SPECIAL REPORT **New penalties for HACs threaten bottom line**

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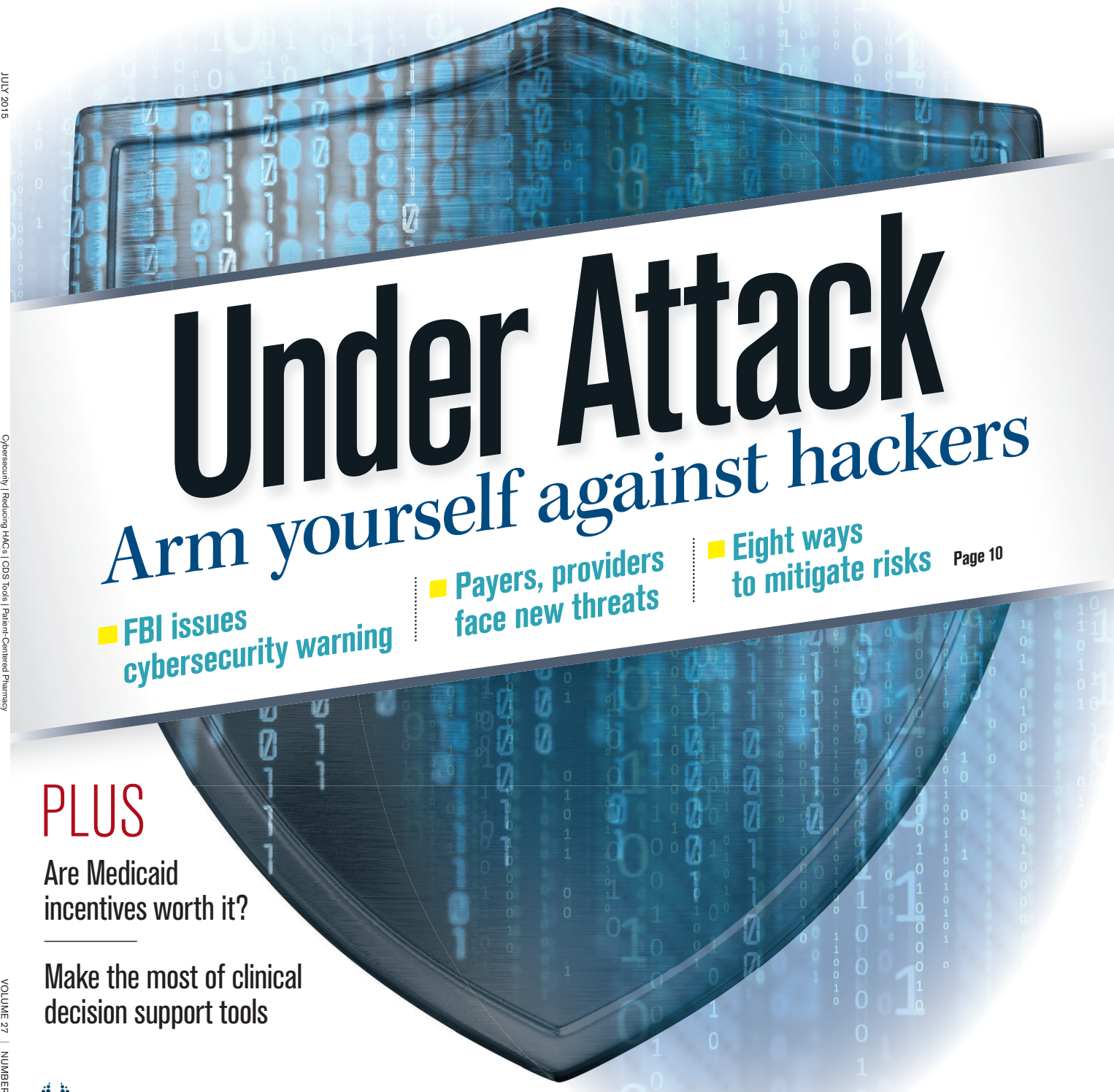

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Are Medicaid incentives worth it?

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UBM

July 2015
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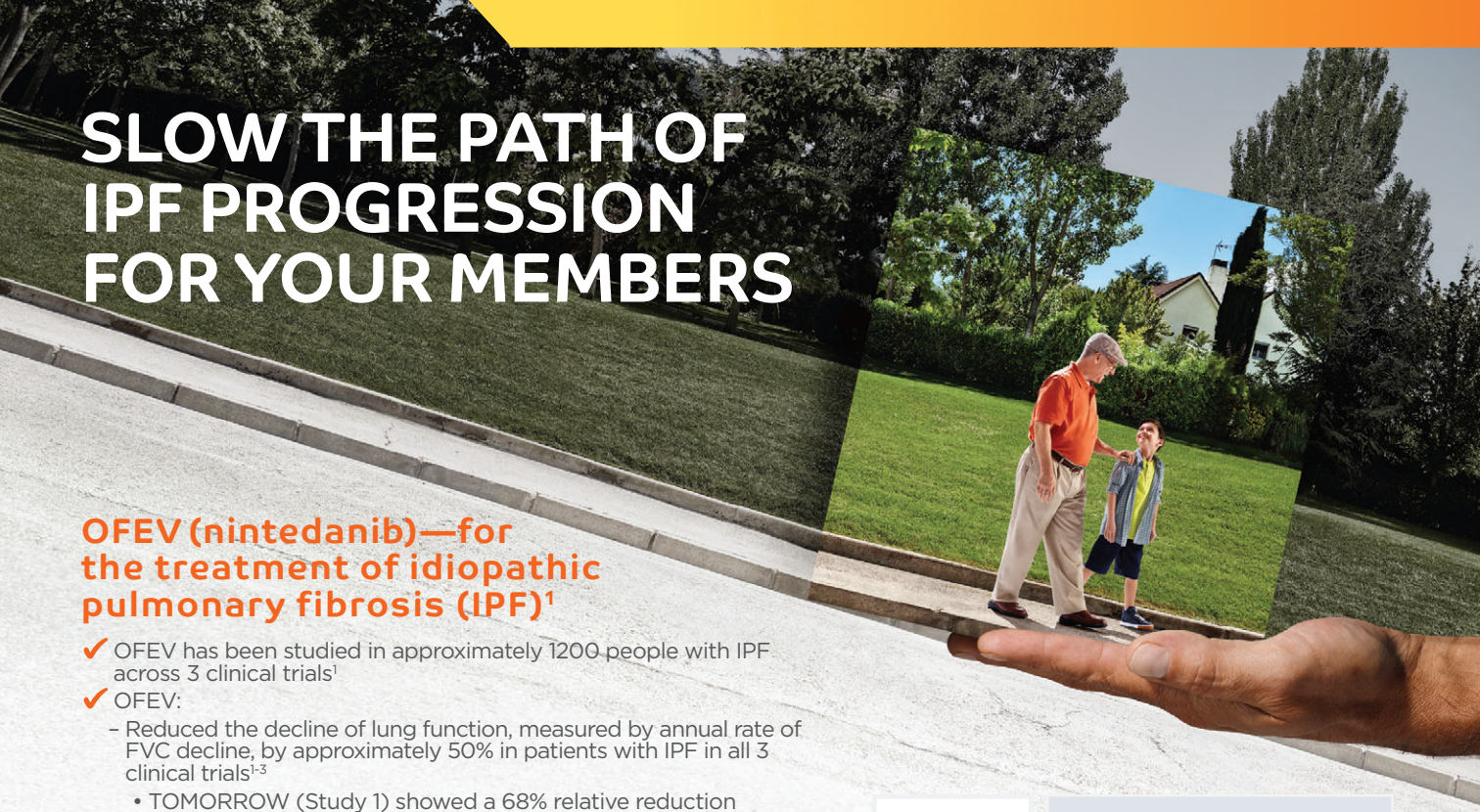
SLOW THE PATH OF IPF PROGRESSION FOR YOUR MEMBERS



OFEV (nintedanib)—for the treatment of idiopathic pulmonary fibrosis (IPF)[1]

- ✓ OFEV has been studied in approximately 1200 people with IPF across 3 clinical trials[1]
- ✓ OFEV:
  - Reduced the decline of lung function, measured by annual rate of FVC decline, by approximately 50% in patients with IPF in all 3 clinical trials[1-3]
    - TOMORROW (Study 1) showed a 68% relative reduction (-60 mL/year for OFEV [n=84] vs -191 mL/year for placebo [n=83]), difference=131, 95% CI=27, 235)[1,2]
    - INPULSIS®-1 (Study 2) showed a 52% relative reduction (-115 mL/year for OFEV [n=309] vs -240 mL/year for placebo [n=204]), difference=125, 95% CI=78, 173)[1,3]
    - INPULSIS®-2 (Study 3) showed a 45% relative reduction (-114 mL/year for OFEV [n=329] vs -207 mL/year for placebo [n=219]), difference=94, 95% CI=45, 143)[1,3]
  - Significantly reduced the risk of time to first acute IPF exacerbation over 52 weeks compared with placebo in 2 out of 3 clinical trials[1]
    - TOMORROW (investigator-reported): HR=0.16 (95% CI=0.04, 0.71)
    - INPULSIS®-1 (adjudicated): HR=0.55 (95% CI=0.20, 1.54; not statistically significant)
    - INPULSIS®-2 (adjudicated): HR=0.20 (95% CI=0.07, 0.56)

ONE CAPSULE, TWICE DAILY WITH FOOD[1]

Not shown at actual size.

THE TOTALITY OF THE EVIDENCE DEMONSTRATES THAT OFEV SLOWS DISEASE PROGRESSION[1,4-7]

To learn more about OFEV, please visit OFEV.com/formularykit

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, and GGT) and bilirubin. 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. The majority (95%) of patients with bilirubin elevations had elevations <2 times ULN.
- 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.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Gastrointestinal Disorders (cont'd)

Nausea and Vomiting (cont'd)

- 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.

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.

OFHCPISIJAN15

References: 1. OFEV® (nintedanib) Prescribing Information. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc; 2014. **2.** Richeldi L et al. *N Engl J Med*. 2011;365(12):1079-1087. **3.** Richeldi L et al; for the INPULSIS Trial Investigators. *N Engl J Med*. 2014;360(22):2071-2082. **4.** Zappala CJ et al. *Eur Respir J*. 2010;35(4):830-836. **5.** Schmidt SL et al. *Chest*. 2014;145(3):579-585. **6.** du Bois RM et al. *Am J Respir Crit Care Med*. 2011;184(12):1382-1389. **7.** Song JW et al. *Eur Respir J*. 2011;37(2):356-363.

