Managed Healthcare®
EXECUTIVE
The C-Suite Advisor
ManagedHealthcareExecutive.com

ACA stakeholders voice hopes, fears going forward

PAGE 17

November 2014
VOL. 24 NO. 11
ADVANSTAR
MEDICAL COMMUNICATIONS GROUP

MISSION STATEMENT: Managed Healthcare Executive provides senior-level decision makers the trends, analysis, strategies and applications they need to innovate value in a rapidly changing healthcare landscape.

EDITORIAL ADVISORY BOARD

The board members and consultants contribute expertise and analysis that help shape the content of Managed Healthcare Executive

Managed Healthcare EXECUTIVE

EDITORIAL

DAVID A. DEPINHO
Executive Editor
(732) 346-3053
ddepinho@advanstar.com

TRACEY L. WALKER
Content channel manager
(440) 891-2732
twalker@advanstar.com

JILL WECHSLER
Washington bureau chief

ROBERT MCGARR
Group art director

Send editorial materials to:
Managed Healthcare Executive
24950 Country Club Blvd. #200
North Olmsted, OH 44070

PRODUCTION

KAREN LENZEN
Production director
klenzen@media.advanstar.com

AUDIENCE DEVELOPMENT

JOY PUZZO
Corporate director
(440) 319-9570
jpuzzo@advanstar.com

CHRISTINE SHAPPELL
Director
(201)-391-2359
cshappell@advanstar.com

JOE MARTIN
Manager
(218) 740-6375
jmartin@advanstar.com

SUBSCRIPTION SERVICES
888-527-7008

PUBLISHING & SALES

GEORGIANN DECENZO
Executive vice president
(440) 891-2778
gdecenzo@advanstar.com

KEN SYLVIA
Vice president, group publisher
(732) 346-3017
ksylvia@advanstar.com

MIKE WEISS
Group publisher
(732) 346-3071
mweiss@advanstar.com

MARGIE JAXEL
Dir. of Business Develpment, Healthcare Technology Sales
(732) 346-3003
mjaxel@advanstar.com

PATRICK CARMODY
Account Manager, Display/Classified & Healthcare Technology
(440) 891-2621
pcarmody@advanstar.com

JOANNA SHIPPOLI
Account manager, recruitment advertising
(440) 891-2615
jshippoli@advanstar.com

DON BERMAN
Business director, emedia
(212) 951-6745
dberman@advanstar.com

MEG BENSON
Special Projects Director
(732) 346-3039
mbenson@advanstar.com

GAIL KAYE
Director of Marketing & Research Services
(732) 346-3042
gkaye@advanstar.com

HANNAH CURIS
Sales support
(732) 346-3055
hcuris@advanstar.com

REPRINTS

877-652-5295 ext. 121/
bkolb@wrightsmedia.com

Outside US, UK, direct dial:
(281) 419-5725. Ext. 121

RENEE SCHUSTER
List Account Executive
(440) 891-2613
rschuster@advanstar.com

MAUREEN CANNON
Permissions
(440) 891-2742
mcannon@advanstar.com

ADVANSTAR

JOE LOGGIA
Chief executive officer

TOM FLORIO
Chief Executive Officer
Fashion Group,
Executive Vice-President

TOM EHARDT
Executive vice president,
chief administrative officer
& chief financial officer

GEORGIANN DECENZO
Executive vice president

CHRIS DEMOULIN
Executive vice president

REBECCA EVANGELOU
Executive vice president,
business systems

JULIE MOLLESTON
Executive vice president,
human resources

TRACY HARRIS
Senior vice president

MICHAEL BERNSTEIN
Vice president, legal

FRANCIS HEID
Vice president,
media operations

ADELE HARTWICK
Vice-President, Treasurer &
Controller

Managed Healthcare® EXECUTIVE

Volume 24 Issue 11
NOVEMBER 2014

COVER STORY

ACA OUTLOOK

17 Leaders rate success of law so far

COMMENTARY

ESSENTIALS

DEPARTMENTS

Twitter.com/MHExecutive

Facebook.com/ManagedHealthcareExecutive

Microfilm or microfiche copies of annual issues available through Advanstar Marketing Services, (800) 346-0085 ext. 477.
Printed in U.S.A.

Managed Healthcare Executive *(ISSN 1533-9300, Digital ISSN 2150-7120) is published monthly by Advanstar Communications Inc., 131 W First St., Duluth MN 55802-2065. Subscription rates: 1 year $99.00, 2 years $145.00 in the United States & Possessions; 1 year $122.00, 2 years $173.25 in Canada and Mexico; 1 year $192.00, 2 years $295.00 in all other countries. For air-expedited service, include an additional $87.00 per order annually. Single copies (prepaid only): $9.00 in the United States, $22.00 all other countries. Back issues, if available: $15.00 in the U.S.; $17.00 all other countries. Include $6.85 per order plus $2 per additional copy for U.S. postage and handling. If shipping outside the U.S., include an additional $10 per order plus $3 per additional copy. Periodicals postage paid at Duluth MN 55806 and additional mailing offices. POSTMASTER: Please send address changes to Managed Healthcare Executive, P.O. Box 6178, Duluth, MN 55806-6178. Canadian GST number: R-124213133RT001, PUBLICATIONS MAIL AGREEMENT NO. 40612608, Return Undeliverable Canadian Addresses to: IMEX Global Solutions, P. O. Box 25542, London, ON N6C 6B2, CANADA. Printed in the U.S.A.*

Cover: Getty Images/iStock Vectors/AlonzoDesign (road); Getty Images/iStock/360/rambo182 (signs)

NOW APPROVED

OFEV®
nintedanib
capsules 150mg

For the treatment of idiopathic pulmonary fibrosis (IPF)

OPENDOORS™
Access to resources for the IPF community

To learn more about patient support services available through the BI OPEN DOORS™ patient support program, please call 1-866-OPENDOOR (673-6366) to speak with an OPEN DOORS™ customer service representative.

To help your members with IPF, and learn more about OFEV capsules, please visit www.OFEV.com. You may also contact your Boehringer Ingelheim Representative to schedule a presentation about OFEV.

INDICATION AND USAGE

OFEV is indicated for the treatment of idiopathic pulmonary fibrosis (IPF).

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Elevated Liver Enzymes

The safety and efficacy of OFEV has not been studied in patients with moderate (Child Pugh B) or severe (Child Pugh C) hepatic impairment. Treatment with OFEV is not recommended in patients with moderate or severe hepatic impairment.

In clinical trials, administration of OFEV was associated with elevations of liver enzymes (ALT, AST, ALKP, GGT) and bilirubin. Liver enzyme increases were reversible with dose modification or interruption and not associated with clinical signs or symptoms of liver injury.

Conduct liver function tests (ALT, AST, and bilirubin) prior to treatment with OFEV, monthly for 3 months, and every 3 months thereafter, and as clinically indicated. Dosage modifications, interruption, or discontinuation may be necessary for liver enzyme elevations.

Gastrointestinal Disorders

Diarrhea

Diarrhea was the most frequent gastrointestinal event reported in 62% versus 18% of patients treated with OFEV and placebo, respectively. In most patients, the event was of mild to moderate intensity and occurred within the first 3 months of treatment. Diarrhea led to permanent dose reduction in 11% of patients treated with OFEV compared to 0 placebo-treated patients. Diarrhea led to discontinuation of OFEV in 5% of the patients compared to <1% of placebo-treated patients.

Dosage modifications or treatment interruptions may be necessary in patients with adverse reactions of diarrhea. Treat diarrhea at first signs with adequate hydration and antidiarrheal medication (e.g., loperamide), and consider treatment interruption if diarrhea continues. OFEV treatment may be resumed at the full dosage (150 mg twice daily), or at the reduced dosage (100 mg twice daily), which subsequently may be increased to the full dosage. If severe diarrhea persists despite symptomatic treatment, discontinue treatment with OFEV.

Nausea and Vomiting

Nausea was reported in 24% versus 7% and vomiting was reported in 12% versus 3% of patients treated with OFEV and placebo, respectively. In most patients, these events were of mild to moderate intensity. Nausea led to discontinuation of OFEV in 2% of patients. Vomiting led to discontinuation of OFEV in 1% of the patients.

For nausea or vomiting that persists despite appropriate supportive care including anti-emetic therapy, dose reduction or treatment interruption may be required. OFEV treatment may be resumed at the full dosage (150 mg twice daily), or at the reduced dosage (100 mg twice daily), which subsequently may be increased to the full dosage. If severe nausea or vomiting does not resolve, discontinue treatment with OFEV.

Embryofetal Toxicity

OFEV is Pregnancy category D. It can cause fetal harm when administered to a pregnant woman. If OFEV is used during pregnancy, or if the patient becomes pregnant while taking OFEV, the patient should be advised of the potential hazard to a fetus. Women of childbearing potential should be advised to avoid becoming pregnant while receiving treatment with OFEV and to use adequate contraception during treatment and at least 3 months after the last dose of OFEV.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Arterial Thromboembolic Events

Arterial thromboembolic events have been reported in patients taking OFEV. In clinical trials, arterial thromboembolic events were reported in 2.5% of patients treated with OFEV and 0.8% of placebo-treated patients. Myocardial infarction was the most common adverse reaction under arterial thromboembolic events, occurring in 1.5% of OFEV-treated patients compared to 0.4% of placebo-treated patients. Use caution when treating patients at higher cardiovascular risk including known coronary artery disease. Consider treatment interruption in patients who develop signs or symptoms of acute myocardial ischemia.

Risk of Bleeding

Based on the mechanism of action (VEGFR inhibition), OFEV may increase the risk of bleeding. In clinical trials, bleeding events were reported in 10% of patients treated with OFEV and in 7% of patients treated with placebo. Use OFEV in patients with known risk of bleeding only if the anticipated benefit outweighs the potential risk.

Gastrointestinal Perforation

Based on the mechanism of action, OFEV may increase the risk of gastrointestinal perforation. In clinical trials, gastrointestinal perforation was reported in 0.3% of patients treated with OFEV, compared to 0 cases in the placebo-treated patients. Use caution when treating patients who have had recent abdominal surgery. Discontinue therapy with OFEV in patients who develop gastrointestinal perforation. Only use OFEV in patients with known risk of gastrointestinal perforation if the anticipated benefit outweighs the potential risk.

ADVERSE REACTIONS

- Adverse reactions reported in ≥5% of patients treated with OFEV and more commonly than in patients treated with placebo included diarrhea (62% vs. 18%), nausea (24% vs. 7%), abdominal pain (15% vs 6%), liver enzyme elevation (14% vs 3%), vomiting (12% vs 3%), decreased appetite (11% vs 5%), weight decreased (10% vs 3%), headache (8% vs 5%), and hypertension (5% vs 4%).
- The most frequent serious adverse reactions reported in patients treated with OFEV, more than placebo, were bronchitis (1.2% vs. 0.8%) and myocardial infarction (1.5% vs. 0.4%). The most common adverse events leading to death in patients treated with OFEV, more than placebo, were pneumonia (0.7% vs. 0.6%), lung neoplasm malignant (0.3% vs. 0%), and myocardial infarction (0.3% vs. 0.2%). In the predefined category of major adverse cardiovascular events (MACE) including MI, fatal events were reported in 0.6% of OFEV-treated patients and 1.8% of placebo-treated patients.

DRUG INTERACTIONS

P-glycoprotein (P-gp) and CYP3A4 Inhibitors and Inducers

Coadministration with oral doses of a P-gp and CYP3A4 inhibitor, ketoconazole, increased exposure to nintedanib by 60%. Concomitant use of potent P-gp and CYP3A4 inhibitors (e.g., erythromycin) with OFEV may increase exposure to nintedanib. In such cases, patients should be monitored closely for tolerability of OFEV. Management of adverse reactions may require interruption, dose reduction, or discontinuation of therapy with OFEV. Coadministration with oral doses of a P-gp and CYP3A4 inducer, rifampicin, decreased exposure to nintedanib by 50%. Concomitant use of P-gp and CYP3A4 inducers (e.g., carbamazepine, phenytoin, and St. John's wort) with OFEV should be avoided as these drugs may decrease exposure to nintedanib.

Anticoagulants

Nintedanib is a VEGFR inhibitor, and may increase the risk of bleeding. Monitor patients on full anticoagulation therapy closely for bleeding and adjust anticoagulation treatment as necessary.

USE IN SPECIFIC POPULATIONS

Nursing Mothers

- Excretion of nintedanib and/or its metabolites into human milk is probable. Because of the potential for serious adverse reactions in nursing infants from OFEV, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Hepatic Impairment

- Monitor for adverse reactions and consider dose modification or discontinuation of OFEV as needed for patients with mild hepatic impairment (Child Pugh A). Treatment of patients with moderate (Child Pugh B) and severe (Child Pugh C) hepatic impairment with OFEV is not recommended.

Smokers

- Smoking was associated with decreased exposure to OFEV, which may alter the efficacy profile of OFEV. Encourage patients to stop smoking prior to treatment with OFEV and to avoid smoking when using OFEV.

OFHCPISIOCT15

Please see accompanying Brief Summary for OFEV on next page.

Boehringer Ingelheim

OFEV® (nintedanib) capsules, for oral use

BRIEF SUMMARY OF PRESCRIBING INFORMATION
Please see package insert for full Prescribing Information, including Patient Information

INDICATIONS AND USAGE: OFEV is indicated for the treatment of idiopathic pulmonary fibrosis (IPF).

