minnesotans buying coverage in the individual market is dwindling; according to Schowalter, about 167,000 Minnesotans bought coverage this year, compared with 270,000 in 2016. Whether this year’s effort to stabilize the individual market will reverse that trend will be something to watch.

Meanwhile, as elsewhere, providers are consolidating, which tends to lead to higher prices. In March, two of the largest health systems in the Twin Cities, Fairview Health Services and HealthEast, announced plans to merge.

Republicans have argued Minnesota would benefit from a healthy dose of competition, and the premium relief legislation included a provision that would have ended the prohibition on for-profit HMOs. More recently, the brakes were applied to “conversion”. Dayton signed legislation that put a two-year moratorium on any of the state’s not-for-profit HMOs being sold to a for-profit company.

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STAT BOX

| % in the individual market: | 8% |
| % uninsured: | 6% |
| Per capita health expenditures (rank): | $7,409 (16) |
While fidget spinners and unicorn-everything are dominating the pop culture scene, the rise of the consumer is easily the trending topic for health care in 2017. In a world where high-deductible health plans, transparency tools, and new entrants are increasing market competition and consumerist behavior, it’s not shocking to hear increased buzz about the consumer-driven health care market. However, unlike the ever-changing list of “hottest trends” on your Facebook feed, consumerism isn’t likely to fizzle as fast as the avocado toast craze.

So, what does that mean for the payers and providers that are actively positioning to succeed in this new marketplace?

Population health connection

The foundations for consumerism and population health are built on the same cornerstones. For the past few years, population health has been on everyone’s mind. For organizations that have moved from thought to action, the pivot to a consumer-centered strategy will come easier. The organizations most successful at population health have generally prioritized three key areas: accessibility, reliability, and affordability. By doing so, they are taking first steps to put the wants and needs of patients—their customers—at the core.

Financial factors are driving a truly consumer-driven marketplace. Today, price, once an afterthought, has become a key differentiator. Multiple factors have converged to precipitate this shift, all of which result in consumers bearing a greater share of overall health care costs. The new awareness of price occurs both when people buy a health insurance plan and when they get medical services. Higher deductibles, copays, coinsurance—they have made active consumers out of previously passive patients.

In addition, more than 40 states have enacted legislation requiring hospitals to post charges or rates. In response, 85% of health plans and 60% of employers now offer price estimation tools; this easily accessible data is empowering consumers to make decisions about their own care by putting the information they need right at their fingertips.

Big losses are possible

Emerging competitors in the marketplace mean consumers have more choice than ever and can more easily shop, particularly for “commoditized” services. This trend has the potential to affect providers in particular; notably, nearly half of a typical community hospital’s commercial book of business is made up of shoppable procedures and services, such as high-volume orthopedic surgeries and various radiologic scans. Despite increased competition, this propensity toward shopping creates a huge opportunity to influence consumer behavior.

A hypothetical four-hospital health system with $1.6 billion in net revenue from patient services may have as much as $40 million at stake if people can shop around for medical services.

If failing to prepare for the consumer-driven market is a recipe for disaster, moving forward with a consumer strategy before fully understanding your consumers’ preferences and propensities for care can be equally dangerous.

Knowing the ins and outs of your market is vital. That starts with a deep understanding of your customers—who they are, how they make decisions, and how you can influence them. Studying them helps prioritize growth investments. Monitoring the extent of consumer activation locally provides clarity on where to focus and how quickly to move. Diagnosis of preferences allows for better competitive differentiation and consumer-oriented product development.

This all adds up to no small shift in strategy. But the awakening of the health care consumer is powerfully good news for the mission of providers and payers. In other industries, the same forces have led to innovation, cost reduction, and heightened value. We should expect health care to be no different—for those organizations that proactively and deeply embrace consumerism today, the rewards could be truly transformational.

Zachary Hafner leads the Advisory Board’s strategy consulting practice.
My first introduction to multiple sclerosis at Jefferson Medical School in 1974 was short and to the point—and fatalistic. I was taught that this is a complex, confusing neurodegenerative disease with a variable course for which there is no effective therapy to change its outcome.

It was treated with high dosages of steroids to interfere in the acute episodes, but deterioration continued in most patients until death, some faster than others. Not long afterward, I would find out that my brother’s sister-in-law would be diagnosed and ultimately die of MS before the FDA had approved any treatment of MS. Interferon for MS didn’t come along until the mid-’90s.

Despite the brevity of my introduction, there is no limit to the complexity of the illness. For example, MS is associated with a large number of immune system–associated genes and a complex set of lifestyle and environmental influences including exposure to sunlight, diet, education, and smoking. There is, as well, a confusing association with Epstein-Barr virus, and some evidence suggesting it may trigger the onset of MS.