Please see accompanying Brief Summary for OFEV on the following pages.

OFEV®
(nintedanib)
capsules 150mg

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]*.

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Volume 25 Issue 7
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COVER STORY

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FBI ISSUES WARNING

EIGHT WAYS TO MITIGATE RISK Page 10

COMMENTARY

ESSENTIALS

SPECIAL REPORT

DEPARTMENTS

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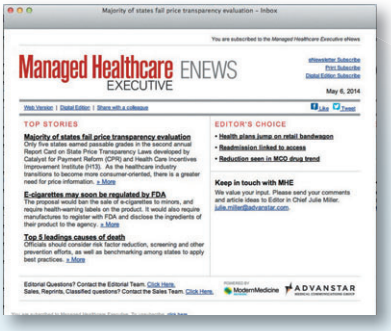

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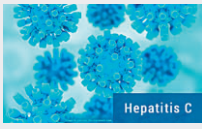
formulary watch

[BLOG] Five drug categories having the biggest impact on pharma spending



The transformations taking place throughout all healthcare sectors will have repercussions for the pharmaceutical industry. **http://bit.ly/1ek2WTt**

[BLOG] Top five ways bacteria are becoming reisistant to antibiotics

Antibiotics, antivirals, and other antimicrobials are losing their effectiveness. **http://bit.ly/1gcCNXW**

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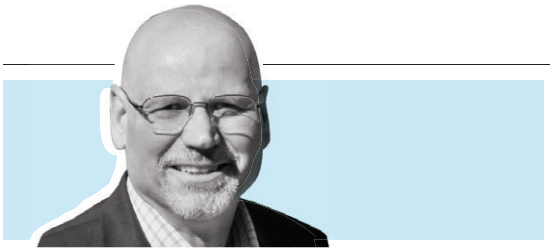

EIGHT WAYS TO RETAIN HIGH-DEDUCTIBLE MEMBERS

In the movie "Joe Versus the Volcano," there is a classic scene when Joe, played by Tom Hanks, walks into his dark, dingy office and his boss is on the phone loudly repeating, "I know he can get the job, but can he do the job?" For many health plan executives, the proliferation and popularity of high-deductible health plans has posed a similar refrain, "I know we can get the member, but can we keep the member?"

High deductible health plans are often the product of choice for relatively healthy people who have little likelihood of exceeding the plan's annual deductible. The main factor in their initial selection of a plan was cost. With low to no use of the plan's contacted providers and no other interaction with the health plan, these members have little loyalty to their plan and will quickly switch to a competitor if it offers a lower premium.

Thus arises the challenge of creating some sort of "stickiness" between a health plan and its members that reduces attrition to competitors.

Below are eight ways a health plan can offer its members value, even when they don't hit their deductible, so that members will renew despite lower cost alternatives.

1 Get the basics right.
At least two weeks before a member's effective coverage date, send an accurate ID card, access to an online directory, benefit details and plan contact information. Let members know they are enrolled and have immediate access to care.

2 Answer member calls as quickly as possible.
Failing to answer calls quickly is probably one of the biggest issues for members—when they call they want to talk with someone and get their problem fixed. Interactive voice response systems have become a bane in the healthcare industry. Ditch the system and answer the phone with real people.

3 Clarify prescription benefits.
The one area where most members access their health plan is through their prescription drug benefits. Spend extra effort helping members understand how to maximize their benefit. Discounts on over-the-counter medications are a nice additional benefit.

4 Help members manage their deductibles.
Offer tools that accurately provide meaningful price and quality transparency and treatment options. Include telehealth alternatives for convenient low-cost access to minor emergency care.

5 Listen to members.
Beyond administering an annual survey, find out what members like, dislike and want to see changed about the health plan. Incorporate their suggestions as much as possible.

6 Help members stay healthy.
Incorporate a healthy practices page on the plan's website with frequently updated information, links to useful sites and discounts on healthy foods and products.

7 Thank members for their business.
Too often the only communication most members receive from their health plan is a premium notice and annual renewal statement with a rate increase. Plan regular communication with members throughout the year and include ways to say thank you for their business.

8 Make satisfaction and retention every employee's job.
From recruiting employees to training, evaluating and rewarding job performance, the member must be at the center. Celebrate and communicate the importance of taking care of the plan's members.

Once you've gotten members enrolled, by incorporating these simple recommendations, you'll be more successful in keeping them enrolled. ◘

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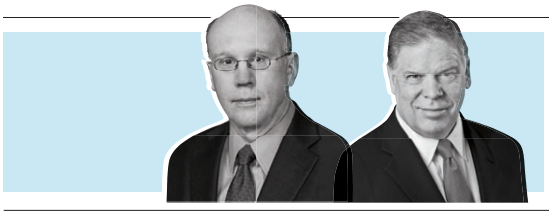

LIABLE FOR A DATA BREACH?

Taking reasonable preventive care is a must to prevail in court

The Anthem data breach has triggered over 90 lawsuits and scrutiny from numerous state insurance commissioners, law enforcement officials and the National Association of Insurance Commissioners. Other significant data breaches have occurred in the healthcare industry, and substantial litigation has ensued.

In the past, most data breach cases were settled or dismissed, because courts concluded that the plaintiffs' injuries were too speculative to support a lawsuit, dismissing the cases either for failure to establish standing or to plead a legally compensable injury. However, a few courts in consumer class actions recently have concluded that the alleged injuries arising from a data breach are sufficiently certain to allow the cases to go forward, allowing plaintiffs to take discovery on how the breach occurred and what the defendant did or failed to do before the breach to prevent it. At the same time, regulators are increasing scrutiny of companies that suffer data breaches. Ultimately, the defendants in these cases and regulatory investigations will have to prove that they took reasonable steps to prevent the data breach before it occurred.

Proving Reasonableness

These developments point to the importance of a company conducting and documenting "an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity and availability of electronic protected health information held by the covered entity" ("Risk Assessment") and determining and documenting the "security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level" ("Written Information Security Plan" or "WISP"). The Risk Assessment and WISP, if properly prepared, can be a company's strongest evidence in defending against data breach claims.

Since the Risk Assessment and WISP may become evidence in a legal proceeding, it is important to obtain legal advice in preparing these documents, as well as technical advice from an IT security expert. All emails, expert reports and drafts prepared in the process of preparing a Risk Assessment and WISP can also become evidence in a legal proceeding, so care must be taken in preparing these preliminary materials as well. Retaining legal counsel to work with the technical expert to provide legal advice regarding the company's legal obligations may protect the confidentiality of the preliminary documents under the attorney client privilege.

In addition, legal counsel can provide input regarding frameworks of potential security controls to consider in formulating a plan. Various organizations have published standards listing potential controls, and there are pros and cons from a legal perspective to selecting each set of standards as a starting point for the analysis. It is important to select industry standards that will have credibility in a court room but, at the same time, are practical. Also, legal counsel can provide input regarding what controls have been the focus of regulatory actions and class action settlements.

Legal counsel can also help structure the process to be consistent with applicable law. For example, IT experts should be asked to identify potential security controls to be discussed with the company. The company, after receiving input from the expert and legal counsel, is responsible for deciding which controls are reasonable from a cost/benefit standpoint. Those decisions should then be implemented and documented in the WISP.

Bottom line: Since a Risk Assessment and WISP and the preliminary documents leading up to them may become evidence in a legal proceeding, legal input is critical in making sure that this evidence will support the company's position and not be used against it. ■

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SUPREME COURT PRESERVES SUBSIDIES

Writing for the majority, Chief Justice rescues ACA for second time

The much-anticipated Supreme Court 6-3 ruling in *King v. Burwell,* upholding the key provision of the Affordable Care Act (ACA) regarding tax credit subsidies payable to economically eligible persons, while wildly anticipated, is unsurprising. Neither, is the majority opinion, for that matter, or the fact that it was written by Chief Justice John Roberts.

This marks the second time that the Chief Justice has authored a controversial decision rescuing the ACA from judicial uprooting. In *National Federation of Independent Business v. Sebelius*, the Chief Justice opined that—despite the way it was originally described by the Administration and its supporters in the Congress and the statute itself as a "penalty" (questionable under the Constitution's Commerce Clause) to which certain non-purchasers of health insurance would be subjected under the individual mandate—the penalty actually should be treated as a tax (consistent with the Constitution's taxation provision). This time, I believe, the Chief Justice was on stronger legal and logical ground as to the ACA's tax credit provision.

On its face, the provision at issue in King limited the relevant subsidies to persons who could participate in "an Exchange established by the State under [42 U. S. C. §18031]." To Justice Scalia and the other two dissenters, this apparently plain language should have ended the inquiry. Thus, Scalia chastises the majority for having created "SCOTUScare" and having engaged in "somersaults of statutory interpretation."

However, the Chief Justice has a compelling position to the contrary. In gleaning congressional intent, he noted not only the centrality of the tax credits to the overall scheme of the ACA, but looking to other parts of the statute which described the availability of the credits to eligible persons generally without reference to exchanges, concluded that there was no real difference between exchanges established by the states and those established by the federal government.

Ultimately, the majority held that "Congress passed the Affordable Care Act to improve health insurance markets, not to destroy them. If at all possible, we must interpret the Act in a way that is consistent with the former, and avoids the latter. [The ACA] can fairly be read consistent with what we see as Congress's plan, and that is the reading we adopt."

There are several healthcare consequences that likely will follow. The first is the political momentum from which the Obama Administration continues to benefit. The ACA is the centerpiece of whatever legacy President Obama will have and he will leave office with the program essentially intact.

Second, and perhaps most importantly, health insurers now gain the certainty that is required for proper rate setting. If the young and relatively healthy could not get the credits and chose to opt out of the system, insurers would have been faced with statistically unhealthier populations and rates would have had to increase substantially, threatening the entire balance that the ACA was intended to provide. Third, eligible employers, particularly smaller businesses, likely will be spurred more quickly to comply with their ACA mandate and will encourage their employees to purchase health insurance (if they are not providing it).

Fourth, a bit more speculatively, will be the effect on the states and their exchanges. The literal language of section 18031 made it more advantageous to citizens of states that had their own exchanges. However, now that any useful distinction between state and federal exchanges has been removed by the Supreme Court, there is little incentive for new state exchanges.