DOSAGE AND ADMINISTRATION: Testing Prior to OFEV Administration: Conduct liver function tests prior to initiating treatment with OFEV *[see Warnings and Precautions]*. **Recommended Dosage:** The recommended dosage of OFEV is 150 mg twice daily administered approximately 12 hours apart. OFEV capsules should be taken with food and swallowed whole with liquid. OFEV capsules should not be chewed or crushed because of a bitter taste. The effect of chewing or crushing of the capsule on the pharmacokinetics of nintedanib is not known. If a dose of OFEV is missed, the next dose should be taken at the next scheduled time. Advise the patient to not make up for a missed dose. Do not exceed the recommended maximum daily dosage of 300 mg. **Dosage Modification due to Adverse Reactions:** In addition to symptomatic treatment, if applicable, the management of adverse reactions of OFEV may require dose reduction or temporary interruption until the specific adverse reaction resolves to levels that allow continuation of therapy. OFEV treatment may be resumed at the full dosage (150 mg twice daily), or at the reduced dosage (100 mg twice daily), which subsequently may be increased to the full dosage. If a patient does not tolerate 100 mg twice daily, discontinue treatment with OFEV *[see Warnings and Precautions and Adverse Reactions]*. Dose modifications or interruptions may be necessary for liver enzyme elevations. For aspartate aminotransferase (AST) or alanine aminotransferase (ALT) >3 times to <5 times the upper limit of normal (ULN) without signs of severe liver damage, interrupt treatment or reduce OFEV to 100 mg twice daily. Once liver enzymes have returned to baseline values, treatment with OFEV may be reintroduced at a reduced dosage (100 mg twice daily), which subsequently may be increased to the full dosage (150 mg twice daily) *[see Warnings and Precautions and Adverse Reactions]*. Discontinue OFEV for AST or ALT elevations >5 times ULN or >3 times ULN with signs or symptoms of severe liver damage.

CONTRAINDICATIONS: None

WARNINGS AND PRECAUTIONS: Elevated Liver Enzymes: The safety and efficacy of OFEV has not been studied in patients with moderate (Child Pugh B) or severe (Child Pugh C) hepatic impairment. Treatment with OFEV is not recommended in patients with moderate or severe hepatic impairment *[see Use in Specific Populations]*. In clinical trials, administration of OFEV was associated with elevations of liver enzymes (ALT, AST, ALKP, GGT). Liver enzyme increases were reversible with dose modification or interruption and not associated with clinical signs or symptoms of liver injury. The majority (94%) of patients with ALT and/or AST elevations had elevations <5 times ULN. Administration of OFEV was also associated with elevations of bilirubin. The majority (95%) of patients with bilirubin elevations had elevations <2 times ULN *[see Use in Specific Populations]*. Conduct liver function tests (ALT, AST, and bilirubin) prior to treatment with OFEV, monthly for 3 months, and every 3 months thereafter, and as clinically indicated. Dosage modifications or interruption may be necessary for liver enzyme elevations. **Gastrointestinal Disorders:** Diarrhea: Diarrhea was the most frequent gastrointestinal event reported in 62% versus 18% of patients treated with OFEV and placebo, respectively *[see Adverse Reactions)]*. In most patients, the event was of mild to moderate intensity and occurred within the first 3 months of treatment. Diarrhea led to permanent dose reduction in 11% of patients treated with OFEV compared to 0 placebo-treated patients. Diarrhea led to discontinuation of OFEV in 5% of the patients compared to <1% of placebo-treated patients. Dosage modifications or treatment interruptions may be necessary in patients with adverse reactions of diarrhea. Treat diarrhea at first signs with adequate hydration and antidiarrheal medication (e.g., loperamide), and consider treatment interruption if diarrhea continues. OFEV treatment may be resumed at the full dosage (150 mg twice daily), or at the reduced dosage (100 mg twice daily), which subsequently may be increased to the full dosage. If severe diarrhea persists despite symptomatic treatment, discontinue treatment with OFEV (nintedanib). Nausea and Vomiting: Nausea was reported in 24% versus 7% and vomiting was reported in 12% versus 3% of patients treated with OFEV and placebo, respectively *[see Adverse Reactions]*. In most patients, these events were of mild to moderate intensity. Nausea led to discontinuation of OFEV in 2% of patients. Vomiting led to discontinuation of OFEV in 1% of the patients. For nausea or vomiting that persists despite appropriate supportive care including anti-emetic therapy, dose reduction or treatment interruption may be required. OFEV treatment may be resumed at the full dosage (150 mg twice daily), or at the reduced dosage (100 mg twice daily), which subsequently may be increased to the full dosage. If severe nausea or vomiting does not resolve, discontinue treatment with OFEV. **Embryofetal Toxicity:** OFEV can cause fetal harm when administered to a pregnant woman. Nintedanib was teratogenic and embryofetocidal in rats and rabbits at less than and approximately 5 times the maximum recommended human dose (MRHD) in adults (on an AUC basis at oral doses of 2.5 and 15 mg/kg/day in rats and rabbits, respectively). If OFEV is used during pregnancy, or if the patient becomes pregnant while taking OFEV, the patient should be advised of the potential hazard to a fetus. Women of childbearing potential should be advised to avoid becoming pregnant while receiving treatment with OFEV and to use adequate contraception during treatment and at least 3 months after the last dose of OFEV *[see Use in Specific Populations]*. **Arterial Thromboembolic Events:** Arterial thromboembolic events have been reported in patients taking OFEV. In clinical trials, arterial thromboembolic events were reported in 2.5% of patients treated with OFEV and 0.8% of placebo-treated patients. Myocardial infarction was the most common adverse reaction under arterial thromboembolic events, occurring in 1.5% of OFEV-treated patients compared to 0.4% of placebo-treated patients. Use caution when treating patients at higher cardiovascular risk including known coronary artery disease. Consider treatment interruption in patients who develop signs or symptoms of acute myocardial ischemia. **Risk of Bleeding:** Based on the mechanism of action (VEGFR inhibition), OFEV may increase the risk of bleeding. In clinical trials, bleeding events were reported in 10% of patients treated with OFEV and in 7% of patients treated with placebo. Use OFEV in patients with known risk of bleeding only if the anticipated benefit outweighs the potential risk. **Gastrointestinal Perforation:** Based on the mechanism of action, OFEV may increase the risk of gastrointestinal perforation. In clinical trials, gastrointestinal perforation was reported in 0.3% of patients treated with OFEV, compared to 0 cases in the placebo-treated patients. Use caution when treating patients who have had recent abdominal surgery. Discontinue therapy with OFEV in patients who develop gastrointestinal perforation. Only use OFEV in patients with known risk of gastrointestinal perforation if the anticipated benefit outweighs the potential risk.

ADVERSE REACTIONS: The following adverse reactions are discussed in greater detail in other sections of the labeling: Liver Enzyme and Bilirubin Elevations *[see Warnings and Precautions];* Gastrointestinal Disorders *[see Warnings and Precautions];* Embryofetal Toxicity *[see Warnings and Precautions];* Arterial Thromboembolic Events *[see Warnings and Precautions];* Risk of Bleeding *[see Warnings and Precautions];* Gastrointestinal Perforation *[see Warnings and Precautions]*. **Clinical Trials Experience:** Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The safety of OFEV was evaluated in over 1000 IPF patients with over 200 patients exposed to OFEV for more than 2 years in clinical trials. OFEV was studied in three randomized, double-blind, placebo-controlled, 52-week trials. In the phase 2 (Study 1) and phase 3 (Studies 2 and 3) trials, 723 patients with IPF received OFEV 150 mg twice daily and 508 patients received placebo. The median duration of exposure was 10 months for patients treated with OFEV and 11 months for patients treated with placebo. Subjects ranged in age from 42 to 89 years (median age of 67 years). Most patients were male (79%) and Caucasian (60%). The most frequent serious adverse reactions reported in patients treated with OFEV (nintedanib), more than placebo, were bronchitis (1.2% vs. 0.8%) and myocardial infarction (1.5% vs. 0.4%). The most common adverse events leading to death in patients treated with OFEV, more than placebo, were pneumonia (0.7% vs. 0.6%), lung neoplasm malignant (0.3% vs. 0%), and myocardial infarction (0.3% vs. 0.2%). In the predefined category of major adverse cardiovascular events (MACE) including MI, fatal events were reported in 0.6% of OFEV-treated patients and 1.8% of placebo-treated patients. Adverse reactions leading to permanent dose reductions were reported in 16% of OFEV-treated patients and 1% of placebo-treated patients. The most frequent adverse reaction that led to permanent dose reduction in the patients treated with OFEV was diarrhea (11%). Adverse reactions leading to discontinuation were reported in 21% of OFEV-treated patients and 15% of placebo-treated patients. The most frequent adverse reactions that led to discontinuation in OFEV-treated patients were diarrhea (5%), nausea (2%), and decreased appetite (2%). The most common adverse reactions with an incidence of ≥5% and more frequent in the OFEV than placebo treatment group are listed in Table 1.

Table 1 Adverse Reactions Occurring in ≥5% of OFEV-treated Patients and More Commonly Than Placebo in Studies 1, 2, and 3

Adverse Reaction	OFEV, 150 mg n=723	Placebo n=508
Gastrointestinal disorders		
Diarrhea	62%	18%
Nausea	24%	7%
Abdominal pain[a]	15%	6%
Vomiting	12%	3%
Hepatobiliary disorders		
Liver enzyme elevation[b]	14%	3%
Metabolism and nutrition disorders		
Decreased appetite	11%	5%
Nervous systemic disorders		
Headache	8%	5%
Investigations		
Weight decreased	10%	3%
Vascular disorders		
Hypertension[c]	5%	4%

[a] Includes abdominal pain, abdominal pain upper, abdominal pain lower, gastrointestinal pain and abdominal tenderness.

[b] Includes gamma-glutamyltransferase increased, hepatic enzyme increased, alanine aminotransferase increased, aspartate aminotransferase increased, hepatic function abnormal, liver function test abnormal, transaminase increased, blood alkaline phosphatase-increased, alanine aminotransferase abnormal, aspartate aminotransferase abnormal, and gamma-glutamyltransferase abnormal.

[c] Includes hypertension, blood pressure increased, hypertensive crisis, and hypertensive cardiomyopathy.

In addition, hypothyroidism was reported in patients treated with OFEV, more than placebo (1.1% vs. 0.6%).

DRUG INTERACTIONS: P-glycoprotein (P-gp) and CYP3A4 Inhibitors and Inducers: Nintedanib is a substrate of P-gp and, to a minor extent, CYP3A4. Coadministration with oral doses of a P-gp and CYP3A4 inhibitor, ketoconazole, increased exposure to nintedanib by 60%. Concomitant use of P-gp and CYP3A4 inhibitors (e.g., erythromycin) with OFEV may increase exposure to nintedanib. In such cases, patients should be monitored closely for tolerability of OFEV. Management of adverse reactions may require interruption, dose reduction, or discontinuation of therapy with OFEV. Coadministration with oral doses of a P-gp and CYP3A4 inducer, rifampicin, decreased exp sure to nintedanib by 50%. Concomitant use of P-gp and CYP3A4 inducers (e.g., carbamazepine, phenytoin, and St. John's wort) with OFEV should be avoided as these drugs may decrease exposure to nintedanib. **Anticoagulants:** Nintedanib is a VEGFR inhibitor, and may increase the risk of bleeding. Monitor patients on full anticoagulation therapy closely for bleeding and adjust

anticoagulation treatment as necessary *[see Warnings and Precautions]*.

USE IN SPECIFIC POPULATIONS: Pregnancy: *Pregnancy Category D. [See Warnings and Precautions]:* OFEV (nintedanib) can cause fetal harm when administered to a pregnant woman. If OFEV is used during pregnancy, or if the patient becomes pregnant while taking OFEV, the patient should be apprised of the potential hazard to a fetus. Women of childbearing potential should be advised to avoid becoming pregnant while receiving treatment with OFEV. In animal reproduction toxicity studies, nintedanib caused embryofetal deaths and teratogenic effects in rats and rabbits at less than and approximately 5 times the maximum recommended human dose (MRHD) in adults (on a plasma AUC basis at maternal oral doses of 2.5 and 15 mg/kg/day in rats and rabbits, respectively). Malformations included abnormalities in the vasculature, urogenital, and skeletal systems. Vasculature anomalies included missing or additional major blood vessels. Skeletal anomalies included abnormalities in the thoracic, lumbar, and caudal vertebrae (e.g., hemivertebra, missing, or asymmetrically ossified), ribs (bifid or fused), and sternebrae (fused, split, or unilaterally ossified). In some fetuses, organs in the urogenital system were missing. In rabbits, a significant change in sex ratio was observed in fetuses (female:male ratio of approximately 71%:29%) at approximately 15 times the MRHD in adults (on an AUC basis at a maternal oral dose of 60 mg/kg/day). Nintedanib decreased post-natal viability of rat pups during the first 4 post-natal days when dams were exposed to less than the MRHD (on an AUC basis at a maternal oral dose of 10 mg/kg/day). **Nursing Mothers:** Nintedanib and/or its metabolites are excreted into the milk of lactating rats. Milk and plasma of lactating rats have similar concentrations of nintedanib and its metabolites. Excretion of nintedanib and/or its metabolites into human milk is probable. There are no human studies that have investigated the effects of OFEV on breast-fed infants. Because of the potential for serious adverse reactions in nursing infants from OFEV, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. **Pediatric Use:** Safety and effectiveness in pediatric patients have not been established. **Geriatric Use:** Of the total number of subjects in phase 2 and 3 clinical studies of OFEV, 60.8% were 65 and over, while 16.3% were 75 and over. In phase 3 studies, no overall differences in effectiveness were observed between subjects who were 65 and over and younger subjects; no overall differences in safety were observed between subjects who were 65 and over or 75 and over and younger subjects, but greater sensitivity of some older individuals cannot be ruled out. **Hepatic Impairment:** Nintedanib is predominantly eliminated via biliary/fecal excretion (>90%). No dedicated pharmacokinetic (PK) study was performed in patients with hepatic impairment. Monitor for adverse reactions and consider dose modification or discontinuation of OFEV (nintedanib) as needed for patients with mild hepatic impairment (Child Pugh A). The safety and efficacy of nintedanib has not been investigated in patients with hepatic impairment classified as Child Pugh B or C. Therefore, treatment of patients with moderate (Child Pugh B) and severe (Child Pugh C) hepatic impairment with OFEV is not recommended *[see Warnings and Precautions]*. **Renal Impairment:** Based on a single-dose study, less than 1% of the total dose of nintedanib is excreted via the kidney. Adjustment of the starting dose in patients with mild to moderate renal impairment is not required. The safety, efficacy, and pharmacokinetics of nintedanib have not been studied in patients with severe renal impairment (<30 mL/min CrCl) and end-stage renal disease. **Smokers:** Smoking was associated with decreased exposure to OFEV, which may alter the efficacy profile of OFEV. Encourage patients to stop smoking prior to treatment with OFEV and to avoid smoking when using OFEV.