Four presentations

Just by way of review, MS is a demyelinating disease of the gray and white matter of the central nervous system that leads to neurodegeneration and progressive disability that may include such symptoms as fatigue, speech difficulties, the need for walking aids, and, ultimately, dependence on a wheelchair. Currently, treatment focuses on tamping down the immune system, but this must be augmented by neuroprotection and repair strategies to limit the damage and keep any disabilities as limited as possible.

Traditionally, MS has been categorized into four different presentations: relapsing remitting, primary progressive, secondary progressive, and clinically isolated. Relapsing remitting is, by far, the most common and accounts for about 85% of all cases. The primary progressive is a distant second and accounts for 15% of cases. Secondary progressive is diagnosed after the course of relapsing remitting MS changes to one that progressively deteriorates. Clinically
Studies 1 and 2 consisted of two randomized, double-blind, double-dummy, active comparator-controlled clinical trials of identical design lasting 96 weeks. These studies were designed as head-to-head comparisons against Rebif, a commonly used interferon drug manufactured by EMD Serono. Ocrevus was dosed at 600 mg every 24 weeks and placebo subcutaneous injections were given three times a week. The active comparator, Rebif, was given three times per week along with a placebo IV infusion every 24 weeks. Admission criteria included having at least one relapse within the last year or two within the last two years and a rating of between 1 and 5.5 on the Kurtzke Expanded Disability Status Scale (EDSS), the standard instrument for rating disability from MS. Patients with primary progressive forms of MS were excluded from these two trials. All patients underwent neurological evaluations every 12 weeks and at the time of any suspected relapse. MRIs of the brain were performed at baseline and at Weeks 24, 48, and 96.

The primary endpoint for both studies was the annualized relapse rate. Secondary outcomes included the proportion of patients with confirmed disability progression, the average number of MRI T1 gadolinium-enhancing lesions at Weeks 24, 48, and 96, and new or enlarging MRI T2 hyperintense lesions. Progression of disability was defined as a 1-point increase in the baseline EDSS score that is attributable to MS when the starting EDSS was 5.5 or less, or a 0.5-point increase if the baseline EDSS was 5.5 or above.

Combined, the two studies included 827 patients who were randomized to receive Ocrevus and 828 who received Rebif. The baseline characteristics were similar in both arms in both studies: 66% of the study volunteers were women, the average age was 37, and their MS had been diagnosed about four years ago. Patients in both studies had had a similar number of relapses—1.3—and their average EDSS score was 2.8.

The results were significantly better for the patients treated with Ocrevus than those treated with Rebif. The primary endpoint, the annualized relapse rate, was roughly half in patients taking Ocrevus than those taking Rebif (0.16 versus 0.29). Results for Ocrevus were also better than Rebif on various secondary endpoints.
TOMORROW’S MEDICINE

Study 3 of primary progressive MS was designed as a placebo-controlled study because there is no FDA-approved treatment against which to compare Ocrevus. Patients were randomized to receive either Ocrevus 600 mg or a placebo every 24 weeks for at least 120 weeks. Selection criteria required a baseline EDSS score of between 3 and 6.5. The primary outcome was time to onset of disability progression attributable to MS with confirmation 12 weeks after onset. A total of 488 patients received Ocrevus and 244 received placebo. Outcomes were statistically significant with 32.9% of the patients treated with Ocrevus experiencing onset of disability progression compared with 39.3% of those assigned the placebo. The results also showed favorable MRI results for patients treated with Ocrevus.

Adverse events are what one would anticipate from any anti-CD20 drug: skin infections, upper and lower respiratory tract infections, infusion reactions, herpes infections—to name a few. Because of the extensive experience with other anti-CD20 drugs, Ocrevus comes with warnings about adverse events—namely, malignancies and virus reactivation—that didn’t occur in the studies of Ocrevus but have occurred with other anti-CD20 drugs.

Huge market
I see two takeaways here. First, Ocrevus is superior to Rebif as a treatment of relapsing remitting MS. Second, and more importantly, it is the only FDA-approved treatment for primary progressive MS.

The market for MS drugs is huge. Some estimates put it at $19 billion in sales per year. Although Teva’s Copaxone is the leading drug by number of patients, its sales are dwarfed by the sales for Biogen’s trio of MS drugs—Avonex, Tysabri, and Tecfidera.

Roche has set a price of $65,000 for a year of Ocrevus compared with a list price of $86,000 for Rebif. Given the ease of administration and the superior results in the clinical trial for relapsing remitting MS, this seems like a bargain.

But as is so often the case, the details matter and the devil resides therein.

Rebif is typically paid for through the pharmacy benefit and is subject to rebates and other discounts. Ocrevus is paid through the medical benefit with a whole different set of rules. As a result, there’s some uncertainty about how the two drugs compare on price.

Still, with a list price that is 25% less than a competing drug, better outcomes, and less frequent dosing, maybe Ocrevus will start a new trend: better outcomes, easier administration—and a lower price. That trifecta is great news for people managing the cost and quality of MS care—and American health care in general.

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