One thus foresees an increasing federal presence at the grass roots of health insurance as the result of a case that marks the triumph of "contextualism" over strict "textualism." ◘

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Under Attack

Arm yourself against hackers

By **JUDY PACKER-TURSMAN**

The U.S. healthcare industry is struggling to keep pace with an ever-widening number of global threats being perpetrated by increasingly sophisticated cyber criminals.

Criminal attacks in healthcare are up 125% since 2010 and are now the leading cause of data breach, according to a recent study by the Ponemon Institute. And while recent attacks on Anthem, Community Health Systems, Premera and CareFirst, compromising millions of Americans' personal data, helped raise awareness, many healthcare payers and providers are still mired in outmoded or unfocused cybersecurity strategies and thus remain vulnerable.

Experts say that unless healthcare organizations utilize strong approaches to manage risk and protect data, the potential costs could be staggering.

MOUNTING CONCERNS

In April 2014, prior to some large publicized attacks, the FBI issued a private industry notification, warning healthcare providers that their networks were too lax compared to other industries. Some industry experts worry that the situation is much the same more than a year later. "They're just being sloppy," chief executive officer Mac McMillan of CynergisTek, Inc., says of the healthcare industry's current efforts to manage data and risks to its environment. McMillan's healthcare information technology (IT) consulting firm focuses on improving privacy, security and regulatory compliance for payers, providers and business associates.

MCMILLAN

"Once you get beyond the shock factor [on recent healthcare data breaches], you wonder ... 'Why did people have all this information?'" says McMillan, who also chairs the Healthcare Information and Management Systems Society

Getty Images/E+/BlackJack3D (shield); Getty Images/E+/Andrey Prokhorov (binary streams in shield); Getty Images/Hemera/Getty Images Plus/Alex Varlakov (binary streams in background)

(HIMSS) Privacy & Security Policy Task Force. "With CareFirst, why do you still have data on former customers that are accessible to anyone to steal? Even if you have a business purpose to retain data, why isn't it in some long-term storage that isn't accessible online? ... We need to be more responsible with how we handle data."

He cites two paradigms in play: For payers, having accessible data is a business driver. For providers, patient care and safety come first and everything else, including cybersecurity, is second. Yet in both scenarios, a rapid response when a breach is suspected is of the essence, says McMillan, former director of security for the U.S. Department of Defense. CareFirst executives had "holes in their security approach," he asserts, since CareFirst saw anomalous behavior months before the breach but didn't follow up until after other payers' breaches.

"There's nothing that healthcare is dealing with that other folks haven't dealt with already," McMillan says. "The same person that shows up at your hospital to work is the same person that worked yesterday in retail ... The only thing special about healthcare is the operational aspect of care to the patient—so you err on the side of caring for the patient first, not protecting the data."

Nationwide, data breaches could be costing the healthcare industry $6 billion, says the Poneman Institute report issued in May. That total arises from two factors: The average cost of a data breach for healthcare organizations is estimated to exceed $2.1 million, and 91% of organizations have had a breach, with four in 10 having had more than five breaches over the past two years.

"There are only two types of [healthcare] organizations right now: Those that know they've been breached and those that don't know they've been breached," says Rick Kam, president and cofounder of ID Experts, the Ponemon report's sponsor. " The problem is, it's already in. And if they're spending millions of dollars assuming they haven't been infected, they're wasting their time and effort."

Broadly speaking, cyberattacks are frequent and swift. Five malware events occurred every second in healthcare in 2014, according to Verizon's 2015 data breach investigations report.

Email phishing has been increasing since 2011, Verizon says, and in 60% of cases, cyberattackers compromised an organization within minutes—with organizations' response time lagging well behind. Healthcare was among the most affected industries for "insider misuse"

> There are only two types of [healthcare] organizations right now: Those that know they've been breached and those that don't know they've been breached."
>
> RICK KAM, ID EXPERTS

and errors made by internal staff—notably system administrators—such as sending sensitive information to incorrect recipients.

It also isn't a matter of cyberattackers only trying to topple giants. Experts say no healthcare organization, regardless of its size, is immune from cyber risks.

NEW TECHNOLOGY RAISES RISKS

As healthcare organizations grow, innovate and and work to comply with regulatory requirements for initiatives like electronic health records (EHRs) and health information exchanges (HIEs), they open themselves up to new cyber threats, experts say. This forces a balancing act between opportunities presented by technology and risks associated with it.

"All this new technology was set up to better share information and get the best value from this data ... It wasn't set up with protection in mind," says Emily Mossburg, a principal with Deloitte & Touche LLP's cyber risk services practice.

The problem, Mossburg says, is that today's cyberattacks are advanced, persistent threats, with the adversary often already inside the network. "This isn't about a point-in-time event, so organizations can't fight it as a point-in-time event."

While the actual threat to healthcare organizations might be coming from the IT space, the impact is to the business as a whole, Mossburg stresses. Health information, which serves as an entryway to identity theft, medical claim and financial fraud, is worth 10 times more than credit card numbers on the black market, experts say. Unlike lone hackers of the past, organized crime rings are now targeting the health industry for profit.

As Ponemon's recent report puts it: Over the past five years, the most-often reported root

EXECUTIVE VIEW

- 91% of healthcare organizations have had a breach;
- Expect your organization to be breached in the next few years.

> Until something bad happens to a company, there's a certain amount of denial."

KATHERINE KEEFE, GLOBAL HEAD OF BEAZLEY'S BREACH RESPONSE SERVICES

cause of a data breach is shifting from lost or stolen computing devices to criminal attacks.

PREPARE FOR THE INEVITABLE

Getting one's house in order and having the resources and team in place before an incident occurs is critical, says Katherine Keefe, global head of Beazley's Breach Response Services. "As much as you can tighten security and use best practices, where you have the creativity of hackers we're seeing, you have to figure it not only could happen to you—it will happen to you," she says.

"Until something bad happens to a company, there's a certain amount of denial," adds Keefe, whose firm provides cyber insurance coverage to the healthcare industry. Since 2009, Beazley has handled about 1,300 breaches for healthcare clients.

The Anthem breach, affecting about 80 million people, "really had some tentacles," notes Keefe, a healthcare regulatory attorney and former deputy counsel at Independence Blue Cross. "We had 80 to 90 companies with our cyber coverage that notified us they'd been impacted."

Keefe cites the difficulty for organizations of all sizes to handle cybersecurity compliance and spend what's needed on tools. A receptionist or office manager might handle compliance issues in small providers' offices, she says, and even large organizations' privacy officers are "very thinly stretched."

Often, healthcare organizations focus on perimeter threats despite the fact that internal threats from business associates, employees, patients and others are increasing, experts say. Many rely on employees within their IT departments to handle risks alongside numerous other pressing issues.

Instead, payers and providers should have dedicated cybersecurity staff and a culture that elevates the discussion to the boardroom level, experts assert. In addition, organizations need policies, procedures and controls in place to prevent or minimize risks and liability now—not after publicly embarrassing, costly cyberattacks.

A long and growing list of healthcare breaches affecting at least 500 patients is available on HHS' website. Incidents—which totaled 1,249 as of June 15—are publicized as part of the Health Information Technology for Economic and Clinical Health (HITECH) Act, created in 2009 to support widespread adoptions of EHRs. Eight incidents were reported in the first half of June, 2015, including theft of a laptop affecting 14,000 individuals in Oregon's Health CO-OP, and "unauthorized access/disclosure" to a network server affecting 843 individuals in Blue Shield of California.

At the Department of Defense, "We were constantly under attack," McMillan says, "and healthcare for the longest time wasn't in that environment." But HITECH requirements exponentially increased attackers' entry points, he says: "So it shouldn't be surprising we're seeing the number of hacks we're seeing in healthcare right now, because it's where the information is. It's where the money is ... and the bad guys know it."

Elsewhere on the federal front, the National Institute of Standards and Technology is working with stakeholders to develop a voluntary framework for reducing cyber risks to critical infrastructure including the healthcare sector. And HHS has developed health IT privacy and security tools for providers' use (bit.ly/security-resources).

To comply with federal privacy rules under the Health Insurance Portability and Accountability Act (HIPAA), healthcare organizations must take steps to discover and address suspicious network activity and vulnerabilities. These include reviewing log data, implementing intrusion detection systems (IDS) and conducting regular system monitoring scans.

McMillan asserts that the healthcare industry remains too focused on HIPAA compliance, even though HIPAA isn't offering a thorough way to protect the environment. "If all you're focused on is HIPAA compliance, then you are going to have breaches," he says. "It's that simple. You need to adopt a legitimate security environment ... and instill discipline."

McMillan makes the case for vendors to handle IDS, citing huge costs associated with a 24/7 undertaking. "Few organizations have the time, money and expertise," he says, noting that, even if a large health system can create its own securities operations center, analysts at a single location only see what's affecting their particular organization. Global system-monitoring vendors "see threats present themselves before it can impact your facility, so they have the ability to get out ahead," typically at less cost, he says.

Against this backdrop, many cybersecurity experts agree on several basic steps to take. Among them:

1. Put data security first

Healthcare executives must recognize cyber risk "as a tier one business issue," not as a technology

issue, says Mark Ford, Deloitte's principal and leader of the cyber risk services practice. "That's the difference between today and even a year ago: The conversation has elevated ... I've talked to more boards in the last six to eight months than I have in my whole career."


FORD

Ford says cybersecurity must be handled by healthcare organizations "at the risk, regulatory and technology intersection." He suggests going "from the business level down to the technical level, starting with an assessment of what risks are presented to your organization uniquely. That's your first stop: to know your exposure to risks. Then you can attack the problem ... but just throwing it over to the IT folks, that's setting you up for failure."

Currently, Ford says his firm is discussing cybersecurity issues with America's Health Insurance Plans, trying to determine how it can help address the problem of being "under attack as an industry."

McMillan and others agree that cybersecurity should be moved out of IT and treated as a business function. "It should be independent—like audit and compliance and legal are—so its voice can be heard," he says. "One of the hallmarks of a smart organization is listening to its advisers ... and why wouldn't you want to hear what security has to say?"

But McMillan notes that most chief information officers are rewarded for innovative strategies and up-time on networks, not on how they protect an organization's security. He asserts that too many people in healthcare cybersecurity lack the background, knowledge and skills to guide their organizations in the right direction, while those with such skills often are lured to other industries.