OVERDOSAGE: In the trials, one patient was inadvertently exposed to a dose of 600 mg daily for a total of 21 days. A non-serious adverse event (nasopharyngitis) occurred and resolved during the period of incorrect dosing, with no onset of other reported events. Overdose was also reported in two patients in oncology studies who were exposed to a maximum of 600 mg twice daily for up to 8 days. Adverse events reported were consistent with the existing safety profile of OFEV. Both patients recovered. In case of overdose, interrupt treatment and initiate general supportive measures as appropriate.

PATIENT COUNSELING INFORMATION: *Advise the patient to read the FDA-approved patient labeling (Patient Information).* Liver Enzyme and Bilirubin Elevations: Advise patients that they will need to undergo liver function testing periodically. Advise patients to immediately report any symptoms of a liver problem (e.g., skin or the whites of eyes turn yellow, urine turns dark or brown (tea colored), pain on the right side of stomach, bleed or bruise more easily than normal, lethargy) *[see Warnings and Precautions]*. Gastrointestinal Disorders: Inform patients that gastrointestinal disorders such as diarrhea, nausea, and vomiting were the most commonly reported gastrointestinal events occurring in patients who received OFEV (nintedanib). Advise patients that their healthcare provider may recommend hydration, antidiarrheal medications (e.g., loperamide), or anti-emetic medications to treat these side effects. Temporary dosage reductions or discontinuations may be required. Instruct patients to contact their healthcare provider at the first signs of diarrhea or for any severe or persistent diarrhea, nausea, or vomiting *[see Warnings and Precautions and Adverse Reactions]*. Pregnancy: Counsel patients on pregnancy planning and prevention. Advise females of childbearing potential of the potential hazard to a fetus and to avoid becoming pregnant while receiving treatment with OFEV. Advise females of childbearing potential to use adequate contraception during treatment, and for at least 3 months after taking the last dose of OFEV. Advise female patients to notify their doctor if they become pregnant during therapy with OFEV *[see Warnings and Precautions and Use in Specific Populations]*. Arterial Thromboembolic Events: Advise patients about the signs and symptoms of acute myocardial ischemia and other arterial thromboembolic events and the urgency to seek immediate medical care for these conditions *[see Warnings and Precautions]*. Risk of Bleeding: Bleeding events have been reported. Advise patients to report unusual bleeding *[see Warnings and Precautions]*. Gastrointestinal Perforation: Serious gastrointestinal perforation events have been reported. Advise patients to report signs and symptoms of gastrointestinal perforation *[see Warnings and Precautions]*. Nursing Mothers: Advise patients to discontinue nursing while taking OFEV or discontinue OFEV while nursing *[see Use in Specific Populations]*. Smokers: Encourage patients to stop smoking prior to treatment with OFEV and to avoid smoking when using with OFEV. Administration: Instruct patients to swallow OFEV capsules whole with liquid and not to chew or crush the capsules due to the bitter taste. Advise patients to not make up for a missed dose *[see Dosage and Administration]*.

OF-BS-10-14 (10-15) OF629900PROF

R_x only

Boehringer Ingelheim

@Managed Healthcare® EXECUTIVE online

YOUR GUIDE TO **MANAGED HEALTHCARE EXECUTIVE.COM**

Download the app today!

FREE Available on the App Store

Get access to all the benefits *Managed Healthcare Executive* offers at your fingertips. The *Managed Healthcare Executive* app for iPad and iPhone is now available for free in the iTunes store. **bit.ly/1mm502d**

E-NEWSLETTER SIGNUP

Get access to all the benefits *Managed Healthcare Executive* offers delivered directly to your inbox. The *Managed Healthcare Executive* e-newsletter is free. Sign up today. **bit.ly/1lj2xgg**

FOLLOW US ON TWITTER

twitter.com/MHExecutive

LIKE US ON FACEBOOK

facebook.com/ManagedHealthcareExecutive

FOLLOW OUR EAB ON TWITTER:

Joel V. Brill, MD @jvbrill

Margaret A. Murray @safetynetplans

Don Hall, MPH @DeltaDonH

Dennis Schmuland, MD @DennisSchmuland

Al Lewis @whynobodybeliev

PART OF THE ModernMedicine NETWORK

Managed Healthcare Executive is part of *the ModernMedicine Network, a Web-based portal for health professionals offering best-in-class content and tools in a rewarding and easy-to-use environment for knowledge-sharing among members of our community.*

formulary watch

[NEWS]

FDA's new hepatitis C approval: Are we a step closer to a cure?

FDA's approval of the first once-daily single tablet regimen for chronic hepatitis C, may signal that industry is at the forefront of a cure. **http://bit.ly/1sN5dKO**

DAVID LASSEN, PRIME

[BLOG]

5 ways formulary managers can help control Enterovirus D68

In recent months, the incidence of Enterovirus D68 (EV-D68) infection has markedly increased across the United States, notably affecting young pediatric patients. What can be done by hospital-based formulary managers to assist in the prevention, evaluation and treatment of EV-D68? **http://bit.ly/1tD3ulm**

[ANALYSIS]

Speciality drugs: A good value despite high costs

While specialty drugs tend to be much more expensive than traditional drugs, they also tend to offer much larger clinical benefits. However, researchers found that not all new drugs were an improvement over existing drugs—despite often being more expensive. **http://bit.ly/1E1kWJS**

SOCIAL MEDIA

Join FormularyWatch online

youtube.com/user/formularyjournal

facebook.com/formulary

twitter.com/formulary_news

ACCOUNTABLE CARE WORKS

Results show better patient care, lower costs

There are many engaging debates about the ways we can improve the healthcare system: Telemedicine, the Affordable Care Act, and electronic health records.

One of the more important, but less-known initiatives also has the potential to truly impact the healthcare system: accountable care.

Challenge is opportunity

Most of us know the benefits of accountable care, a healthcare delivery approach that focuses on improving patient outcomes, quality and cost. It's widely seen as a superior method for structuring healthcare than the traditional model, known as fee-for-service.

In the fee-for-service system, physicians earn more money by ordering more procedures and the patient's ultimate health outcome isn't a factor in the provider's compensation formula.

It is also widely accepted in the medical community that fee-for-service has contributed to problems of overtreatment for some patients, resulting in increased costs.

It delivers results

Many providers are entering into these value-based agreements, yet we still have a long way to go. How do we help providers transition from a fee-for-service model to an accountable care model?

Start with results. In my 20-plus years of experience as a medical oncologist, I have seen firsthand that a value-based approach is beneficial for everyone involved, physicians, patients and insurers. The Medicare Advantage program, where health coverage companies operate under an accountable care model, has led to better health outcomes at a lower cost than traditional Medicare.

In the accountable care model, providers are rewarded for taking steps that produce the best results. Accountable care requires putting the primary care physician at the center, where he or she can focus on the patient's overall health by coordinating care with other providers. This can help prevent duplicative procedures and tests and also ensure one prescription medication isn't negatively interacting with another.

It takes commitment

Providers must understand that you get out of accountable care exactly what you put in. It requires increased collaboration between doctors and health coverage companies that process claims data and may have information (ER, urgent care visits) that the patient's primary care physician might not be aware of otherwise. This helps address gaps in care that are all too common in the fee-for-service system.

This cooperation can also mean that a patient not only gets treatment for the cold that ails her today, but also a flu shot to keep her healthy in the future. Likewise, patients with colon polyps receive colonoscopies and those with diabetes receive regular eye examinations.

When practitioners are held accountable for the health of the people they treat, engagement with patients goes up; there is greater trust, and a greater likelihood for healthier outcomes.

It's a new world

I spend a great deal of time thinking about how to help consumers change their behavior in order to achieve their best health. A consumer-centric, accountable care approach to providing and managing healthcare will foster a patient/physician relationship that can help modify unhealthy behaviors that result in chronic diseases.

For patient care to be effective and affordable, it must also be accountable. Accountable care not only will improve our healthcare system, it's also inevitable. Its implementation will require a continued adjustment, certainly, but it's one we need to make. If we do it right, we'll improve the health of our patients and our long-ailing healthcare system for generations to come. ◘

ABOUT THE AUTHOR

Roy Beveridge, MD, is chief medical officer at Humana, and serves on the Editorial Advisory Board of MHE.

EBOLA'S IMPACT ON HEALTH INSURERS

World Bank estimates global cost could reach $32 billion by 2015

LISA SMITH
CONTRIBUTOR

THE ECONOMIC impact of an Ebola pandemic could reach $32 billion by 2015, according to the World Bank, with costs to the healthcare insurance industry dependent on how quickly the disease is controlled in countries with high insurance penetration, according to the Insurance Information Institute.

The World Health Organization (WHO) warned on Sept. 22 that "unless the Ebola control measures in West Africa are enhanced quickly," more than 20,000 people will be infected in that area by November. The Centers for Diesease Control and Prevention (CDC) says new cases could number 1.4 million by January 2015 if current trends continue.

In areas of the world where there is little or no health insurance, the economic impact to insurers will be minimal, according to Stephen Weisbart, Ph.D., CLU, senior vice president and chief economist for the III.

"There is a wide variation in the use of insurance worldwide," Weisbart tells *Managed Healthcare Executive*. Because there is almost no life or health insurance in West Africa, the cost of treatment and control "is pretty much a governmental expense," he notes, with help coming from outside agencies such as the CDC and WHO.

But in the U.S, where insurance penetration is high along with the cost of treatment, a significant rise in infections will likely lead to losses among healthcare insurers. Those losses can be spread worldwide because "many of the reinsurance companies are overseas," says Weisbart.

The U.S. government will bear the economic costs of patients who are on Medicare and Medicaid, notes Weisbart.

Meanwhile, healthcare workers infected in the course of their jobs will likely be covered by worker's compensation insurance. While some of those policies are managed by state agencies, the providers are generally private insurers, says Weisbart.

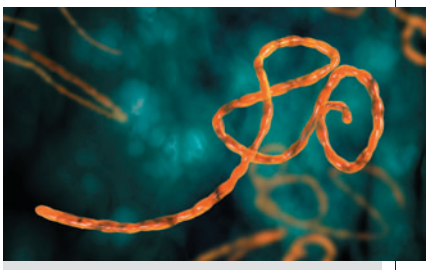
Healthcare facilities that might be impacted by government shutdowns or quarantines also carry insurance to protect themselves from revenue losses, adds Weisbart. NAS Insurance Services of California announced Oct. 14 that it would offer coverage against business losses resulting from Ebola-related government-ordered closures, according to the *Denver Post*, and Boston-based brokerage William Gallagher Associates announced a similar business interruption insurance product on Oct. 15, according to *Business Insurance*.

Richard Bryant, a senior underwriter at Ark Syndicate Management Ltd., which is underwriting the policy for Gallagher, notes that coverage for Ebola-related losses is a necessity. "This could be potentially catastrophic for any medical-related facility," he says in a statement.

Some insurers have already indicated that they are launching awareness campaigns, a move that the Insurance Information Institute strongly encourages.

"One would expect them to do that," says Weisbart.

The CDC is recommending that anyone traveling to countries where outbreaks of Ebola have occurred have full health insurance coverage, including coverage for emergency medical evacuation.



Shutterstock/Festa

5 ways formulary managers can brace for ebola

- Educate healthcare personnel about Ebola, its symptoms, and the risk of transmission in the hospital setting
- Help prevent by emphasizing appropriate infectious control measures
- Coordinate work practices that can detect persons possibly infected with Ebola or other infectious diseases
- Communicate plans for administrative, environmental, and communication measures before any potential Ebola case occurs
- Stay updated on the latest developments concerning Ebola and help make this information available to hospital colleagues

For more in-depth information visit http://bit.ly/1zEbT2S

Celebrating one year as Texas' largest not-for-profit, all-for-patient.

Just one year ago, Baylor Health Care System and Scott & White Healthcare became one. Today, we're looking toward the future of health care for everyone—a future we're building together.

Because even in a time of tremendous growth, we sharpened our focus on our patients.

We've increased access to quality care for patients with more than 800 access points for 5.3 million patient encounters annually. We've expanded our commitment to community needs through $861 million in community benefit spending*. And we've created the Baylor Scott & White Quality Alliance, a 3,700 physician-strong network designed to deliver a new level of wellness-based, compassionate care to our patients.

Separately, we shared a vision for vibrant future for our communities and patients. One year later, we share the resources to bring that vision to life.

Baylor Scott & White HEALTH

BaylorScott*and*White.com

**Calculated for Baylor Scott & White not-for-profit hospitals in accordance with Texas Health and Safety Code Chapter 311*

Photography may include models or actors and may not represent actual patients. BSWH_48_2014 Moroch

HHS, INSURERS GEAR UP FOR ACA OPEN ENROLLMENT

Will health plans have a harder time attracting new enrollees this year?

As many as 7 million new enrollees could sign up for health insurance during the Affordable Care Act's second open enrollment cycle which begins November 15, according to the Congressional Budget Office (CBO).

Last year 8 million individuals signed up during the first open enrollment cycle, and 7.3 million paid their premiums. The CBO predicts that there may be as many as 25 million new enrollees through the federal marketplace by 2017.

Sylvia Burwell, secretary of the U.S. Department of Health and Human Services (HHS), has been in office for four months and during that time she's overseen a major effort to fix the problems experienced last year when the healthcare.gov website went live. Burwell has brought in new management and industry IT pros to streamline the system and subject it to testing by outside firms, alpha testing with plan issuers, and end-to-end testing of the whole system.

The aim is to make the healthcare.gov website more consumer friendly so that enrollment will be faster and easier. Most new customers will face only 16 screens when completing a basic application versus 76 from the last enrollment cycle, and they'll be able to shop on a limited basis for insurance before signing up. HHS officials say the system can handle at least 125,000 simultaneous users. But searching for specific providers in plans does not yet work.

Attracting new enrollees might be a challenge, though. Many of the initial participants had pre-existing conditions or sufficiently low income to qualify for subsidies and were eager to sign up. Now it might be more difficult to bring in those who sat out last year's sign-up period. But the program's success has attracted more insurers, with HHS anticipating a 25% increase in firms offering coverage through the federal marketplace this year. The increased competition could limit premium hikes, but the range of options and rates will vary greatly from state to state.