"I can't tell you the number of hospitals we work with that have lost their entire security team because of more opportunities elsewhere," he says. His advice to small healthcare organizations? Outsource the whole thing. For small- to mid-range health systems, it's difficult to attract and hold on to people with the right skills, he says. Annual salaries of cybersecurity beginners without much experience may exceed $100,000, making them unaffordable to many healthcare organizations, he adds.

2. Develop strategies

Deloitte's Mossburg describes cybersecurity as a constantly moving process, "and as you're shifting, there are new vulnerabilities." An enormous amount of data is coming off myriad devices, and handling the required analytics is tough, she says. Thus, she says, "It's about securing your environment, then staying vigilant and monitoring for what appears outside of the norm.

"One of the biggest challenges we find with our clients, regardless of industry, [is that] they don't even know where all of their data is," Mossburg says. "You need to identify your most critical data assets ... and you can't protect everything with the same level of rigor ... so you've got to prioritize."

3. Minimize access

While healthcare organizations need to retain some records, they should determine what data are absolutely necessary from a regulatory perspective, says Mossburg.

"Minimization isn't just about fewer records. It's about fewer copies of records as well," Mossburg says, noting that information in many cases is moving across several systems at once, including provider and insurance processing networks.

"You want to give people the least privilege, so they only have access to what they need," says Jessica Dore, senior manager at Rehmann, a technology risk-management firm. "Many organizations aren't taking this approach," she adds, "and it's becoming more and more of a threat" because of many more risks and internal paths to fraud.


DORE

To determine access, organizations must define workers' roles, Dore says. A medical clerk doesn't need the access that an administrator needs, for example, while physicians, nurses and many administrators typically don't need financial access.

Given the broad mix of users, devices and applications in the healthcare industry, it's a challenge to create an encompassing data protection policy and have sufficient technical control over it, says Scott Gordon, chief operating officer of FinalCode, Inc. Yet organizations must get a sense of types of data (i.e., confidential versus sensitive and regulated), who is using it, how it is being used, and the risk of potential exposure.


GORDON

FinalCode's product protects sensitive files'

> One of the biggest challenges we find with our clients, regardless of industry, [is that] they don't even know where all of their data is."


EMILY MOSSBURG, DELOITTE & TOUCHE LLP

> There is an adage in security:... If you don't need data, destroy it."

BRAD CYPRUS, NETSURION LLC

confidentiality, extending controls over shared files as they leave the client organization's environment, Gordon explains. It identifies authorized recipients of files, encrypts files on the receiving side, determines the length of receivers' access and whether they can copy files, and lets files be remotely deleted if necessary. All of this is required in a healthcare environment experiencing an upswing in internal threats from contractors and employees alike because "the likelihood of data leakage is greater because they're already inside the organization."

While many IT and health security companies are focused on perimeter security, "building thicker and higher walls against cybercriminals, what they're not doing as much is preventing problems on the inside," says Randy Vanderhoof, executive director of the Smart Card Allianc, a non-profit, multi-industry association working on adoption of smart card technology.

To alleviate internal threats, Smart Card Alliance advocates the creation of more secure credentials for hospital employees, among others. "We know usernames and passwords can be easily compromised," he says. Using a smart card instead would involve using an ID card with an embedded chip, along with a biometric marker such as a fingerprint, and a required password to enter secure parts of a facility.

If insurers were to issue member cards with smart technology, network providers could read electronic information off the chip, replacing manual forms, he says. It could streamline billing and leave an electronic audit trail to confirm visits, thus reducing medical claims fraud.

VANDERHOOF

"We're actively in discussions with the insurance industry and the health IT industry to help them recognize it's more cost-effective to build security into systems rather than going back after the fact into networks," Vanderhoof says.

4. Train employees

While there is a broad range of security threats, Deloitte's Mossburg says, "There is almost always, in every attack, some level of social engineering. There's a human element to this."

Sometimes the attack takes the form of a targeted email that seems to come from the chief executive officer to the chief financial officer or controller, stating that a wire transfer to a certain (false) account must be initiated. Adversaries are watching traffic patterns, figuring out how to make movements within the organization at accepted times—and they "have user identities and access, so they can go in the front door," says Mossburg.

In the last nine months to a year, Beazley's Keefe says her firm has handled an increasing number of phishing attacks directed toward healthcare leadership and senior teams in hospitals, including medical directors. The email message may be tailored by finding online information on executives, she says, describing the creativity of some phishing emails as "extraordinary .... and people are fooled by them.

"Training is so critical," Keefe says. "HIPAA has had a training requirement for a long time, but you need regular reminders to staff, not an annual training, on data security." Some healthcare organizations are building security hygiene into employees' annual review/evaluation, she notes.

To minimize phishing, healthcare organizations can buy services to phish their employees as a training exercise, she says. As a way of "building teeth", employers can structure workplace policies that levy corrective action if workers violate the phishing policy more than a certain number of times.

Dore agrees that employee training is key, including stressing that workers question whether they were expecting certain types of email. "The phishing emails [that attackers] are using now have become extremely sophisticated," she says. "Previously, they had spelling errors [and other noticeable flaws] ... but now it can look legitimate, so it's difficult to know." Many organizations are trying to put in more sophisticated spam filtering systems, "but you can't protect from everything," she says.

5. Jettison old data

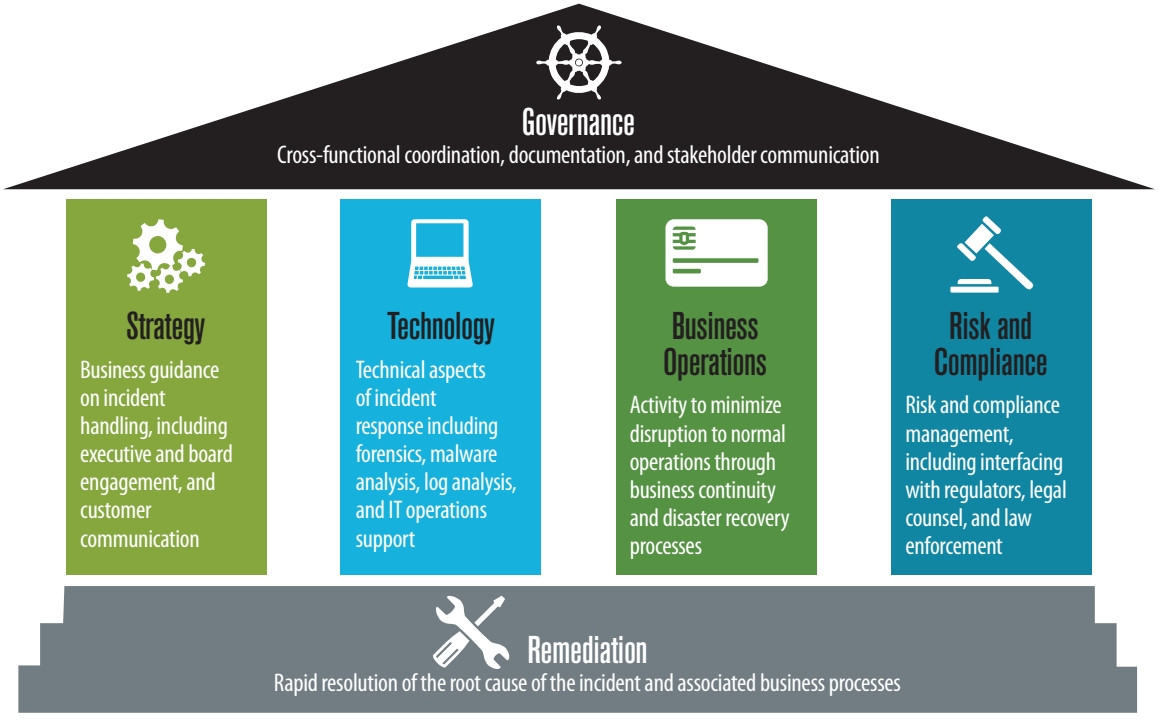
Keefe says proper security measures include looking at whether data are encrypted at rest as well as in transit, whether intrusion measures are in place—and whether data are destroyed in a timely manner. "We've had larger breaches because organizations kept data too long," she says.

"There is an adage in security [that applies to] every industry," says Brad Cyprus, chief of security and compliance at Netsurion LLC, a firm providing cloud-managed IT security services. "If you don't need data, destroy it." Cyprus also cites the importance of having a firewall, knowing how it's managed, and making sure it's regularly monitored.

Organizations often prioritize to keep hackers from breaking into systems, but it's just as important to protect the data within the system,

Cyber Incident Response Framework

Full recovery from a cyber incident requires an integrated approach involving multiple disciplines and stakeholders



says Cyprus. Thus, he says, the database server should lock down information as much as possible. "Databases are like huge file cabinets: You can ask questions ... [and] it's possible to limit to whom it will respond." Thus, you might have malware in your system, but it would be prevented from sending anything. "Your outbound policy is ultimately your last defense against a breach," he says.

He cites a "huge uptick" in hackers' attempts to infiltrate healthcare organizations using remote-access tools to get into networks. For example, a large U.S. hospital's computer help desk for its workers may be located in Singapore. If hackers were to gain access to the remote access system, they might introduce malware into the hospital's system to steal data.

6. Conduct penetration tests

"If you are housing a huge amount of sensitive information ... you should do penetration testing multiple times a year" to look at the system's most vulnerable areas, Cyprus says. In essence, that means hiring a former hacker whose job is to try to break into your system.

"You need to educate your employees," Cyprus explains. "A penetration test is not just technology. It also looks at hardware, software, procedures, and physical security—down to how your file cabinets are locked."

7. Give cyber risk its due

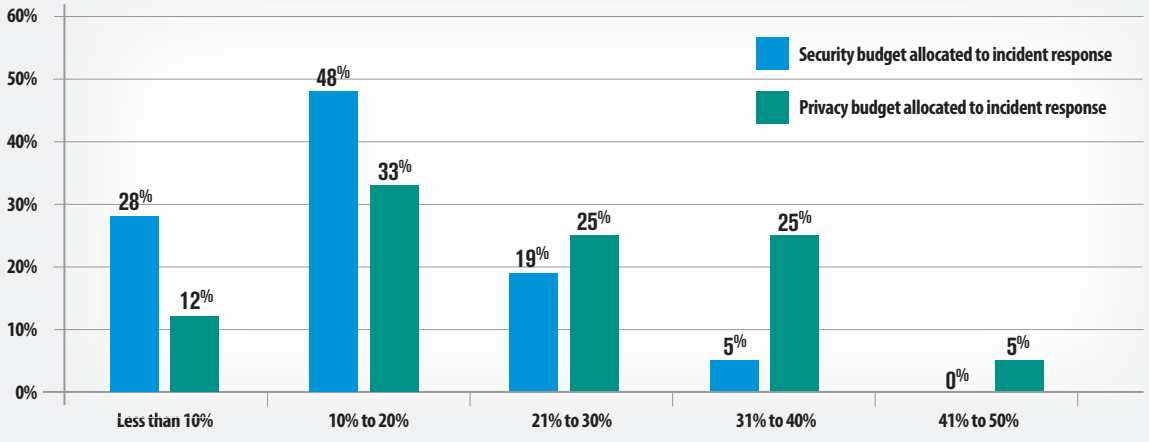
A healthcare organization needs an appropriate governance structure around its cyber risk program that goes well beyond IT, Deloitte's Mossburg says. And the cyber risk go-to person must have the ability to understand the business as a whole and have appropriate interface with others in the organization.