An important issue for industry is whether the improved system will be able to transfer enrollment information to insurers, a shortcoming that took months to fix. Work on the program's back-end may not be finished until early next year, creating uncertainty about just when plans will be able to obtain updated data on beneficiary income and appropriate subsidies.

Retaining is key

To reach even unofficial enrollment goals, the program needs to retain those who signed up during the initial open enrollment cycle, which ran through March 2014. Insurers have sent out renewal notices with 2015 premium information, and returning plan members who take no action will be automatically renewed as of January 1.

However, it's not clear what beneficiaries should do if a plan has changed or is no longer the best deal for the individual in terms of costs, provider networks and drug coverage. HHS is encouraging enrollees to revisit the marketplace to make sure their personal information is correct so they get the right subsidy. But accessing current coverage information requires a 14-digit identity code, which many consumers may not know. Returning users will not be able to use the revised application process to make changes in coverage. And some 6 million beneficiaries with subsidized coverage may not realize there are changes.

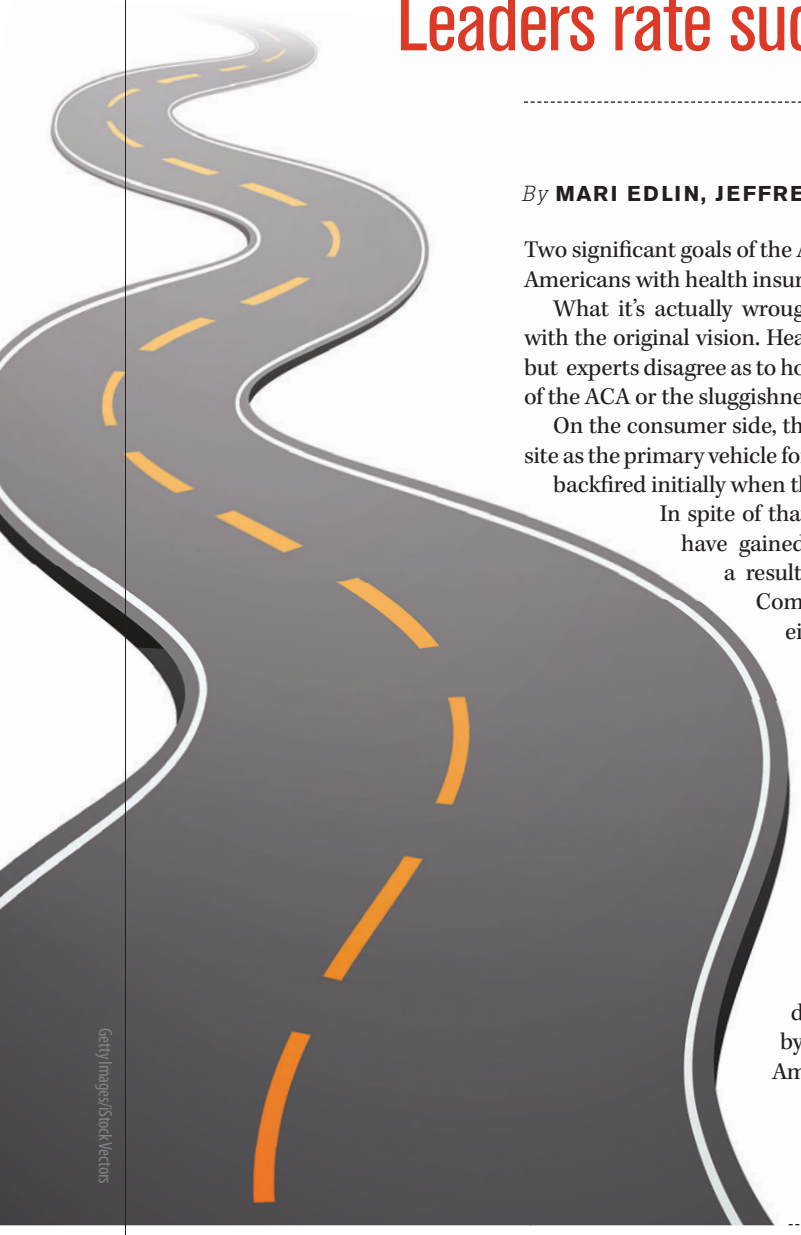
An added problem for insurers is that current beneficiaries have until February 15 to change coverage, which means it will be uncertain just who is staying in a plan until the end of the sign-up period. ■

ABOUT THE AUTHOR

Jill Wechsler, a veteran reporter, has been covering Capitol Hill since 1994.

ACA stakeholders voice hopes, fears going forward

Leaders rate success of law so far



Getty Images/iStockVectors

By **MARI EDLIN, JEFFREY BENDIX** *and* **LISA SMITH**

Two significant goals of the Affordable Care Act (ACA) are to provide more Americans with health insurance and lower the overall cost of healthcare.

What it's actually wrought so far hasn't always aligned with the original vision. Healthcare cost growth has slowed, but experts disagree as to how much that is due to the effects of the ACA or the sluggishness of the economy.

On the consumer side, the use of the healthcare.gov website as the primary vehicle for enrolling people in health plans backfired initially when the technology failed.

In spite of that misstep, 20 million Americans have gained health insurance coverage as a result of the ACA, according to The Commonwealth Fund. That includes eight million who purchased new healthcare plans through the insurance marketplace—outpacing the Congressional Budget Office's (CBO's) estimate of six million young adults who gained coverage under their parents' policies.

The number also includes adults and children eligible for Medicaid or the Children's Health Insurance Program, and individuals buying policies directly from insurers. The CBO estimates that by 2017 the ACA will result in 26 million fewer Americans being uninsured.

Continued on page 18

EXECUTIVE VIEW

- The ACA has helped more Americans obtain healthcare insurance.
- The ACA has not affected the underlying factors driving up healthcare costs.
- Efforts to repeal the ACA probably will not succeed.

"One of the things we know in our system is that primary care has been subjugated in order to give people a more direct route to...specialists and all the downstream procedures they do to make money."

– BRIAN KLEPPER, PH.D., CHIEF EXECUTIVE OFFICER, NATIONAL BUSINESS COALITION ON HEALTH

Continued from page 17

The ACA also set minimum standards for all health insurance policies, including coverage for preventive services and immunizations. In addition, it prohibits insurers from dropping members for any reason other than fraud and from rejecting anyone due to pre-existing conditions.

Critics of the legislation, including most Republicans, point to the penalty for not obtaining health coverage, the growth of narrow networks, new taxes, cyber threats, increased bureaucracy, and potentially higher premiums as reasons for repeal.

To gain perspective on whether the ACA is achieving its goals, *Managed Healthcare Executive* recently asked four key stakeholders to share their thoughts on what the legislation has accomplished thus far and its potential future impact.

Brian Klepper

Brian Klepper, Ph.D., is chief executive officer of the National Business Coalition on Health, a national, non-profit membership organization of purchaser-led healthcare coalitions.

Klepper credits the law with helping to solve America's uninsurance problem, but says the bill was distorted by excessive lobbying by the health industry—"$1.2 billion in 2009, the year the law was formulated."

"The industry successfully focused on two major goals. It achieved a 10% enhancement of coverage at public expense, increasing funding for their services. To my mind, this was a good thing because America's uninsurance problem has been and continues to be a national disgrace," Klepper says.

But that same lobbying "really did a number on any meaningful ability to control costs," he adds. "The result is that current cost patterns that are so excessive haven't changed much, and there's not much prospect for them to change, particularly until we move away from fee-for-service and go onto some form of risk. And things have gone very slowly in that direction."

"So far the ACO [accountable care organization] movement is going almost nowhere. And that's because they're still being paid effectively on fee-for-service, so there's really no incentive for them to change the way they deliver care or cost."

Pricing data transparency and safety and health outcomes are other areas that have yet to be impacted by the ACA, notes Klepper. "So far, still, the Medicare Physician database is only available to a few players. It's not really publicly available yet. So far we don't really have a national payer claims database that allows us to get access to health information that's more meaningful."

Another area yet to be reformed is primary care, which is "still subjugated very significantly," says Klepper. As a result, "we have a system that's upside down. Everyone else in the industrialized world has 70% primary care and 30% specialists. We have exactly the opposite. And our costs are double."

"One of the things we know in our system is that primary care has been subjugated in order to give people a more direct route to more lucrative services, to specialists and all the downstream procedures they do to make money. You see this most clearly in the work that's been done in the RUC [Relative Value Scale Update Committee]," says Klepper.

"What has happened over the last 20 years or so is that the RUC has systematically reduced the value, the weight of the evaluation and management codes in primary care, which in turn has caused primary care doctors to make their office visits shorter and shorter so they can get more visits in during the day and keep their rev-

Continued on page 20

Timesheet

Tork dispensers manage paper use to a T, cutting down on wasted cost and time every day. Just another way Tork helps your business run like clockwork.

towel | tissue | soap | napkins | wipers | torkusa.com

SCA *Care of Life*

Continued from page 18

enue up," says Klepper.

A primary care physician who's only getting paid for the office visit is financially incented to refer complex cases. "So whereas 25 years ago they might have handled it in their office, now they send it on," says Klepper.

"If you look at any commercial health plan claims data, you'll see somewhere between 25% and 35% of all employees and their family see a specialist during the course of a year. If you look at any industrialized country with a more rational primary care system, you'll see that system is around 10% to 12%."

Regarding recent slowdowns in the growth of healthcare costs, Klepper belives it's due to the economy. "There's good data now on that. If you knock a bunch of people out of work you get cost slowing. But there's nothing structurally in the ways that care is delivered or cost is created, there are no major changes in that. And that's ultimately what matters."

Klepper says narrow networks are useful when done right. "Some organizations, particularly conventional health plans, are going into the market and saying, 'Okay, who'll take the least amount of money?' And that's the wrong way. The right way is to use analytics to say, 'Okay, with a given condition in a given market, which physician, which hospital, consistently get better health outcomes that are quantifiable?'"

According to Klepper, using a narrow network to "focus my business on the people who get the best outcomes at the lowest costs is a great way to say: 'I only want the people who perform best,' and 'I'm going to put financial pressure on poor performers to come up to speed.' So there are all kinds of healthy things that come out of these."

Summary of the Affordable Care Act

2010

- Prohibit individual and group health plans from placing lifetime limits on the dollar value of coverage and prohibit insurers from rescinding coverage except in cases of fraud.
- Provide dependent coverage for children up to age 26 for all individual and group policies.
- Require all plans to offer screenings and preventive services without charging a copayment or deductible.
- Improve care coordination for dual eligibles by creating a new office within the Centers for Medicare and Medicaid services to more effectively integrate Medicare and Medicaid benefits
- Provide small employers with no more than 25 employees and average annual wages of less than $50,000 that purchase health insurance for employees with a tax credit.
- Authorize the Food and Drug Administration to approve generic versions of biologic drugs and grant biologics manufacturers 12 years of exclusive use before generics can be developed.

2011

- Create the Center for Medicare and Medicaid Innovation to test new payment and delivery system models that reduce costs while maintaining or improving quality.
- Restructure payments to Medicare Advantage (MA) plans by setting payments to different percentages of Medicare fee-for-service (FFS) rates.
- Require pharmaceutical manufacturers to provide a 50% discount on brand-name prescriptions filled in the Medicare Part D coverage gap.
- Develop a national quality improvement strategy that includes priorities to improve the delivery of healthcare services, patient health outcomes, and population health.
- Provide a 10% Medicare bonus payment for primary care services and general surgeons practicing in health professional shortage areas
- Require insurers to spend at least 80% of premiums collected on medical care.

2012

- Reduce Medicare payments to hospitals that exceed the cap for excess (preventable) hospital readmissions.
- Establish a national Medicare pilot program to develop and evaluate paying a bundled payment for acute, inpatient hospital services, physician services, outpatient hospital services, and post-acute care services.
- Impose new annual fees on the pharmaceutical manufacturing sector
- Allow providers organized as accountable care organizations (ACOs) that voluntarily meet quality thresholds to share in the cost savings they achieve for the Medicare program.

Source: The Kaiser Family Foundation. More at http://bit.ly/1tRjRTO

Paul Markovich

Paul Markovich is president and chief executive officer of Blue Shield of California, a 3.3-million-member, not-for-profit health plan serving the state's commercial, individual and government markets.

According to Markovich, "there's a tendency to attribute to the ACA everything good and bad that's happened in the healthcare system since the law's enactment. Clearly, that's unfair."

"The ACA had three major goals: expand access to care to lower- and middle-income people; reform the individual and small group health insurance markets; and nudge the healthcare system toward higher quality and greater cost efficiency. Those are the benchmarks that ought to be used to judge the law's success."

As for the intended versus actual effects of the law, Markovich says they are largely the same.

"Millions have gained coverage, pre-existing conditions are no longer a barrier to buying health insurance, and ACOs and other initiatives to reduce costs and improve quality have been launched all across the country," says Markovich.

"Unquestionably, there have been glitches and disruption, as is inevitable with any policy change as sweeping as this one. But those have been implementation problems that can and will be ironed out, as opposed to defects in the basic policy design of the law."

Signed into law March 23, 2010 (not a comprehensive list)

2013

- Require states to maintain current income eligibility levels for children in Medicaid and the Children's Health Insurance Program (CHIP) until 2019 and extend funding for CHIP through 2015.
- Increase Medicaid payments in fee-for-service and managed care for primary care services to 100% of the Medicare payment rates for 2013 and 2014.
- Require disclosure of financial relationships between health entities, including physicians, hospitals, pharmacists, other providers, and manufacturers and distributors of covered drugs, devices, biologicals, and medical supplies.

2014

- Expand access to coverage by requiring most U.S. citizens and legal residents to have health insurance.
- Prohibit insurers from denying coverage based on a pre-existing condition.
- Create an essential health benefits package and four categories of plans to be offered through the exchanges.
- Limit deductibles for small group health plans to $2,000 for individuals and $4,000 for families unless contributions are offered that offset deductible amounts above these limits.
- Provide refundable and advanceable premium credits to eligible individuals and families with incomes between 100% to 400% federal poverty level (FPL) to purchase insurance through the exchanges.
- Optional, state-level Medicaid expansion to all non-Medicare eligible individuals under age 65 with incomes up to 133% of the FPL based on modified adjusted gross income.
- Impose an annual fee on the health insurance sector.
- Create state-based Small Business Health Options Program (SHOP) Exchanges where individuals and small businesses with up to 100 employees can purchase coverage.