It remains a struggle to ensure alignment between people dealing with cybersecurity from the technical perspective and from the business perspective, Mossburg says. But, she adds, "this is the reality now. It's not going to go away and we need to adapt to it ... and keep pace with the attackers and adversaries."

8. Prepare a response plan

Mossburg says it's more a question of when a healthcare organization is going to have a cy-

Percentage of security and privacy budget allocated to incident response for healthcare organizations



Source: Ponemon Institute

berattack, not whether it will occur, and organizations must be prepared to respond immediately. Rehmann's Dore urges organizations to make sure they have incident response plans in place because a cyberattack "could come on very quickly, and the more preparation, the more ease in handling it."

Recent cyberattacks also illustrate the need to have proper controls in place and use them, Dore says. Target, for example, had a monitoring tool in place but essentially wasn't using it, she says. Had Target properly implemented the software, it would have helped to identify the problem before the company was compromised, though using the tool would have taken away some of the system's ease of use.

UNDERSTAND YOUR PLACE

In the end, collaboration is key to guarding against cybersecurity threats, says Jennifer Covich Bordenick, chief executive officer of Washington, D.C.-based eHealth Intiative, an independent, non-profit group trying to drive improvements in healthcare's quality, safety, and efficiency through information and IT. The national group, whose board chair is Sam Ho, MD, UnitedHealthcare's chief medical officer, represents all stakeholders in the industry.

Despite legal concerns about working with private-sector competitors, Bordenick says, the fact remains that cybersecurity often breaks down outside of one's organization. Thus, she says, there is "starting to be a new level of acceptance" toward collaboration efforts to combat breaches.

According to Bordenick, eHealth Initiative seeks to create information-sharing standards across the healthcare industry. It is also developing principles for a secure common platform that will allow industry stakeholders to share information on how to handle cybersecurity issues. Its executive advisory board on privacy and security, which issued a meeting report on healthcare and cybersecurity in November 2014, regularly invites regulators to closed-door forums for public sector input because regulations must change to keep up with the times.


BORDENICK

"You can't just look internally," Bordenick says. "It's all about when information leaves through different doors ... and [healthcare] organizations have hundreds of doors ... Every partnership, every vendor, every third-party that they deal with is a different door—and patients and providers have access to that information as well."

Bordenick says that is why healthcare organizations must conduct thorough self-audits of their vulnerabilities and security protocols, complete with an understanding of downstream organizations—especially since small provider groups, vendors and third parties may lack the resources for robust cybersecurity systems. "It's really about understanding your place in the world," she says.

Judy Packer-Tursman is a writer in Washington, D.C.

Reducing HACs

Penalties for hospital acquired conditions cut into bottom line

by **DAVID RICHARDSON**

It's an irony that one of the most serious risk factors for deteriorating health in the U.S. is admission to a hospital. In fact, one in 25 people admitted to hospitals acquires infections during their stay that were not present when they first sought medical intervention, according to the Centers for Disease Control and Prevention.

Hospital acquired infections (HAIs) caused illness in 722,000 patients in 2011, resulting in loss of life in 75,000 cases. Other causes of potential harm are not so easy to quantify. As Ashish Jha, MD, professor of health policy at the Harvard T.H. Chan School of Public Health, says, "Most hospitals have no idea how many people have fallen."

JHA

Jha says until recently, healthcare payment policies have, through a perverse incentive, reinforced this reality. That's because hospitals previously were able to bill payers for treating Hospital Acquired Conditions (HACs), sometimes at rates higher than the initial condition that brought the patient in for medical care.

In an effort to flip that model, the Centers for Medicare and Medicaid Services (CMS) created the HAC Reduction Program, which penalizes hospitals with HAC incidents that exceed the norm.

PENALTIES FOR HOSPITALS

The HAC Reduction Program revolutionizes the payment system for patient care in a way intended to galvanize attention on the safety aspect of the quality of patient care and not just on the quantity of care patients receive, Jha explains. In the past, he notes, patients' cases were assigned to one of the various diagnosis-related groups based on the medical condition coded in the patient's record. Payments were tied to the categorization of the case. If patients experienced an event that might prove more costly to treat than the original condition with which they presented, their cases were simply moved to the higher pay scale and insurers such as Medicare were billed accordingly.

The HAC Reduction Program, established by the Affordable Care Act (ACA), penalizes hospitals in the lowest performing quartile for HACs, imposing a 1% across-the-board reduction against overall Medicare pay-

"We all need to be concerned. It's about the health and safety of the patients; we need to do everything we can to avoid harm."

LOUISE-MARIE DEMBRY, MD, YALE UNIVERSITY SCHOOL OF PUBLIC HEALTH

ments starting in fiscal 2015. Deductions are calculated and assessed after any adjustments for value-based purchasing programs or other federal initiatives that affect the institution's net Medicare payment.

Jha says the initiative, along with value-based purchasing, represents a first salvo "in the federal government's attempt to connect financial realities to the safety and quality of care patients receive in hospitals."

IMPLEMENTATION CONCERNS

While many healthcare organizations laud the goals of the HAC Reduction Program, others including the American Hospital Association (AHA) are wary. Aside from the uncertainties they say administrators may face from being graded on a curve, the AHA maintains that the program's unwavering 1% across-the-board penalty on all Medicare payments will have a disproportionate negative impact on certain types of hospitals. Along with the Association of American Medical Colleges, the AHA cites the potential levy against indirect medical education payments as an area where funding is at risk, even though the funds do not directly relate to patient care.

Likewise, with a greater proportion of their overall financial needs funded by Medicare resources, disproportionate share hospitals appear to be at higher risk for triggering the penalty, according to a December 2014 analysis by the Essential Hospitals Institute. The institute forecasts that the penalty could limit access to care in communities where patients suffer a distinct disadvantage in financial resources. Furthermore, research indicates that hospitals in underserved communities face a disproportionate likelihood of incurring the penalty, in part due to the prevalence of underlying borderline health issues that might reveal themselves during a hospital stay in patient populations that have experienced diminished access to healthcare over extended periods of time.

Other criticisms arise from the debate over root causes of hospital acquired conditions. A 2014 study of post-operative HACs in cancer surgeries and a subset of gastrointestinal surgeries, published in the *Journal of Gastrointestinal Surgery* by lead author Daniela Molena, MD, of the Johns Hopkins University School of Medicine, concluded that "The development of [HACs] is strongly associated to pre-operative patients' characteristics and not only to sub-optimal perioperative care, therefore suggesting that the nonpayment policy might be excessively penalizing."

No critique of a policy based on metrics would be complete without noting the objection that the HAC Reduction Program criteria would benefit from adjustments. Says Jha: "You've got to measure the right things—our analysis suggests we're not necassarily penalizing the very worst hospitals. We might be penalizing hospitals that take care of sicker patients or that just pay more attention to these problems."

Nonetheless, he adds, "The wrong way to look at it is that, 'The measurements aren't great so I don't want to look at [them].'" In Jha's view, exclusively criticizing the policy for its statistical or implementation shortcomings misses the mark. "If you're an organization that wants to be a leader, what you have to [acknowledge] is that, chances are, private insurance companies and Medicare are going to work on improving the measures and eventually [you] will be on the hook for the right stuff," says Jha. "And during that time [you] still have the moral responsibility to make care better." There are specific things an organization can do, Jha adds. "There is lots of good evidence for how to reduce infections in hospitals; in some cases they can be down to zero and others should be at low rates. That to me is low-hanging fruit in an organization."

SPECIFIC MEASURES

Where HACs are related to hospital-acquired infections, CMS also now penalizes hospitals for weak performance in preventing central line-associated bloodstream infections (CLABSI) and catheter associated urinary tract infections (CAUTI) across the entire facility. Additional categories of infection such as abdominal surgical site infection rates and MSRA and C. difficile rates are scheduled for inclusion over the 2016 and 2017 payment cycles, respectively.

DANFORTH

That's good news for patients, caregivers and those who prioritize quality healthcare says Melissa Danforth, senior director of hospital ratings for the Leapfrog Group.

"We've been pushing for something like this for a long time," she says.

Regardless of the question of whether a hospital's overall safety profile can be extrapolated from the specific measures selected by CMS for the HAC Reduction Program, Danforth says the measures do represent significant areas of concern for patient health and safety.

Of the two infection criteria which CMS has designated as Domain 2, Danforth says CLABSI can be a significant cause of mortality. While incidences of CAUTI might be less deadly, Danforth says they do cause "a great deal of pain and discomfort in patients" when they do occur and thus merit scrutiny.

Louise-Marie Dembry, MD, agrees. "We all need to be concerned," says Dembry, professor of epidemiology at Yale University School of Public Health and co-director of Yale-New Haven Hospital Quality Improvement Support Services. Beyond the financial ramifications for the institution, she notes, "It's about the health and safety of the patients; we need to do everything we can to avoid harm."

HAC Reduction Program Scoring

Measures used in FY 2015

- **AHRQ Patient Safety Indicators composite measure.**
  (Performance Period from July 1, 2011 to June 30, 2013)
  35%
- **Central Line Associated Bloodstream Infections (CLABSI) measure and Catheter Associated Urinary Tract Infections (CAUTI) measure.**
  (Performance period from January 1, 2012 to December 31, 2013)
  65%

Payment adjusted for discharges between October 1, 2014 to September 30, 2015.

Additional measures to be used in FY 2016

Surgical Site Infections

- **Colon surgery**
- **Abdominal hysterectomy**

Payment adjusted for discharges from October 1, 2015 to September 30, 2016.

Additional measures to be used in FY 2017

- **Methicillin-resistant Staphylococcus aureus (MRSA)**
- **Clostridium difficile infection (CDI)**

In a separate grouping of criteria designated Domain 1 under the HAC Reduction Program, CMS selected eight measures of hospital safety categorized as Patient Safety Indicators (PSI) 90 criteria, that include hip fracture, accidental puncture, pressure ulcer and five other serious adverse events. The two domains, combined through a weighted formula, are used to calculate each facility's ranking.

According to Dembry, incoming president of the Society for Healthcare Epidemiology of America, there are some newly available technologies and shop-tested procedures that, at minimal expense, can mitigate the prevalence of HACs. But, she says, to achieve success, there needs to be an overarching "culture of safety in place within the hospital." At the top of her list is handwashing, which she says has been simplified by technology with the advent of waterless alcohol-based solutions "which makes hygiene a lot easier than when we had to look around to find a sink to do it."

Jha says another area where immediate progress can be made is in tackling medication errors. He advises hospitals to "Get the electronics and recordkeeping in gear and make sure electronic prescription systems are working properly."

A CULTURE OF SAFETY

Dembry says the culture of a hospital can make a big difference in whether infection control and safety protocols are followed. For instance, she says, if a staff member observes a doctor or someone higher up in the hospital hierarchy failing to follow proper procedures, "It needs to be safe for them to go up and say they might be making a mistake." She concedes that, in the traditional pecking order of hospital culture, that conversation is not always graceful and workers often find the idea of pointing out flaws across the lines of hierarchy somewhat intimidating if not downright terrifying.

Dembry conducts extensive orientations and training on developing a culture of safety, covering the role of every staff member at

> "You've got to measure the right things—our analysis suggests we're not necessarily penalizing the very worst hospitals."
>
> ASHISH JHA, MD,
> HARVARD T.H. CHAN SCHOOL OF PUBLIC HEALTH

> "The process of thinking about this creates a culture. By thinking about it they start to think about infections in a different way." JOHN REILING, SAFE BY DESIGN

Yale-New Haven Hospital from the clinical staff to the kitchen workers and even administrative staff. With the focus of training on "creating a team approach to healthcare," she believes a lot of incidents can be avoided "by bringing things to attention before they lead to an infection." For example, during her training sessions, she emphasizes to medical professionals at all levels that when a nurse advises a physician that he has overlooked proper hand sanitation, it should not result in a confrontation or reprisal. Instead, the physician should say, "Thank you for reminding me to wash my hands," and perform the necessary infection control protocol.

Dembry adds that check lists "can help remind us what to do and hold other people accountable."

According to Dembry, all of the hospitals in Connecticut have adopted a training model similar to the one she employed at Yale-New Haven in an effort to move towards an all-encompassing, state-wide culture of safety.

CHIPPING AWAY AT RISK

Jha suggests putting in a standard protocol that nurses have the authority to remove urinary catheters as quickly as possible once the patient is appropriately stabilized, without requiring physician approval.

John Reiling, former president and chief executive officer of SynergyHealth, the health system that includes St. Joseph's Hospital in West Bend, Wisconsin, documented an 80% decline in HAIs when this approach was implemented at St. Joseph's.

Reiling, who says safe hospitals don't happen by accident, views safety through three key arenas: processes, culture and facilty.

With billions of dollars flowing annually to hospital capital improvement projects, "Institutionalizing safety into facility infrastructure is an area that holds a lot of unrecognized potential benefit," says Reiling, current president of Safe by Design, which consults with hospitals and health systems nationwide on facility and patient care designs that emphasize safety, error reduction, and quality.

Sub-optimal facility design, explains Reiling, "creates adverse events through bad ventilation, hard floors, excessive noise, chaotic workspaces and challenging sight lines in the work environment such as between nurse stations and ICU beds."

He says a collaborative, team-oriented approach to safety must be endorsed before the facility plan even hits the drawing board. Capital improvement initiatives are a great place for hospitals to put in place systems to emphasize safety, he says, adding that built-in safety measures should be central to every plan for new construction or facility redesign.

Specific features that deserve a close look, says Reiling, are UV disinfectant systems for heating ventilation and air-conditioning systems; uniformity of treatment room layouts; softer floors to combat fatigue among staff while reducing the risk of fractures for patients; and careful consideration of sight lines.

But, says Reiling, the most important factor is full participation. Highlighting the importance of "getting the entire staff involved rather than just top level management," he adds, "The process of thinking about this creates a culture. By thinking about it they start to think about infections in a different way." In addition the collaboration encourages a broad-based "sense of ownership" of the safety mission.

In promoting safety, Reiling cautions planners not to rely too heavily on evidence-based approaches alone. Rather he says, "a risk reduction approach" makes a more reliable guide to overall safety. "You don't want to go into it saying, 'Prove to me that using UV can reduce infection rates. Unless you prove it, we don't see why we should do it.' It's not the right [reasoning]. Does it get rid of bugs? Yes. You can't really relate that directly to infection but it reduces the risk," he says. "A single design feature is not how you create less risk. You can't just do one thing, you have to do a cluster of things." ◘

David Richardson is a writer in Washington D.C.

THE NEW PATIENT-CENTERED PHARMACY

Emphasis is on relationships, engagement

by **MARI EDLIN**

Accountable care organizations and medical homes have set the pace for an emerging trend toward patient-centered pharmacies—a not-yet clearly defined model but one that could connect all the pieces of the healthcare puzzle.

Patient-centered pharmacies put consumers and their relationship with pharmacists and caregivers at the center of the business model, says Mike Cantrell, vice president of pharmacy network development for Ateb. The model produces improved outcomes primarily through medication use optimization, but also by expanding the scope of services and utilizing effective engagement and communication, Cantrell notes. Ateb, based in Raleigh, North Carolina, offers pharmacy technology systems that help implement and manage a patient-centered model.

"Patients are fully engaged when they are making the most of the healthcare services that are available to them," says Cantrell. "Pharmacies can influence a patient's willingness to engage by helping to improve health literacy and providing education regarding medications and health conditions and how they are related."

A patient-centered pharmacy also contributes to patients receiving coordinated, timely and proactive care by leveraging the frequency with which they visit pharmacies to pick up prescription medications, adds Jonathan Niloff, MD, chief medical officer for McKesson.


NILOFF

Niloff points out that those with chronic conditions are apt to fill prescriptions monthly, giving pharmacists an opportunity to expand their role in patient care.

Cantrell sees patient-centered pharmacies transitioning from the traditional transaction-based focus on filling prescriptions to a holistic approach that ensures optimal delivery of patient-focused care.

He says the new model also emphasizes pharmacist collaboration and communication with other care team members on behalf of a patient to ensure safe, effective, and coordinated care. "The process is enhanced through the use of information technology systems that create bidirectional data flow and facilitate communication."

An expanded role for pharmacists, Niloff says—outside of medication management and driving adherence—might include reminding patients to get preventive care screenings and required interventions for specific chronic conditions, such as HbA1c tests for diabetes; counseling; administering immunizations; and collecting clinical data—weight, blood pressure—to share with a patient's primary clinician.

Walgreens' focus

Although it has not officially adopted a patient-centered pharmacy model, Walgreens has introduced a large and growing panoply of programs and services that emphasize the consumer and advance the role of a pharmacist, says Jim Cohn, a Walgreens spokesperson.

"This all starts with providing greater access to high-quality,

"Patients are fully engaged when they are making the most of the healthcare services available to them."
—MIKE CANTRELL, ATEB

MD LIVE mobile application.

affordable care, offering a broader range of healthcare services and providing more personalized care to our patients," he says. "The pharmacist/patient relationship is critical, and we put the patient first in everything we do."

Cohn points out, however, that Walgreens already offered immunizations, medication therapy management, patient counseling, blood pressure testing and collaboration between pharmacists and other providers.

In many of the stores, pharmacists sit in front of the counter to spend more time talking with and consulting patients. Walgreens has extended the service to mobile and online applications called Pharmacy Chat that allow customers to communicate with pharmacists 24/7. First launched in 2010, the program conducts more than 10,000 chats each week.

Many other services offered by Walgreens take advantage of the online and mobile tools and resources available today and enable its pharmacists to extend their reach to consumers.

Its Refill by Scan program has been available since 2011, and enables consumers to scan the barcode on their prescription labels and submit it to refill medications.

Its 24/7 access to MDLIVE's network of U.S. board-certified doctors for virtual consults, which started as a mobile application in California and Michigan in December 2014, recently expanded to Colorado, Illinois and Washington and is now available through Walgreens' website on desktop and tablet devices. On June 10, Walgreens announced that it will expand round-the-clock access to customers in 25 states by the end of the year.

Last year Walgreens developed its Balance Rewards program. By completing certain wellness activities and adopting healthier lifestyles, users earn points that can be redeemed for merchandise at Walgreens stores. Rewards program results indicate higher medication adherence and greater weight loss.

In addition, Walgreens partnered with WebMD last year to launch Digital Health Advisor, a virtual wellness coaching program that enables participants to create customized goals and plans to support lasting lifestyle changes and engage in smoking cessation, weight management, exercise and emotional health interactive programs.

Taking it one step further, Walgreens pharmacists can proactively reach out and ask participants if they need assistance or advice to help them reach their goals.

Cohn says many of these services have indicated improvement in patient health, adherence, and outcomes and "in the end, these all help to strengthen that relationship (between pharmacists and customers) and drive strong customer loyalty."

Advantages/challenges

The advantages of a patient-centered pharmacy are manifold, according to Cantrell:

- Better customer health, improved quality of life and greater satisfaction;
- More efficient pharmacies leading to greater profitability;
- Better use of pharmacists' skills and

PATIENT-CENTERED PHARMACY MODEL

- Consumer/ pharmacist relationship is at the center of the model
- Medication use optimization is utilized
- Expanded scope of services offered
- Effective comunication and engagement is key
- Health literacy and education is stressed
- Collaboration between pharmacist and patient's other care members
- IT systems that utlize bidirectional data flow are in place

expertise;
- Collaboration between physician and pharmacist to improve performance of both;
- Benefits for health plans by assisting them in achieving better performance against quality metrics, such as Star Ratings and HEDIS scores.

Niloff believes that patients with chronic conditions stand to benefit most from the new pharmacy model, through increased compliance with clinical guidelines; more intense, regular monitoring based on the frequency of visits to a pharmacy; and the convenience of being able to "drop in" for a quick blood pressure check in their neighborhoods without an appointment.