2015 AND BEYOND

- Assess employers with 50 or more full-time employees (FTEs) that do not offer coverage and have at least one FTE who receives a premium tax credit a fee of $2,000 per FTE, excluding the first 30 employees from the assessment.
- Assess employers with 50 or more FTEs that offer coverage but have at least one FTE receiving a premium tax credit: $3,000 for each employee receiving a premium credit or $2,000 for each FTE, excluding the first 30 employees from the assessment.
- Require employers with more than 200 employees to automatically enroll employees into health insurance plans offered by the employer. Employees may opt out of coverage.
- Impose an excise tax on insurers of employer-sponsored health plans (Cadillac tax) with aggregate values exceeding $10,200 for individuals and $27,500 for families.

> While it is too early to judge the effectiveness of the...experiments in quality improvement and cost effectiveness launched by the ACA, the law has already had a big impact on the mindset within the healthcare industry on these issues."
>
> — PAUL MARKOVICH, PRESIDENT AND CHIEF EXECUTIVE OFFICER, BLUE SHIELD OF CALIFORNIA

As for the ACA's progress, Markovich believes that its best assessed on a state-by-state basis.

"There has been a wide variation in success by state. As someone who supported from the outset the goals of the ACA, I feel good about what the law has accomplished so far, particularly in California. First and foremost, we've seen enormous progress in helping people with modest incomes become covered at an affordable cost. Expanded eligibility for Medicaid and premium tax credits are now helping make coverage affordable for millions of Americans. That alone is a huge accomplishment.

"In addition, the individual insurance market has been transformed so that coverage is now available on a guaranteed issue, modified community-rated basis and with a level of standardization that makes it a lot easier for consumers to do comparison shopping," Markovich says. "All of that has been done while avoiding the huge price spikes that many were worried would be an unavoidable side effect.

"While it is way too early to judge the effectiveness of the myriad experiments in quality improvement and cost containment launched by the ACA, the law has already had a big impact on the mindset within the healthcare industry on these issues," he says.

"The ACA has been a clarion call to all of us in the industry to improve our performance on costs and quality, and that will deliver benefits that go well beyond those envisioned by the law itself."

Stakeholder reaction in California has been "quite supportive," notes Markovich. "State officials have received significant help from insurers, as well as consumer advocates, in setting up a health insurance exchange that, despite growing pains, has succeeded in signing people up for coverage and keeping rates reasonable. The law and the attention it has focused on the need for reform has also helped to spur doctors, hospitals and insurers to collaborate on cost reduction and quality improvement. This is evidenced by the steady stream of new ACOs that we and other insurers and providers across the state launched."

Markovich says he expects opposition to the law to subside as outcomes emerge.

"I think with a little more time, the partisan heat around the ACA will dissipate and Republicans and Democrats will be able to work together on the reforms we still need," he says. "As we saw with the broad bipartisan support last year for draft legislation to move Medicare provider payment from volume-based fees to value-based fees, agreement exists between the two parties on key reforms. We'll get there; it's just a question of how soon."

Meg Murray

Margaret A. (Meg) Murray, MPH, is chief executive officer of the Association for Community Affiliated Plans, (ACAP), which represents 58 nonprofit Safety Net Health Plans in 24 states.

Murray says that health reform's first measure of success "is the degree to which it reduces the prevalence of uninsurance or underinsurance in the United States. The high rate of uninsurance is our health system's most glaring defect." To that end, Murray says, the ACA is succeeding.

As for critics, Murray notes that "facts always win out in the long run."

"We're getting to the point where the facts on the ground are beginning to win out over political rhetoric," Murray says. "Uninsurance rates are going down. Premiums haven't skyrocketed; they've risen very modestly. Consumers in the individual market with pre-existing conditions can now find reasonably priced, full-benefit coverage through the marketplaces."

She cites several provisions of the law that could reform healthcare delivery, including the collection of a core set of quality measures

for children and adults enrolled in Medicaid. "While data on pediatric care has been collected for a couple of years, we'll see the first report on adult core measures this fall. Collecting these data nationally will be a crucial guide for policymakers to better analyze what we purchase for our healthcare dollar and improve Medicaid," she says.

State reporting, however, is voluntary, notes Murray. "Only two-thirds report anything, and most report on a subset of measures. Sen. Jay Rockefeller (D-W.V.) has proposed a bill that would mandate states report on all the core measures."

Murray says the U.S. Supreme Court decision leaving Medicaid expansion up to each state altered the course of the ACA. "It's allowed for some creative implementations of the expansion. The Arkansas model is a well-covered example of this and there are some interesting features in Pennsylvania's recently approved waiver.

"However, more than 20 states have not yet expanded Medicaid. While ACAP believes that states will eventually do the right thing and expand their programs, this is of little comfort to people in those states who urgently need care today."

She expects more states will continue to expand Medicaid as results become known. "When states with Republican-controlled statehouses like Pennsylvania, Wyoming and Indiana are taking up the Medicaid expansion, that sends a clear signal about the direction in which we're headed," she says.

Murray says the ACA has sparked new initiatives like the Safety Net Health Plans and accelerated others already in the works.

"The Medicaid expansion in particular has served as a real opportunity for Safety Net Health Plans and others to demonstrate the value that they add to the healthcare system. Many plans are devoting resources to addressing social factors that have an outsized influence on health. For instance, it's sometimes less costly and more effective for a Safety Net Health Plan to connect a member to housing than to keep them in a nursing home.

"Our plans have also expanded into new spaces: Sixteen Safety Net Health Plans have entered the marketplace. Another 17 are participating in, or planning for, dual demonstration programs in states around the country," she says.

Murray adds that the law has the potential to reform the nation's healthcare delivery system "in a way that puts health above healthcare, that moves purchasers towards being smarter healthcare shoppers, and that gets us away from reimbursing care by the encounter or by the procedure."

Her organization is exploring the use of bundled payments that would provide a single payment for a given medical episode. "This has appeal to payers," notes Murray, "because it provides greater cost certainty while at the same time providing incentives for better quality and fewer avoidable complications. Accordingly, we have established a collaborative of a small number of Safety Net Health Plans that are working together such that they can implement bundled payments where they're called for. It's an exciting development."

"When states with Republican-controlled statehouses like Pennsylvania, Wyoming and Indiana are taking up Medicaid expansion, that sends a clear signal about the direction in which we are headed."

— MEG MURRAY, MPH, CHIEF EXECUTIVE OFFICER, ASSOCIATION FOR COMMUNITY AFFILIATED PLANS

Greg Vigdor

Greg Vigdor, JD, is president and chief executive officer of the Arizona Hospital and Healthcare Association, which serves as an advocate for issues that impact the quality and accessibility of healthcare in Arizona.

Vigdor urges patience when assessing the ACA's progress. "History is replete with examples of policy initiatives prematurely—and incorrectly—judged a success or failure. And few of these compared to the ACA in terms of

> It seems clear that the ACA has already provided additional health coverage to many of the uninsured in the country...and prospects are good that these expansions of coverage will sustain, at least in the near term."

– GREG VIGDOR, JD, PRESIDENT AND CHIEF EXECUTIVE OFFICER, ARIZONA HOSPITAL AND HEALTHCARE ASSOCIATION

scale and scope.

"It seems clear the ACA has already successfully provided additional health coverage to many of the uninsured in the country and in Arizona, where I live—and prospects are good that these expansions of coverage will sustain, at least in the near term," notes Vigdor.

Less clear, he says, "is whether the Act will trigger real reductions or control in our level of healthcare spending and, if it does, whether these are positive savings related to real improvements in care, or just government or private-sector price cutting. Sustainability of improvement will be key to identifying whether these changes are embedded into long-term policy or merely aberrations."

As for Republican promises to repeal the law, Vigdor notes they appear to be subsiding. "This was predictable, as large numbers of Americans are now receiving health coverage per the ACA, so its repeal would come at a significant political cost. We saw a similar evolution in recent decades with regard to political support for Medicare.

"Now, both political parties scramble for the high ground when it comes to protecting Medicare. In Arizona, we are hopeful the prolonged fight over Medicaid restoration and expansion is finally concluded. In the recent primary election, voters overwhelmingly sided with legislators who supported the Medicaid initiative, giving wins to every Republican lawmaker who voted in support of the law. Now it appears certain neither the next legislature nor governor intends to undertake an effort to repeal the law."

Vigdor faults the ACA for trying to be all things to all stakeholders. "Several times we have seen deadlines come and go, replaced by significant delays in moving forward with key parts of the act. Whenever this happens, it communicates that government remains a great source of unpredictably for those trying to implement the most difficult pieces of the law-providers trying to reshape delivery systems to provide better care at lower cost," he says.

"The government needs to become far more reliable in this regard," Vigdor adds. "Providers are highly sensitive to these abrupt changes, as it can mean the difference between success and failure in what are already high-risk strategic responses."

Vigdor says the narrow networks model "as a contracting strategy is making the provider world nervous.

"It may be seen as an opportunity by some, but it makes most wonder how these networks will affect their current patient relationships. Even if communicated well, many patients are unhappy to discover that they can no longer see 'their' physician or hospital. It isn't usually communicated that well, which makes this change even more difficult for continuity of patient care. Worse yet is when patients discover that they have to travel great distances to access care under that 'cheaper' plan they selected. We have seen that occur across our very large and geographically dispersed state and it is a real hardship."

As far as the ACA advancing the move away from fee-for-service, Vigdor says that's happening in the private insurance world too, but "moving from a volume-based payment approach to one of value is far easier said than done.

"For one, the shift must be comprehensive enough or providers will be in the nightmare scenario of trying to deliver care within both models. While providers do now see the need to shift to a new model, they also know that moving too soon will put them in financial peril.

"The ACA is critical to this transformation in approach because Medicare is such a large book of business for most," says Vigdor. "And… one of the problems is that the government has been a most unpredictable partner in this transition, moving timelines and approaches without enough sensitivity to how this impacts providers trying to change this core payment model.

"They've got to do better in this regard, or providers will be forced to hang on to the fee-for-service payment model for dear life—and even fight the change itself."

CO-OPs cautiously optimistic

Better rates, website improvements could boost enrollment

by **BOB PIEPER**

Considering the challenges they faced during the first Affordable Care Act (ACA) health insurance marketplace open enrollment period, Consumer Operated and Oriented Plans (CO-OPs) overall are doing "very well," according to Janice VanRiper, JD, PhD, executive director and chief executive officer of the National Alliance of State Health CO-OPs (NASHCO).

The new consumer-directed, not-for-profit health plans have signed up some 450,000 members across the nation—less than the 575,000 originally forecast for their first year, but still representing 18% of all ACA exchange plan enrollees to date. While NASHCO has not established a national enrollment target for the next ACA open enrollment period, which begins Nov. 15, CO-OP organizers are cautiously optimistic.

Under-performance among CO-OPs during the last enrollment period is generally attributed to several factors, VanRiper said.

CO-OPs rely heavily on Healthcare.gov and state insurance exchange websites—which were famously subject to technical problems last year—as an enrollment mechanism. Enrollment through the websites is generally expected to be much improved this year, VanRiper notes.

Although the nonprofit CO-OPs were developed in part to help ensure the availability of low-cost health plans on the exchanges, lacking sufficient actuarial data, many of them set premium rates above those of competing commercial plans. This year, with better data in hand, most CO-OPs are either cutting premiums or not raising them as much as competing commercial plans, meaning they should be attractive to consumers during the upcoming enrollment period, VanRiper says.

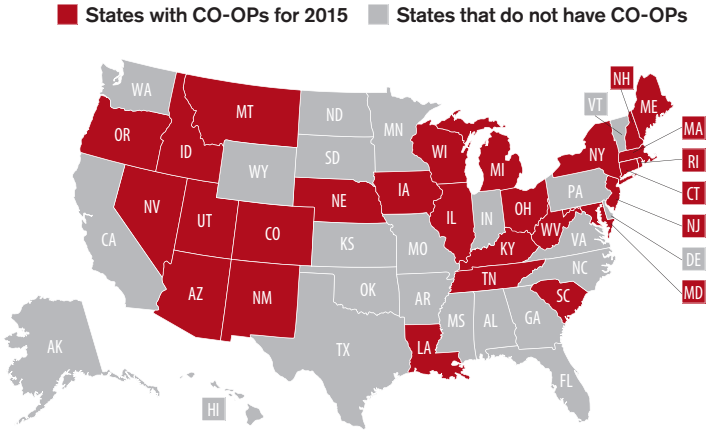
In addition, the Obama administration's decision to allow anyone with insurance to keep their existing plans reduced the market for all new entrants in the health insurance market, including CO-OPs, VanRiper notes.

CO-OP plans face "the challenges of any new product entering the insurance market," VanRiper says. Many consumers may not be familiar with the concept of an insurance CO-OP or its potential advantages for enrollees. Federal law prohibits the use of federal CO-OP funding for marketing, although some CO-OPs have raised additional capital with which to undertake advertising or marketing.

Despite challenges, all 23 of the CO-OPs that offered health plans on exchanges last year will be back for 2015 and some are even expanding. The Montana Health CO-OP will offer coverage in Idaho. The Kentucky Health Cooperative will start selling plans in West Virginia. Minuteman Health of Massachusetts and Maine Community Health Options both are expanding into New Hampshire. InHealth Mutual will enter Ohio's health insurance marketplace in 2015 after selling off-marketplace plans during 2014.

Because last year's "fiscal cliff" budget agreement cut off federal CO-OP start-up funding, no new CO-OPs will be entering the market this year. However, no CO-OPs are dropping out of the market, VanRiper says.

Consumer Operated and Oriented Plans*



Source: National Alliance of State Health CO-Ops
*As of October 1, 2014

For 2014, premiums for health insurance exchange plans were 9% lower in states with CO-OP plans.

Among the 24 organizations that have applied for ACA CO-OP funding, only one, the Vermont Health CO-OP, is not operational. The Centers for Medicare and Medicaid Services (CMS) recalled the Vermont cooperative's federal loans in September 2013—before the opening of the ACA insurance exchanges—after state regulators refused to issue the CO-OP an insurance license. Regulators doubted that the CO-OP could attract sufficient membership with the state moving to establish a single-payer insurance program in 2017.

CO-OP critics, including U.S. Rep. Darrell Issa, chair of the House Oversight and Government Reform Committee, have expressed concern that CO-OPs may not be able to repay their government loans, leaving taxpayers with a sizable bill, or may dissolve, leaving beneficiaries with unpaid medical bills.

Federal CO-OP start-up funding provides separate loans for working capital and to meet state solvency requirements. Repayments for both classes of loans are not required for five years. For that reason, CO-OPs are generally expected to have little trouble meeting state solvency requirements, maintaining operations, or paying claims through 2017.

VanRiper reports that all of the nation's ACA CO-OPs are currently meeting state solvency requirements and "absolutely" will be able to repay the loans provided by the federal government.

"If there were any danger of that, plans would already be talking with CCIIO [Center for Consumer Information and Insurance Oversight], the agency within CMS that regulates CO-OPs, and none are," VanRiper said. All CO-OPs have been submitting required state and federal filings in a timely manner, she adds.

However, internal government reviews and a federal audit suggest 10 or more CO-OPs may encounter financial problems.

Attracting sufficient enrollment this year to maintain fiscal viability will be important, VanRiper acknowledges. In addition, first-year enrollment results among the nation's health insurance CO-OPs has been "varied," she says.

Nine of the nation's 23 CO-OPs met or exceeded targets for their first open enrollment period, according to an analysis by the *Wall Street Journal*, with several greatly exceeding expectations. Those nine accounted for the overwhelming majority of CO-OP enrollment for 2014, with several under-performing CO-OPs substantially missing targets.

SURPASSING EXPECTATIONS

Among those surpassing enrollment goals during their initial enrollment period was Health Republic Insurance of New York (formerly the Freelancers Health Service Corporation) cooperative, which is often cited as the nation's most successful ACA CO-OP. The CO-OP had some 112,000 enrollees as of April 2014—compared with a goal of 30,000—attracting 19% of those who purchased insurance through New York State of Health, the state's ACA insurance marketplace.

The CO-OP offered some of the lowest premiums on the exchange. It was developed by the Freelancers Union, an association of independent New York workers, which has been offering a highly popular health insurance program for decades. However, the union recently spun off the CO-OP as a separate entity and sold its traditional insurance program to Empire BlueCross BlueShield.

Others exceeding their expectations include Maine Community Health Options, which attracted 44,000 members—more than 80% of the exchange plans purchased by Mainers for 2014. CoOportunity Health has more than 85,000 members in Iowa and Nebraska. The Kentucky Health Care Cooperative is also widely cited as a CO-OP success story. The CO-OP captured 75% of the business on Kentucky's health insurance

exchange during its initial open enrollment period.

Among those pretty much hitting enrollment projections were the Montana Health CO-OP with 5,400 enrollees, and Colorado HealthOp, which garnered about 10% of exchange enrollment in its state. New Mexico Health Connections enrolled about 10,000 members.

The Nevada Health Cooperative, hampered by problems with the state's malfunctioning Nevada Health Link exchange, fell a bit below its enrollment goal, despite signing up 37% of the 13,000 Nevada residents who purchased insurance through the exchange.

Among the CO-OPs facing challenges is Illinois' Land of Lincoln Mutual Health Insurance Company, which enrolled just 2,451 members and lost more than $4 million in its first quarter of operations. Over that period, the Chicago-based insurer recorded $1.9 million in premium revenue against $6.1 million in expenses, including $1.6 million in payments for medical services and prescription drugs and $4.5 million in claims adjustment and administrative expenses, according to a filing with the National Association of Insurance Commissioners.

Massachusetts' Minuteman Health, Inc. is re-launching, after attracting about 2,000 members against projections of 37,000. The CO-OP got off to a late start with no products listed on the marketplace until January 1, 2014.

Massachusetts Health Connector's website failures presented additional problems. Because of technical glitches, officials allowed 300,000 residents to enroll in temporary Medicaid and another 100,000 to remain in the state's Commonwealth Care program for another year—thereby reducing the potential market for Minuteman's products.

CO-OPs everywhere will be aggressively pursuing membership growth during the upcoming marketplace enrollment period, VanRiper says. However, enrollment is not the sole measure of success, she adds.

CO-OPs were included in the ACA to provide additional competition for commercial plans in health insurance exchanges and exert downward pressure on premiums. For 2014, premiums for all health insurance exchange plans were 9% lower in states with CO-OP plans, compared with states having no CO-OPs, according to NASHCO.

A McKinsey & Company report found that CO-OPs offered the most products among all new insurance companies in the marketplaces, creating more choices for consumers. The same report showed that CO-OPs offered 37% of the lowest priced plans in the states in which they operate, and were the most likely of all insurers to have plans within 10% of the lowest priced option. Savings realized from lower premiums could be in the billions for both consumers and taxpayers as a result of fewer subsidies paid out, according to NASHCO.

"CO-OPs and HMOs exhibited significantly lower premiums than other plan types," Amy Burke, Arpit Misra and Steven Sheingold say in a June research brief from the U.S. Department of Health & Human Services Office of the Assistant Secretary for Planning and Evaluation.

Although CO-OPs are intended to appeal to price-conscious consumers, most CO-OPs reported that their members generally have selected premium-level plans, according to NASHCO.

CO-OPs are intended to facilitate development of a more patient-centered healthcare system, VanRiper says. As defined in the ACA, CO-OPs must be consumer-directed, with a majority of board members being premium-paying plan enrollees. All 23 CO-OPs will meet that requirement this year. Many have already held board elections and some boards are composed entirely of CO-OP members.

Proponents believe that consumer orientation ultimately will be a key factor in making CO-OPs a force in the healthcare insurance marketplace. "When you have that kind of direct consumer input to the plan management, you really know what your consumers want," VanRiper says.

The ACA also stipulates that CO-OPs should facilitate high-quality, patient-oriented care—a requirement they have begun to meet in just their first year of operation, VanRiper says. Coordinated care is heavily emphasized by virtually all CO-OPs, with one maintaining its own network of four patient-centered medical homes (PCMH) and others maintaining relationships with one or more PCMHs.

Many CO-OPs offer provider incentives for coordinated care and have integrated behavioral health services. At least one has medical homes with a behavioral health component. Another offers beneficiary incentives for early utilization of behavioral care resources, she says.

Bob Pieper *is a freelance healthcare writer based in St. Louis.*

WHAT EMPLOYERS WANT FROM HEALTH PLANS

Defined contributions help control costs

by **JOANNE SAMMER**

Employer-sponsored healthcare benefits are not insulated from the changes taking place in the broader healthcare marketplace. However employers, particularly large employers, are attempting to drive the conversation and actions toward issues that are important to them. One of the best ways to do that is to pressure health plans to help them achieve their healthcare goals.

Quite simply, given the large cost increases employers continue to face, they want more for their money and they expect health plans to help them get it. Whether they are self insured with administrative services only (ASO) arrangements or fully insured, employers expect more from health plans.

Data analytics

No matter what their size or situation, employers are looking for data. "They want data to support how pricing was developed [and to understand] what kinds of claims are driving costs and what kinds of wellness or education programs can be implemented to improve health and productivity," says Rudy Garcia, president of Qandun Insurance Agency, Inc. in Glendale, California. Better health and productivity can not only control the cost of health benefit programs but also "reduce workers compensation claims and keep employees healthy and at work, reducing absenteeism, presenteeism and overall turnover of the workforce," he says.

If that seems like a tall order, it is. But that doesn't mean employers won't stop asking for what they want. "The data and analytics piece in healthcare is becoming increasingly sophisticated," says Ash Shehata, a partner at KPMG LLP.

"Employers are demanding greater transparency in the cost and quality of healthcare," Shehata says. He notes that data analytics can allow health plans to be more predictive about the expected costs of healthcare even down to the individual employee level.

Another way employers want to use data is to identify whether their efforts at managing costs and care are working as expected and where to concentrate those efforts. "This can include data that highlight where an employer's experience with medical service price variation or inappropriate care—seeking behaviors can be addressed through new programs or consumer tools," says Greg Mansur, a principal in the healthcare practice of PricewaterhouseCoopers in Los Angeles.

New performance metrics

In the past, strong administration and customer service were key employer focuses when evaluating health plans. Employees and their dependents had to have access to the care they needed and the health plan had to deal with the resulting claims quickly and accurately. The performance metrics employers used to measure health plan performance reflected this and tended to focus on performance guarantees for areas such as claims service, customer service, network adequacy, and various process measures around other service functions such as ID card

> "The Triple Aim is on the minds of many employers today:
>
> **1** improving the health of their populations,
>
> **2** improving outcomes for patients while improving the patient/care experience and
>
> **3** reducing per capita costs."
>
> --GREG MANSUR, A PRINCIPAL IN THE HEALTHCARE PRACTICE OF PRICEWATERHOUSECOOPERS IN LOS ANGELES

delivery and medical management performance, says Mansur.

Now, employers are looking for health plan partnerships focused on much broader objectives. "The 'Triple Aim' is on the minds of many employers today: (1) improving the health of their populations, (2) improving outcomes for patients while improving the patient/care experience and (3) reducing per capita costs," says Mansur. "Health plans are viewed as critical partners in these objectives."

Metrics associated with wellness extend beyond health insurance claims. "Employers are also looking at managing disability costs and what the health plan is doing to keep people well," says Shehata. To that end, employers are focused on metrics relevant to those goals, such as days lost to disability. In addition, employers want to identify what can prevent large medical claims, such as metrics on the success of smoking cessation programs, how well individuals adhere to their medication regimens, and the outcomes of disease management programs. For example, the latter might translate into simple questions such as, "Are my diabetic employees staying out of the ER?" says Shehata.

Meeting performance expectations is not the only metric of success in today's employer/health plan relationship. "We are seeing a greater emphasis now on how carriers achieve outcomes that reduce costs, improve health or improve consumer engagement," Mansur says.

Defined contribution health benefits

One of the most significant developments in employer-provided healthcare benefits is the slow but growing shift toward a defined contribution approach to financing these benefits. Much like the shift from traditional pension plans to 401(k) plans for retirement, the move to defined contribution healthcare benefits would provide employees with a defined contribution toward their healthcare coverage rather than a set benefit. In other words, instead of employers offering one or more plans with employees contributing a certain percentage or amount for the coverage, employers using a defined contribution approach would provide employees with a lump-sum amount that employees can use to purchase healthcare coverage. If the coverage costs more than the employer's contribution, the employee must make up the balance.

"Employers see a defined contribution as a way to better control their costs," says Shehata. In support of this shift, "private exchange products are gaining a lot of traction among employers." Health plans that work with employers moving toward this defined contribution approach will also need to do things a bit differently.

For one thing, "a defined contribution model needs to operate within the parameters of the health reform law and this means that the cost of plans that meet the minimum thresholds for plan value and affordability stay that way," says Mansur. "Health plans need to deliver better trend performance for employers to make the transition to defined contribution a real success."

A major part of that is finding ways to help individuals become better and more informed consumers of healthcare services. "Being able to effectively engage consumers so that they make good care decisions [will help to ensure] that the health plan network is delivering real value in terms of cost and quality," he says.

Joanne Sammer is a freelance writer based in Kansas City.

A continuing role for brokers, but for how long?

In this environment, brokers will continue to play an important role, especially for small and mid-sized employers. However, instead of transactional relationships, smart brokers are developing more consultative client relationships. In addition to offering expertise and advocacy when choosing and evaluating health plans, brokers are looking for ways to add value by providing new insight, services and expertise to help employers do everything from managing their regulatory requirements under the Affordable Care Act, to managing costs and providing needed insight and advice on how to achieve goals for their employee health benefit programs.

For example, brokers can "provide a third-party perspective on the cost, service and value propositions of different carriers," says Mansur. Then, they can help match the carrier to that employer's unique business needs and the characteristics of the covered population. Beyond that, brokers can also help "employers analyze contribution strategies, value the impact of plan changes, negotiate with carriers on price and service and assist employers in monitoring the results, helping them to understand how the service and value they are receiving compares to the current state in the marketplace," he says.

How well brokers are meeting these expectations is open to question. According to the 2014 Broker Services Survey of 3,725 insurance buyers conducted by technology firm Zywave, the vast majority of employers expect more from their brokers but are not always receiving it. While almost all employers surveyed want help keeping current with regulatory and legal requirements and help with wellness programs, only about half actually receive the help they want.

AUTISM: TAMING A NIGHTMARE

No cure, no cause, but still some options

by **SCOTT BALTIC**

In many ways, autism is a nightmare condition for health plans. Its prevalence appears to be skyrocketing, it typically requires long-term treatment, diagnoses are being made at younger and younger ages, there is a plethora of therapies (some evidence-based, some entirely fanciful), and some therapies can be very expensive. Oh, and there's no cure for the condition, nor even a firm evidence-based etiology for it.

Fortunately, a few things do mitigate what might otherwise seem like an overwhelming situation.

How many cases?

Most prominent is the fact that, despite some scare-mongering, autism has not actually surged out of control.

Talk of an "autism epidemic" is misleading, says Allison Singer, MBA, president of the Autism Science Foundation. "We know there's an increase in measured prevalence, but we don't know if there's an increase in incidence."


SINGER

When Singer's older brother was diagnosed with autism in 1968, she explains, autism's prevalence was estimated at 1 in 10,000. It was a time when diagnostic criteria for autism were much more restrictive than those currently used.

Autism in the 1960s was still often diagnosed as "childhood schizophrenia." It wasn't until 1980, and the publication of the Diagnostic and Statistical Manual (DSM)-III that autism was distinguished as a separate condition. In 1994, the DSM-IV added Asperger syndrome, and in 2013, the DSM-V rolled all subcategories into the autism spectrum disorder (ASD) diagnosis.

So it should have been no surprise when the Center for Disease Control and Prevention's (CDC) *Morbidity and Mortality Weekly Report* for March 28, 2014, estimated that (per 2010 data) one in 68 U.S. 8-year-olds has an ASD diagnosis (not classic, severe autism *per se*.) Even though the CDC noted that the 1-in-68 figure was not necessarily reflective of the U.S. population as a whole, the number was large enough—and enough of an increase over the 2012 estimate of one 8-year-old in 88—to fuel renewed media coverage of an "autism epidemic."