On the other hand, he outlines three key challenges:

- Finding pharmacists with requisite training and a clinical comfort level to perform the services that are beyond the traditional pharmacist's role.
- Creating patient-specific interventions generated in a software system that is part of a health system or plan, along with shared IT that delivers patient-specific recommendations to a pharmacist at the point of dispensing for care coordination.
- Developing an economic model that makes it worthwhile for a pharmacist to engage in expanded activities.

"Such better care and easier access should decrease total costs of care and reduce the number of physician office and emergency room visits and hospitalizations," Niloff says.

Cantrell emphasizes scalability, cost, provider execution and payer/provider alignment of incentives as key challenges.

AVERAGE TIME AND COST FOR PATIENT VISITS

Setting	Average Visit	Average Cost
Emergency Room	1.5 hours	$570
Urgent Care	1.2 hours	$156
Office Visit	4 hours	$120
MDLIVE Virtual Visit	12 minutes	$49

Integrating technology

As mobile and other technologies become standards in healthcare, they are capable of being at the forefront of a patient-centered pharmacy. These technologies are aggregating data and sharing them among care teams, providing actionable information to patients, creating accountability, providing education and safeguarding patients' protected health information, Cantrell says.

But, Cantrell adds, "While it is difficult to overstate the future role of mHealth in healthcare delivery with respect to pharmacy, mHealth is not the primary driver of transition to a patient-centered model. The bigger driver is the emphasis on quality improvement, cost control/reduction, access to providers and related market pressures."

To enable pharmacies to engage patients, Ateb deploys its Patient Management Access Portal, a single portal for managing all patient interventions that tracks and schedules progress and patient activities and measures and manages performance in achieving objectives.

Services include education on medication use and successfully managing specific chronic diseases, identification and resolution of medication-related problems and improvement of medication adherence.

One of the features Cantrell emphasizes is an appointment-based model of pharmacy practice. Supported by the American Pharmacists Association, it designates a specific appointment day for consumers to pick up all medications, allowing pharmacists to call in advance to identify changes and confirm drugs are ready for refilling—hopefully improving medication adherence.

"This efficiency," he says, "affords the pharmacy time to deliver additional, highly valuable pharmacy services for which bandwidth otherwise does not exist. The longitudinal nature of the model is the ultimate facilitator of patient engagement and empowerment."

Evolution or Revolution?

Cantrell admits that, while the current prevalence of a patient-centered pharmacy is modest, its tremendous positive clinical and economic impact is driving a steep upward trend.

He anticipates more pharmacies will move in this direction following government and payer projections that 75% of their payments will be value-based by 2020. When that happens, notes Cantell, "Payment will be contingent on pharmacies' abilities to produce a given result or outcome, not on the processes, actions and services they must provide to get there." ■

Mari Edlin is a writer in Sonoma, California.

FIVE WAYS TO MAXIMIZE CLINICAL SUPPORT TOOLS

IT tools can make information actionable

by **SHERREE GEYER**

Clinical Decision Support (CDS) tools are improving outcomes for patients across the country.

"CDS is often a misnomer to describe electronic health record (EHR) alerts that provide guidance on care delivery. However, the term can mean any tool that assists team members in making timely, informed decisions about patient care that will improve their outcomes," says Jonathan French, director of health information system, quality and patient safety at the Healthcare Information and Management Systems Society (HIMSS). Those tools can include computerized alerts and reminders for providers and patients; clinical guidelines; condition-specific order sets; focused patient data reports and summaries; documentation templates; diagnostic support; and contextually relevant reference information, according to HealthIT.gov.

French describes how CDS has improved outcomes at the four-hospital, Hawaii Pacific Health (HPH) system in Honolulu. "Despite having a patient population with much higher colorectal cancer rates than the national average, their ambulatory clinics were in the bottom 50th percentile in delivering cancer screenings. HPH established a standard alert that red-flagged patients overdue for screening and created workflow to schedule screenings," he says. The result: "After implementation of the intervention, measurement and reporting system and incentive program, HPH quickly improved to the 90th percentile nationally in colorectal screening."

The most effective CDS tools, says French, "deliver the right information to the right person using the correct CDS intervention format sent through the correct channel and at the right point in workflow."

Indeed, HIMSS information states that CDS should enhance health-related decisions and actions "with pertinent, organized clinical knowledge and patient information to improve health and healthcare delivery." Recipients of such tools include those involved in patient care delivery. The information sent may include general clinical knowledge, guidance, and/or patient data.

Hard-wire it into the EHR

Scott Weingarten, MD, senior vice president and chief clinical transformation officer at Cedars-Sinai Medical Center in Los Angeles, California, says a CDS system "should be evidence based, accepted by clinicians, clinically meaningful, have low false-positive rates to prevent 'alert fatigue' and a measurable positive impact on patient care."

Weingarten helped usher in Choosing Wisely, his hospital's CDS, based on recommendations from dozens of medical specialties. He asserts that the best way to share CDS with clinicians is hard-wiring it into the EHR. "This will provide actionable information to influence clinical decision-making at the point of care," says Weingarten, who underscores the importance of attaining Meaningful Use (MU) of EHRs. "The federal government made a $30 billion investment (in 2009) to subsidize the purchase of EHRs by physicians and hospitals and is seeking a clinical and financial return on investment (ROI). CDS, if properly implemented, could enable that ROI," he says.

Make the value clear to providers

Dan Armijo, vice president and director of health innovation and technical assistance at Altarum Institute, Ann Arbor, Michigan, cautions that "the decision to implement CDS is about much more than check-


ARMIJO

ing the regulatory box. Deploying CDS tools has to be driven by expectations for measurable improvement in clinical and financial outcomes. The aim is better aligning clinical practice to the evidence base. Meeting regulatory requirements is just something you do along the way."

French calls CDS "the best way to improve adherence to best practices. This is critically important as the recent repeal of the Sustainable Growth Rate ensures that all Medicare reimbursement be tied to improved clinical outcomes and value starting in 2019."

Form a CDS work group

Providers must use five CDS interventions at the point of care to receive incentives offered by MU, says French. The American Health Information Management Association identifies the five rights as:

- The right information,
- to the right person,
- in the right intervention format,
- through the right channel, and
- at the right time.

"Providers receive an incentive by meeting the CDS metric and other measures of [meaningful use]. Nonetheless, CDS does not provide incentives for improved outcomes," says French, who advises those wishing to embark on CDS to "first identify a local problem or poor adherence to best practice.

"To ensure provider acceptance, form a collaborative CDS work group composed of key stakeholders across the care delivery setting. Then, conduct a CDS five rights review. If the intervention doesn't deliver on all five rights, identify another intervention," he suggests.

"Healthcare executives should decide the intent of their CDS system prior to implementation, whether to improve patient safety, quality of care or safely reduce healthcare costs." – SCOTT WEINGARTEN, MD

Define your objectives

Weingarten says CDS should be evidence-based and come from a reputable source. "Healthcare executives should decide the intent of their CDS system prior to implementation, whether to improve patient safety, quality of care or safely reduce healthcare costs," notes Weingarten. "Once the objectives have been identified, the executive should understand the types of CDS currently available. Then, they can decide whether they should make the CDS themselves, partner with other organizations who develop CDS, or buy from vendors."

Make it relevant

Armijo advises that, when considering an investment in CDS, "focus on the key areas—such as clinical relevance of content, workflow integration, and usability. Incorporate the support of physician champions to verify the clinical utility and socialize peers.

"The key is to be relevant to the provider. If the physician or healthcare provider doesn't see value in CDS content, then what you've done is add another bureaucratic layer to the delivery process and launched the provider community on a pursuit for creative documentation workarounds," he says.

Lastly, says Armijo, "Look for products that allow you to tailor or overlay content to address specific organizational priorities or quality improvement efforts. Products have matured significantly over the past few years and thoughtful integration of CDS logic and content external to EHRs is, in many cases, less costly to maintain, more agile and up to date, and can be implemented in ways that are truly seamless to the user." ◘

Sherree Geyer *is a writer in Phoenix, Arizona.*

ADVERTISER INDEX

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Partnering on COPD for savings, outcomes

Boehringer Ingleheim taps collaborations for cost control, improved care

by **DONNA MARBURY**

Chronic obstructive pulmonary disease (COPD) is the third leading cause of death in the United States, affecting up to 24 million adults. The lung disease cost the healthcare system $32.1 billion in 2010 and is estimated to increase to $49 billion by 2020, according to the Centers for Disease Control and Prevention (CDC). COPD complications also contribute to 16.4 million lost work days, and $36 billion in lost productivity.

Boehringer Ingelheim Pharmaceuticals, Inc., one of the leading pharmaceutical companies that focuses on respiratory diseases, saw those staggering statistics as an opportunity to bring its expertise to a market that needed assistance with lowering COPD complications.

"With the market changes we are all facing, we as a pharmaceutical company wanted to be a more meaningful player in the industry. We wanted to change how we develop our products, and we realized the best way to figure that out is to talk to the people who are actually providing care," says Ruchin Kansal, executive director and head of Business Innovation at Boehringer Ingelheim. A five-year partnership that initially focuses on COPD between Boehringer Ingelheim and Sutter Health, a California-based nonprofit health system that serves more than 3 million patients, aims to understand COPD patients' behavior using mobile and digital technology paired with data analytics. The collaboration comes right on time: The state of California is estimated to spend $2.8 billion in COPD medical costs by 2020, according to the CDC.


KANSAL

"From that perspective, this collaboration is an opportunity for us to build off the experiences of providers, and the challenges they face," Kansal says. "Sutter Health is unique in the fact that they have actually invested internally in research with an objective of finding efficiencies. Our collaboration will get deeper into care delivery and how it is provided."

The goals of the partnership are to:

- **Create a tablet or kiosk data collection system that patients fill out themselves at each healthcare visit;**
- **create tools that make it easier for patients and providers to communicate; and**
- **use visuals and other technology to help patients and providers collaborate on decision-making processes.**

The companies will be using clinical data to get a better understanding of patient behavior in hopes of making COPD more manageable, Kansal says.

"We will be focusing more on electronic health records data. The value in that will be focused on why patients behave the way they behave. We can become really proactive about managing a disease, and begin to build cost predictions," Kansal says.

Boehringer Ingelheim has been collaborating with payers to decrease healthcare cost for the past few years. In 2014, Boehringer Ingelheim, WellPoint and HealthCore collaborated on a multi-year project to create evidence-based guidelines for non-valvular atrial fibrillation. In 2013, the company partnered with Humana to improve outcomes and decrease healthcare costs for patients with COPD, cardiovascular disease, and other chronic diseases.