Singer says the term 'autism' is clinically meaningless because the diagnostic criteria are so much broader now. "It doesn't describe a distinctive cluster of symptoms any more," she notes.

Its quasi-replacement, ASD, is also fairly meaningless, she contends, because it provides no guidance for therapy. (Does the patient exhibit aggression? Self-injury? Does the patient have speech difficulties? A low IQ? A high one?)

The evolving definitions of autism in successive DSMs have wrought havoc on diagnosis and on research, Singer says.

"The definition [of autism] has changed drastically over time," says Susan Levy, MD, MPH, of the Children's Hospital of Philadelphia and member of the autism subcommittee of the American Academy of Pediatrics' Council on Children with Disabilities.

She agrees with Singer that there is no autism epidemic, that is, no sudden increase in cases traceable to a risk factor, though she's more amenable to the changed diagnostic criteria in DSM-V, saying, "It's better science."

Another factor in the general increase in ASD prevalence, Levy suggests, is that the average age at diagnosis was age 5 or 6 years about 10 years ago, whereas now it's starting to dip below age 4 and has the potential to drop closer to age 2.


DR. LEVY

Finally, ASD cases might actually be on the rise. Dr. Levy believes that environmental exposures to chemicals are a likely culprit.

"There has been a major shift in how we define, recognize and even conceptualize autism," starting in the 1970s and throughout the 1990s, says Jon Baio, Ed.S. an epidemiologist with CDC's developmental disabilities branch.

A major concern, he says, is "whether the rapid and recent increase in autism prevalence estimates is attributable to changes in etiologic risk factors or simply to our shifting classification and perception of autism, our increased focus on autism in science and the media, and our expanded funding and


BAIO

legislation for autism services.

"It seems unlikely that the steady rate of increase in reported ASD prevalence estimates is still closely tied to the introduction of DSM-IV 20 years ago. There are clearly other factors at play," Baio says.

Regarding the CDC, he says, "the biggest question is not about 'measured' vs. 'actual' prevalence, it is why such wide variation exists among different U.S. communities, racial/ethnic groups, and socioeconomic classes in how individuals are getting evaluated, diagnosed, and served for their autism, and what can be done to reduce these disparities."

Costs and reforms

Behind all the questions about autism's prevalence, of course, looms the issue of cost.

In 2005, after Judith Ursitti's son was diagnosed with autism at age 2 as a result of routine developmental screening, Ursitti was referred to a pediatrician who prescribed several therapies including speech therapy, occupational therapy, physical therapy (for a delay in walking) and applied behavior analysis.

Ursitti's health insurer denied coverage for all these therapies, because autism was specifically excluded under her policy. The interventions cost the family $3,000 to $5,000 per month at that time, says Ursitti, who is now director of state government affairs for Autism Speaks, an advocacy group.

As a result of that experience Ursitti, then living in Texas, became an advocate for a law in that state requiring that evidence-based ASD therapies be covered by state-regulated insurers. The law was enacted, initially covering children ages 2 through 5, though the upper age was later raised to 10, and now there is no age limit, says Ursitti.

Meanwhile, the family had moved to Massachusetts, where Ursitti again got involved in an effort to pass state-level autism insurance reform. The law was enacted in 2010, so Ursitti's family finally has insurance coverage for autism interventions.

Ursitti says 37 states now have similar laws. And as a gauge of costs, the average premium impact on state-employee health plans has been 31 cents per month per member, she says.

URSITTI

Insurers' initial fears that premiums would surge, Ursitti adds, were based on "a misunderstanding of the autism spectrum."

Meanwhile, Medicaid has been adding its voice. On July 7, the Centers for Medicare & Medicaid Services (CMS) and Children's Health Insurance Program Services issued an informational bulletin clarifying Medicaid coverage of services to children with autism.

Though the bulletin does not create new coverage requirements, it might cause some state Medicaid programs to provide "additional or expanded ASD treatment services," with an emphasis on the early and periodic screening, diagnosis and treatment requirement, according to the American Academy of Pediatrics (AAP). California, according to the AAP, has begun to cover applied behavior analysis services as a result of the CMS bulletin.

Not insurers alone

Another mitigating factor on the ASD front is that mainstream advocacy groups aren't pushing for reimbursement for anything beyond evidence-based therapies.

"We're not asking for dolphin therapy," says Ursitti, nor chelation therapy, nor experimental treatments, nor supplements, nor hyperbaric oxygen, all of which are unproven.

Levy adds that some non–evidence-based ASD interventions can be dangerous, including stem cell transplants, exclusion diets and chelation.

A June article in *JAMA Pediatrics* reported findings by a team of researchers from the United States and United Kingdom, who had estimated the lifetime direct and indirect economic costs for one individual with ASD.

They found that for individuals with autism and intellectual disability, the average lifetime cost was $2.4 million in the United States and a surprisingly similar—given how different the two countries' health systems are—$2.2 million in the United Kingdom.

For individuals without intellectual disability, the average lifetime cost was $1.4 million in either country. For children with ASDs, the largest costs were for special education and parents' lost wages, and for adults with ASDs, they were residential care and lost wages.

Medical services costs comprised 30.9% of the average total annual costs for an adult with ASD with intellectual disability and 27% of such costs for an adult with ASD without intellectual disability. The corresponding portions for children were 16% and 13.4%, respectively.

One lesson that can be drawn from this study is that autism has costs and ramifications far beyond the healthcare realm.

For example, Ursitti notes that the federal Individuals with Disabilities Education Act (IDEA) mandates certain kinds of assistance—not healthcare, but instead aiming at educational goals—for children with disabilities, including ASD.

"In theory, that's a great idea," she says. "In practice, there's no money." Still, Ursitti adds, "We're not asking insurers to handle it all."

That is, part of the ongoing ASD cost burden will be borne by the educational system, local social services and potentially Medicaid, she says, adding, "it's not appropriate to expect health insurers to cover everything." ■

Scott Baltic *is a freelance writer based in Chicago.*

WEIGHING THE BENEFITS OF ANTI-OBESITY DRUGS

Few insurers reimburse for the drugs

by **MARI EDLIN**

Despite the fact that approximately 2.74 million patients used anti-obesity drugs in 2011, according to information services company IMS Health, the majority of health plans are following the lead of the Centers for Medicare and Medicaid Services and not covering them.

More than one-third of adults (34.9%) and 17% of youth in the United States are obese, according to the Centers for Disease Control and Prevention (CDC). The estimated annual medical cost of obesity in the U.S in 2012 was $190.2 billion, or nearly 21% of annual medical spending, according to the *Journal for Health Economics*, and the medical costs for obese people were $1,429 higher than those of normal weight, according to the CDC.

Caroline Apovian, M.D., professor of medicine and pediatrics at Boston University School of Medicine, attributes the small number of plans that cover weight-loss drugs to an historical perspective that obesity is a "matter of will power." She applauds the American Medical Association for declaring obesity a disease last year, a decision hopefully "making many payers stop in their tracks."

Apovian combines diet, exercise and weight-loss medications as treatment for her patients and says that most lose 5% to 10% of their body weight in six months to a year.

The high prices of obesity drugs, a lack of primary care physicians who specialize in treating obesity, and the fact dieticians are not reimbursed by most insurers are other factors keeping the drugs off many formularies.

Apovian notes that many health plans do reimburse physicians for counseling and treating obese patients with comorbidities during office visits, however.

Measuring benefits of two weight-loss drugs

Aetna is taking a pioneering step in the pharmacotherapy arena of weight-loss drugs. The Hartford, Connecticut-based insurer announced a pilot program in January to test the benefits of Qsymia (VIVUS) and Belviq (Eisai)—both approved in 2012—in conjunction with lifestyle support, for self-insured plan sponsors who choose to cover prescription weight-loss drugs. While there is no specific launch date, companies are expected to join on an ongoing basis through 2015. The pilot will measure potential improvement in health outcomes, productivity and medical costs.

More than 4,000 members currently have coverage for prescription weight-loss drugs and are eligible to participate in the pilot. By the beginning of 2015, Aetna expects more than 35,000 members will be eligible to participate.

Members are eligible if they meet the body mass index (BMI) clinical requirements outlined for the two drugs (see "Third anti-obesity drug is approved for use in U.S.", page 4) and have a doctor prescribe the medications. Other prescription weight-loss drugs may be covered, but only Belviq and Qsymia will be evaluated as part of the pilot.

In collaboration with the manufacturers of Qsymia and Belviq, the pilot offers outreach to high-risk members and doctors outlining covered weight-loss options. Members who qualify will also receive free premium membership to the mobile app "Lose It!" by signing up through Aetna Navigator and CarePass.

"Weight loss is a complex, physical and emotional challenge," says Ed Pezalla, M.D., national medical director for pharmacy policy and strategy at Aetna. "A single approach to weight loss will not be right for everyone.

"We want to help our members make healthy lifestyle choices with their doctors by providing access to clinically proven options, information and support that may deliver better results and new hope for those struggling to lose weight," he says. "At the same time, plan sponsors have the option to cover these prescription weight-loss medications in Aetna's health benefit plans. We are conducting the pilot to give plan sponsors more information about the potential value of weight-loss drugs."

Pezalla says that the majority of self-insured employers do not offer coverage for prescription weight-loss drugs. If they do elect coverage, the medications

may be subject to coverage for medical necessity only and require preauthorization following a set of requirements.

Patients using Belviq and Qsymia also require reauthorization at 12 weeks. Patients taking Belviq have to show a documented weight loss of at least 5% of baseline body weight. For Qsymia, the requirement is at least 3% of baseline body weight.

For companies in the pilot who do cover weight-loss drugs, the medications are available on tier 2—preferred branded drugs—through retail and mail order pharmacies.

If the drugs are covered under the medical benefit, they are reimbursed through a weight-loss rider.

Aetna plans to evaluate results in the next 12 months.

Coverage: Not an easy decision

Determining if weight-loss drugs should be covered by insurers is definitely not cut and dried, says Andrew Behm, Pharm.D., vice president of clinical evaluation and policy for Express Scripts, a St. Louis-based pharmacy benefits manager.

Although he says the obesity epidemic has grown and Express Scripts' clients are more open to drug and non-drug related solutions, the high cost of these medications, along with uncertain benefits for health and productivity, need to be weighed carefully before coverage decisions are made.

The price for a 30-day supply of Belviq and Qsymia, using coupons or discounts from their manufacturers, ranges from $110 to $178, according to GoodRx.com.

"The potential benefits of these new anti-obesity medications need to be compared against their risks and cost," Behm says.

"In light of these shortcomings, plan sponsors have a variety of ways that they address weight-loss medications," Behm says. "At Express Scripts, we commonly see three approaches: outright coverage without any restrictions, outright benefit coverage exclusion; and perhaps the most common approach, drug therapy coverage as long as the patient meets specific body mass index requirements, plus or minus specific risk factors, and is actively engaged in behavioral modification and/or restricted caloric intake."

He notes that all of the current medications provide relatively marginal weight loss results for the vast majority of patients, and the initial weight loss benefits are frequently not sustained over an extended period—even for patients who adhere to drug and lifestyle changes.

Behm does not view weight-loss medications and bariatric surgery as competing therapies because drugs only reduce weight in the range of 3% to 10% when used in combination with lifestyle modifications. On the other hand, most patients eligible for surgery are often several hundred pounds over their ideal body weight. Instead, he says, physicians likely will guide patients to the appropriate solution based on the patient's baseline BMI.

Apovian, along with other healthcare professionals and the Obesity Society, are trying to make legislators aware of the potential for diet, exercise and medications to reduce the cost of healthcare by preventing chronic diseases such as diabetes. So far, their efforts have been unsuccessful. ■

Mari Edlin is a freelance writer based in Sonoma, Calif.

THIRD ANTI-OBESITY DRUG APPROVED FOR USE IN U.S.

Besides the two obesity drugs approved in 2012— Belviq and Qsymia—FDA approved Contrave this past September. Developed by Orexigen Therapeutics, It is a combination of two FDA-approved drugs, naltrexone and bupropion, in an extended-release formulation. Naltrexone treats alcohol and opioid dependence, while bupropion is approved to treat depression and as a smoking cessation aid.

In a clinical trial of 1,074 obese patients (BMI >=30), 42% of patients treated with Contrave lost at least 5% of their body weight compared with 17% of patients treated with placebo over 56 weeks of treatment. In another trial of 387 obese diabetic patients (BMI >=27), also 56 weeks in duration, 36% of patients treated with Contrave lost at least 5% of their body weight compared with 18% of patients on placebo.

Boston University School of Medicine's Apovian believes that Contrave's combination of drugs that blocks addiction and treats depression has known mechanisms of action and should be able to help patients lose weight.

Getty Images/iStock/360

COORDINATING BUNDLED PAYMENTS

Bundled payments: The first step toward coordinated care

by **JAMIE J. GOOCH**

In the shift away from fee-for-service to coordinated care models, healthcare organizations are reaping benefits by bundling payments for particular episodes of care. While still in the early stages, bundled payments promise to save costs and improve quality, and have already improved communication and collaboration among major players along the continuum of care.

"Episodes or care [a.k.a. bundles] provide a middle ground between fee-for-service and full capitation that allows for a level of planning, analysis and cross organization comparison that is fair and equitable," says Graham Hughes, MD, chief medical officer for the SAS Center for Health Analytics and Insights, a provider of analytical software and services headquartered in Cary, North Carolina. "Bundles hold the promise of creating an apples-to-apples comparison for the most common types of care episodes — and one that allows for competition based on cost and quality standards that can then be compared fairly across institutions."

Key to the early success of bundled payment initiatives is the ability to focus on distinct episodes of care, rather than taking on a complete payment system overhaul. The bundled payments for particular episodes of care can be created, in large part, using existing claims data.

"I once heard episodes of care described as a bite-sized strategy to improve and transform how healthcare is delivered and paid for in the United States," says Lili Brillstein, director, Episodes of Care, Horizon Blue Cross Blue Shield of New Jersey. "It's true. You can pick an episode and look at that piece, and begin to understand how one has to transform healthcare to deliver better quality outcomes at a lower cost."