Collaborative models have become more commonplace between healthcare entities that previously never communicated. Historically, fee-for-service models and a lack of technology made it harder for payers and providers to establish trust and receive equal benefit from partnerships.

Payers reported that building trust, aligning incentives and calibrating goals with providers would improve patient outcomes and position organizations for success, in a 2013 survey of more than 300 healthcare executives conducted by Quintiles, a biopharmaceutical development company. More than 70% of respondents agreed that sharing data and informa-

tion across stakeholder groups is instrumental to the success of an interoperable healthcare system. Despite these perspectives, only half of payers and providers said they were willing to be transparent.

"We are really starting to investigate how we can provide good quality care at a reasonable cost," says Kansal, adding that all health systems need to start thinking about how care is provided throughout a patient's experience. "To be able to do that I think the healthcare industry has to move away from the way we operated in the past—in silos. Whether it's a payer, provider or a pharmaceutical company, the end goal is to provide the best patient care possible. If we can come together we can think about the real challenges and how we can solve them together."

As the Affordable Care Act (ACA) demands price transparency and better data collection and analytics, collaborations between payers and providers have become one of the most effective ways to better understand and report information on patients, according to an April 2015 report on payer analytics post-ACA published by IDC Health Insights.

"While today's payer analytics applications provide a comprehensive set of executive-level and individual line-of-business reporting capabilities, there is room for future improvement in terms of the potential for better big data management and the integration of clinical, financial, wearable, remote, and other important sources of healthcare data," says Deanne Primozic Kasim, research director, Payer Health IT Strategies at IDC Health Insights. The report finds that the Centers for Medicare and Medicaid Services' value-based and pay for performance programs incentivize collaborative business models in the healthcare industry.

Kansal adds that regulations and policies can sometimes limit collaborations, but there is still room for innovation between healthcare systems. He adds that Boehringer Ingelheim continues to consider partners who have the same goals and are willing to put up equal resources in order to obtain meaningful outcomes.

"In my mind there is only one issue and that is centered around the patient and how he is behaving today. Patients are taking on more financial burden, and are looking at healthcare services like they do retail services. Technology is making it easier for payers and providers to communicate for the sake of the patient," Kansal says. ■

Donna Marbury is a writer in Columbus, Ohio.

PAYER/PROVIDER COLLABORATION CHECKLIST

Through a commitment to collaboration, hospitals and payers will be able to clearly define patient care goals, how costs will be paid and the tools needed to deliver the best care. To help ensure success, improve trust and facilitate collaboration, payers and providers should consider the following best practices, says Steve Lamb, vice president and lead partner of Implant Partners:

- **Appoint a facilitator:** This role is important in helping gain buy-in around difficult decisions. This individual needs to have a high level of trust, reputation and the ability to develop consensus.
- **Receive equal incentives:** Shared savings plans such as bundled payments enable everyone to receive the economic rewards that come from controlling costs and quality.
- **Develop partnerships:** Design and implement a joint operating committee that brings together provider and payer leadership for strategic discussions and working sessions.
- **Work together:** Healthcare stakeholders must work together to align goals that replace competing incentives with process efficiencies. Payers and providers need to invest in change management to ensure trust and cooperation. Activities that support change include setting realistic expectations, developing outcomes, aligning incentives and committing to ongoing communication and training.
- **Share information:** Since both parties are working toward a shared goal of cost reduction, hospitals and payers must provide regular data and analytics to help determine the best care scenarios for patients at the appropriate costs. Sharing information fosters a commitment to continuous learning, process improvements and trust.

HHS investigates rise in generics

Agency wants price tag on cost to Medicaid program

by **TRACEY WALKER**

The U.S. Department of Health and Human Services (HHS) will investigate how much money Medicaid has lost over the past decade paying for rising generic drug prices by comparing price increases between 2005 and 2014 against the rate of inflation.

Sen. Bernie Sanders (I-Vt.) and Rep. Elijah Cummings (D-Md.) requested the HHS review after pharmaceutical companies refused to comply with their request to turn pricing information over to their offices. Under federal law, drug makers are required to turn that data over to the HHS.

Nearly 10% of generic drugs more than doubled in price in a recent year, according to an analysis from the Centers for Medicare and Medicaid Services (CMS). The data also showed that half of all generic drugs went up in price between July 2, 2013, and June 30, 2014.

In a letter to the HHS inspector general, Sen. Sanders and Rep. Cummings said the traditional cost savings realized by Medicaid and Medicare beneficiaries from the use of generics is threatened by spiraling prices. As a result, they want generic manufacturers to pay a rebate to Medicaid when drug rates rise faster than the rate of inflation, a provision that's currently in place for brand-name drugs. It's a move that the Congressional Budget Office estimates would save $500 million over 10 years.

Generics represent approximately 80% of total managed care prescription drug volume.

Generics represent approximately 80% of total prescription drug volume today for managed care and nearly that much for hospitals, according to F. Randy Vogenberg, PhD, RPh, a partner at consultancy Access Market Intelligence, and principal, Institute for Integrated Healthcare, Greenville, South Carolina.

To hold down costs, most managed care and hospital pharmacy purchasing managers will continue to focus on contracting and rebates, consolidating volume where possible with a single generic manufacturer, Vogenberg says. "Should a single manufacturer raise product costs or have a production problem, then that organization could be even more vulnerable."


VOGENBERG

Higher prices will have a negative effect on generic sales as costs shift to consumers and in turn impact adherence, persistency, and abandonment, says Vogenberg.

"From a total cost of care perspective in commercial markets, the goal is cost-effective outcomes that meet patient and purchaser [employer] expectations. In any event, failure to perform at the highest levels of care could risk loss of commercially insured patients," he says.

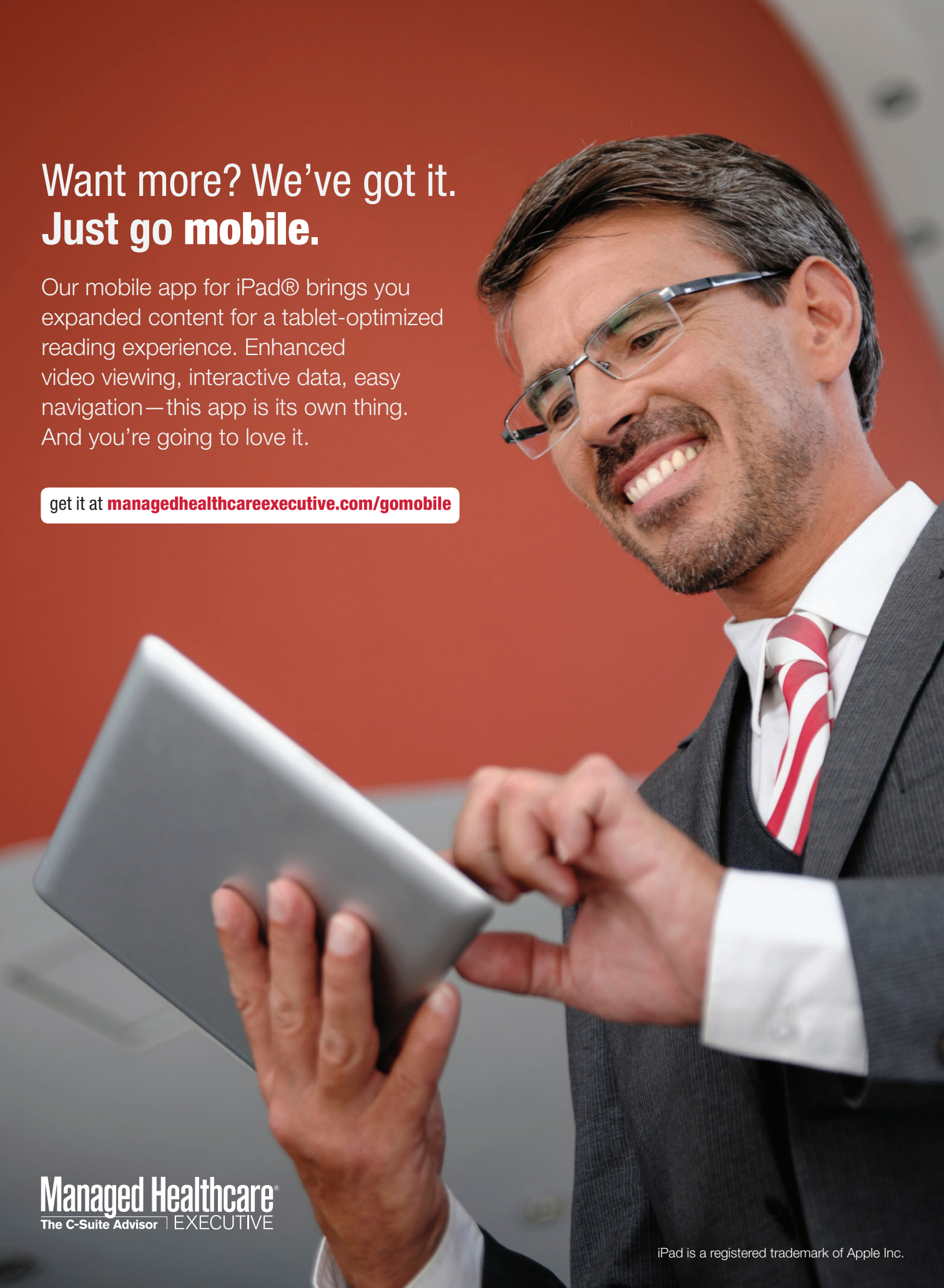
"For years, PBMs have used their formularies to encourage patients to choose generic drugs by including all generics in the bottom, or lowest out-of-pocket cost, formulary tier," says Anna Goldbeck, a principal in the National Pharmacy Practice at Buck Consultants at Xerox. "Some PBMs are reacting to the rising cost of generics by creating new tiers that require members to pay higher copayments for 'non-preferred' generic drugs."

Goldbeck says factors driving price increases for generics include:

- **Consolidation among generic drug companies;**
- **Shortage of raw materials;**
- **Supply and demand; and**
- **Regulatory issues**

Clever contracting strategies, either with the brand manufacturer and/or a specific generic company offering rebates in exchange for preferred status, could offer some relief from rising prices, Goldbeck adds.

Tracey Walker *is content channel manager for Formulary Watch.*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