The U.S. Centers for Medicare and Medicaid Services' (CMS) Bundled Payments for Care Improvement initiative (BPCI) defines four financial and performance models for 48 episodes of care. The episodes of care include diagnosis-related groups (DRGs), which allow healthcare organizations to use claims data to estimate a bundled payment. The more distinct the episode of care, the easier it is to correctly estimate a bundled payment.

While payers have claims data readily available, they may not have the technology infrastructure in place to automatically analyze that data. However, several third-parties can provide that service.

"If you're using the best practices in implementing the bundled payment program, including retrospective reconciliations, selecting a 'quarterback' for the episode, instituting stop-loss arrangements, using standard definitions of episodes, there are very few challenges," says Francois de Brantes, MBA, executive director of the Health Care Incentives Improvement Institute in Newtown, Connecticut. "If you're a payer and want to fully scale a bundled payment program, you need a claims adjudication system that can handle these payments, and that's a significant challenge for almost all payers."

Building the right bundle

North Shore-LIJ Health System, Great Neck, New York, was approved by CMS for nine bundles revolving around orthopedic, cardiac surgery, stroke and chronic obstructive pulmonary disease. Howard Gold, executive vice president and chief managed care and business development officer for North Shore-LIJ, says surgical episodes are the best place to start because they're more clearly defined in terms of finances and services provided.

"Bundled payments are one of most intensive programmatic initiatives we've been involved in since ACA," he says.

Gold says North Shore-LIJ Health System's implementation of bundled payments took about a year of work and involved about 100 people. It's effective start date was in January of this year.

"It required extensive preliminary analysis," he says. "We looked at claims data on Medicare to determine the total cost of care, then polled a lot of physicians and administrators to determine which categories could be managed to effect a savings and better outcome. We looked at a tremendous amount of data and worked with an outside consultant."

When it comes to implementing a new model for healthcare payments that brings payers, providers and administrators together, a year is a relatively short timeframe. North Shore-LIJ Health System should know the initial

results soon, but Gold expects to save more than the planned 3%. He says he has already seen less-tangible benefits.

"Bundled payments have the potential to teach us how to organize care across the continuum," he says. "They require us to take care of the patient for a longer time. They require us to organize physicians in each hospital and administrators and every service line who would touch the patient, including nursing homes and pharmacies."

Gold calls the BPCI initiative one of the most potentially effective program pilots coming out of the ACA.

"When we started, no one knew what a bundle was," he says. "This taught people more about taking care of the whole patient over a longer period of time than almost anything else."

Horizon Blue Cross Blue Shield of New Jersey started its bundled payment pilot in 2010 with total hip and knee replacements. That was three years before the CMS BPCI initiative began in earnest. Horizon uses the PROMETHEUS algorithms from HCI3.

By the end of 2012, Brillstein says, the insurer had seen enough success interms of improved patient quality, patient satisfaction (over 95%) and cost reduction, that it decided to expand its bundled payments efforts to additional orthopedic episodes, as well as obstetrics, colonoscopy and oncology. During the pilot phase from 2010 to 2013, Horizon Blue Cross Blue Shield of New Jersey completed an estimated 1,100 episodes, cumulatively. In 2014 alone, that number will jump to 8,000.

Retrospective vs. prospective payments

Like three of the BPCI models, both North Shore-LIJ Health System's and Horizon Blue Cross Blue Shield of New Jersey's initiatives are retrospective, meaning costs are reconciled against a target price after an episode of care. The fourth BPCI model, and one that is more challenging is a prospective model.

"In the prospective model, providers are given a certain amount of money up front (i.e., before the episode begins)" Brillstein says. "Most providers are not in a position to accept up front payment and don't have the infrastructure or downstream agreements to manage and distribute payments across the healthcare continuum."

In Horizon's retrospective implementation, all providers throughout the continuum get paid at fee-for-service rates as their care is delivered. All episodes are reviewed against quality benchmarks and patient experience thresholds. Then, if costs come in below budget, savings are shared with the "conductor" as Brillstein refers to the provider who is contracted for the episode management.

Brillstein says she doesn't think she'll see a time when bundling is only prospective, but she does expect to introduce it in the future in conjunction with their retrospective program.

Gold agrees that widespread use of a prospective model is still far in the future for bundled payments.

"We're not there yet," he says. "It would require different administration, an infrastructure for payment distribution and stopping fee for service altogether."

But retrospective bundled payments are laying the important groundwork for trust between payers and providers that will be needed for a prospective model to succeed. Horizon Blue Cross Blue Shield of New Jersey has provider partners who are already interested in moving toward a prospective model. That willingness to move forward with quality-based care is one of the most important outcomes of Horizon's bundled payment initiative, Brillstein says.

The insurance company has become "the facilitator of change on the provider side," she says, by creating opportunities for doctors and other providers to talk to each other and share best practices. "One of greatest successes of this effort is that doctors want us to engage their colleagues. They believe in the program and they see it working," she says. "They actually like us now. It is very collaborative." ◘

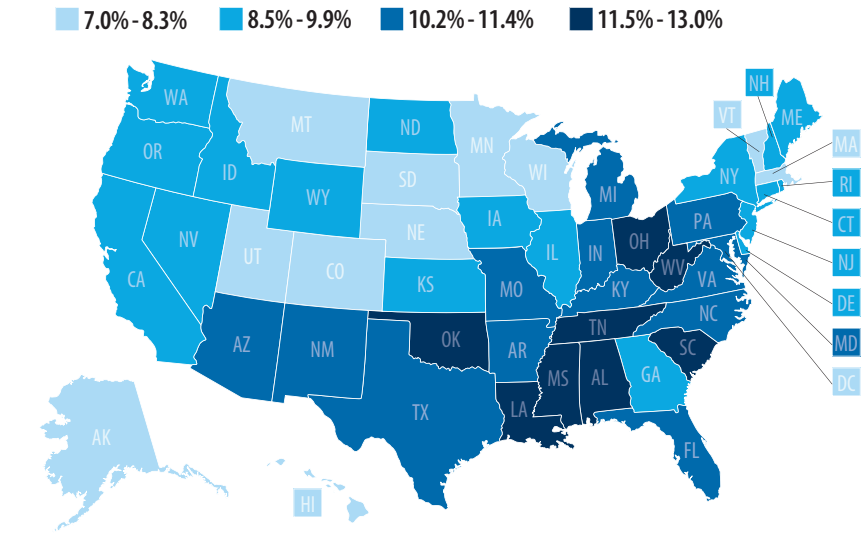
> "I once heard episodes of care described as a bite-sized strategy to improve and transform how healthcare is delivered and paid for in the United States. It's true."
>
> -- LILI BRILLSTEIN, DIRECTOR, EPISODES OF CARE, HORIZON BLUE CROSS BLUE SHIELD OF NEW JERSEY.

Jamie J. Gooch is a Cleveland-based freelance writer.

ADVERTISER INDEX

The following is a list of the advertisers in this issue. Although every effort is made to ensure accuracy, this publication assumes no liability for errors or omissions.

Percent of adults who have ever been told by a doctor that they have diabetes



Source: The Henry J. Kaiser Family Foundation

HEALTH MANAGEMENT

A surge in emergency department visits and hospitalization rates on the part of newly-insured **Medicaid** patients is a mostly temporary phenomenon created by pent-up demand, according to a report by **UCLA's Center for Health Policy Research (HPR)**. The study, released in October, eases fears that large numbers of new Medicaid patients would overwhelm the system and strain budgets.

As of July 2014, California had logged 1.5 million new Medicaid enrollees due to the state's decision to expand Medicaid as part of the Affordable Care Act. That number includes 650,000 who were transitioned from the state's Low-Income Health Program (LIHP).

The study looked at claims data from two consecutive Medicaid-voucher programs in California, the Health Care Coverage Initiative (HCCI), which ran from September 2007 to October 2010, and LIHP, which ran from July 2011 to December 2013.

Both provided coverage to individuals who were not eligible for Medi-Cal or other low-income programs at the time, and who would have been eligible for Medicaid under Medicaid expansion.

Results were that those individuals with the highest pent-up demand initially had 600 emergency room visits for 1,000 enrollees, but the rate quickly dropped and then remained relatively constant, eventually falling to 183 out of 1,000 individuals during the second year of analysis.

The next highest-demand group showed a significantly smaller initial number of visits that then remained constant, and the lowest-demand group had a had a smaller number of initial visits that remained constant.

Hospitalization rates among those with the highest pent-up demand followed a similar trend, spiking at first and then rapidly declining.

"We believe Medicaid expansion is sustainable because the initial high cost of newly enrolled beneficiaries does not persist beyond the first year of enrollment for the vast majority of new enrollees," Gerald F. Kominski, Ph.D., director of the HPR, told *Managed Healthcare Executive*. The report "suggests that the higher costs and utilization among newly enrolled Medicaid beneficiaries is a temporary rather than permanent phenomenon."

BUSINESS

Walmart is continuing its expansion into healthcare by partnering with Direct Health to launch Healthcare Begins Here, an in-store program to educate customers about insurance options. Customers will be able to shop for insurance through directhealth.com, an aggregator site that provides access to more than 1,700 plans from 12 leading carriers including Aetna, Cigna, Humana, United Healthcare, and participating Blue Cross and Blue Shield companies. Stores will be staffed by independent, licensed health insurance agents from DirectHealth.com who can enroll customers in certain health insurance plans, according to Walmart. Agents can also enroll customers into Medicaid during the Affordable Care Act's open enrollment period, which begins Nov. 15, 2014. Walmart says the partnership will bring "transparency and simplicity to the changing health insurance market."

Walmart entered the primary care arena this year, opening eight company-owned clinics since April with four more planned by year's end.

STATEMENT OF OWNERSHIP, MANAGEMENT, AND CIRCULATION

(Requester Publications Only) (Required by 39 USC 3685)

1. **Publication Title:** Managed Healthcare Executive
2. **Publication Number:** 1533-9300
3. **Filing Date:** 9/30/14
4. **Issue Frequency:** Monthly
5. **Number of Issues Published Annually:** 12
6. **Annual Subscription Price (if any):** $99.00
7. **Complete Mailing Address of Known Office of Publication:** 131 West First Street, Duluth, St. Louis County, Minnesota 55802-2065

   Contact Person: Joe Martin

   Telephone: 218-740-6375
8. **Complete Mailing Address of Headquarters or General Business Office of Publisher:** 2501 Colorado Avenue, Suite 280, Santa Monica, CA 90404
9. **Full Names and Complete Mailing Addresses of**

   Group Publisher: Mike Weiss, 485F US Highway 1 S, Suite 210, Iselin, NJ 08830-3009

   Group Content Director: Dan Verdon, 24950 Country Club Blvd., North Olmsted, OH 44070

   Content Channel Director: Tracey Walker, 24950 Country Club Blvd., North Olmsted, OH 44070
10. **This publication is owned by:** Advanstar Communications Inc., 2501 Colorado Avenue, Suite 280, Santa Monica, CA 90404. The sole shareholder of Advanstar Communications Inc. is: Advanstar, Inc., whose mailing address is 2501 Colorado Avenue, Suite 280, Santa Monica, CA 90404.
11. **Advanstar Communications Inc. is a borrower under Credit Agreements dated June 6, 2013, with various lenders as named therein from time to time. As of August 7, 2014, the agent for the lenders is: Goldman Sachs Lending Partners LLC, Administrative Agent, 30 Hudson St, 4th Floor, Jersey City, NJ 07302.**
12. **Does Not Apply**
13. **Publication Title:** Managed Healthcare Executive
14. **Issue Date for Circulation Data Below:** August 2014
15. **Extent and Nature of Circulation**

		Average No. Copies Each Issue During Preceding 12 Months	No. Copies of Single Issue Published Nearest to Filing Date
A.	**Total Number of Copies**	36,947	37,182
B.	**Legitimate Paid and/or Requested Distribution**		
1.	Outside County Paid/Requested Mail Subscriptions Stated on PS Form 3541	24,521	24,345
2.	In-County Paid/Requested Mail Subscriptions Stated on PS Form 3541	0	0
3.	Sales Through Dealers and Carriers, Street Vendors, Counter Sales, and Other Paid or Requested Distribution Outside USPS	9	11
4.	Requested Copies Distributed by Other Mail Classes Through the USPS	0	0
C.	**Total Paid and /or Requested Circulation** (Sum of 15b (1), (2), (3), and (4))	24,530	24,356
D.	**Non-requested Distribution**		
1.	Outside County Non-requested Copies Stated on PS Form 3541	12,033	12,478
2.	In-County Non-requested Copies Stated on PS Form 3541	0	0
3.	Non-requested Copies Distributed Through the USPS by Other Classes of Mail	0	0
4.	Non-requested Copies Distributed Outside the Mail	275	297
E.	**Total Non-requested Distribution** (Sum of 15d (1), (2), (3) and (4))	12,307	12,775
F.	**Total Distribution** (Sum of 15c and e)	36,837	37,131
G.	**Copies not Distributed**	110	51
H.	**Total** (Sum of 15f and g)	36,947	37,182
I.	**Percent Paid and/or Requested Circulation**	66.59%	65.59%

16. Electronic Copy Circulation
    *If you are not claiming electronic copies, skip to line 17
    a. Requested and Paid Electronic Copies
    b. Total Requested and Paid Print Copies (Line 15C) + Requested/Paid Electronic Copies
    c. Total Requested Copy Distribution (Line 15F) + Requested/Paid Electronic Copies
    d. Percent Paid and/or Requested Circulation (Both Print & Electronic Copies)
    ☐ I certify that 50% of all my distributed copies (electronic and print) are legitimate requests or paid copies.
17. **Publication of Statement of Ownership for a Requester Publication is required and will be printed in the November issue of this publication.**
    Name and Title of Editor, Publisher, Business Manager, or Owner: Christine Shappell, Audience Development Director

    Signature: Christine Shappell

    Date: 9/30/14

    I certify that the statements made by me above are correct and complete.

NOW APPROVED

HARVONI™
ledipasvir/sofosbuvir
90 mg/400 mg tablets

One tablet contains ledipasvir and sofosbuvir

GILEAD