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SOCIAL MEDIA

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Dual eligibles—people who are enrolled in both Medicare and Medicaid—represent some of the poorest, least-healthy and most-costly beneficiaries served by either program. Dual eligibles have typically been forced to navigate three sets of benefits—one set of benefits financed by a state Medicaid program, medical benefits financed by Medicare, and a third set of benefits for prescription drugs paid for under Medicare Part D.

To better integrate benefits, Congress created the Dual Eligible Special Needs Plan (D-SNP) program as part of the Medicare Modernization Act of 2003. The Affordable Care Act took the integrated care model for dual eligibles a step further by establishing Financial Alignment Demonstrations ("duals demonstrations"), which aim to improve care coordination and outcomes, implement new care delivery systems for beneficiaries, and control costs.

Although these demonstrations are in their early stages, some states are migrating their dual-eligible populations to this new model. In San Mateo County, California, about 7,000 beneficiaries have moved from Health Plan of San Mateo’s D-SNP to its Medicare-Medicaid Plan (MMP) that participates in the California duals demonstration, Cal MediConnect. The plan’s MMP implemented a pilot program that connects high risk members to medical care, intense case management and housing support services that help them live and thrive in the community. In one case, a 69-year-old woman was admitted to a skilled nursing facility for rehabilitation after shoulder surgery. She had lived for 26 years in a Section 8 apartment. After a year at the nursing facility, her barrier to discharge was securing a new Section 8 unit. Her case manager worked with a local housing non-profit to find a unit that would accept her Section 8 voucher. They found an apartment, helped her move in, and secured a waiver to help her obtain furniture and houseware free of charge.

That’s the kind of thing Safety Net Health Plans can do through the duals demonstrations. MMPs manage almost all Medicare and Medicaid benefits for dual eligibles, which incentivizes innovation and better care management. However, these plans know through experience that these gains are precarious. Policymakers can stabilize D-SNPs and duals demonstrations by addressing the way that plans serving dual eligibles are reimbursed.

An ongoing challenge particular to plans serving duals is a gap between the plans’ reimbursement rates and the health status of the populations they serve. The current Medicare Advantage risk-adjustment methodology does not adequately account for the higher costs of the sickest dual-eligible beneficiaries.

In its Rate Adjustment and Final Call Letter issued in April, the Centers for Medicare & Medicaid Services (CMS) took one particularly promising step to address issues with risk adjustment for dual eligibles: CMS signaled its intent to pay more accurately based on the extent to which a plan serves full-benefit or partial-benefit (i.e., only eligible for cost-sharing assistance) duals. A report by MedPAC and MACPAC shows that full-benefit duals are costlier than partial-benefit duals. But the Medicare Advantage risk-adjustment system pays the same for these two groups of beneficiaries. CMS’ willingness to look into this issue could improve the accuracy of payments to plans that serve full-benefit dual eligibles.

However, CMS is implementing a “clinically-revised” risk-adjustment model that would effectively slash reimbursement rates up to four percent for D-SNPs and MMPs. The revised model will harm most plans that exclusively enroll high-cost, full-benefit dual eligibles, because these plans do not enroll healthy Medicare beneficiaries whose costs are overestimated by risk adjustment.

Many not-for-profit net plans already operate in negative margins. This change could drive plans out of the duals demonstration and D-SNPs, and introduce uncertainty and change for beneficiaries. These programs hold tremendous promise. Let’s make changes early on to ensure their success.

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Letter of the Law

thoughts from JOHN KELLY, MATT CURLEY, and SHUCHI PARIKH

AVOID DATA MISREPORTING RISKS

Plans can incur liability for failure to report accurate information

As the managed care industry continues to grow, Medicare Advantage (MA) organizations and Medicare prescription drug plans (PDPs) have seen a noticeable uptick in enforcement activity aimed at combating fraud and abuse. One of the biggest enforcement risks stems from the misreporting of data to the Centers for Medicare and Medicaid Services (CMS). Because data misreporting can lead to significant consequences including exposure to civil litigation and administrative penalties, managed care plans should be aware of the specific sources of liability to avoid becoming a target.

CMS pays managed care plans a monthly capitated amount instead of reimbursing on a fee-for-service basis. To determine the value of the monthly capitated payment, plans submit information showing how sickly their patient population is, which CMS then compares to a benchmark. As a condition for receiving payment from Medicare, plans must certify that the information in their submissions is accurate, complete and truthful. Therefore, to avoid allegations of overbilling the government, it is crucial that managed care plans not misreport data.

Within the realm of data misreporting, risk adjustment—the process by which CMS adjusts a health plan’s monthly payments based on the health of enrollees—is a growing area of enforcement. Plans that have sicker members receive higher Medicare payments to offset the costs of enrolling a riskier patient population, and vice versa. One of the challenges MA plans face is that there is a great deal of reliance on the accuracy of physicians’ documentation because the data initially comes from providers.

In the past several years, a handful of civil False Claims Act (FCA) actions have been filed in federal courts alleging that MA organizations submitted inaccurate risk adjustment data to inflate their Medicare premiums. Some have resulted in significant settlements: In United States v. Janke, the owners of an MA plan and its primary care provider agreed in November 2010 to pay $22.6 million to the federal government to resolve allegations that they submitted false diagnosis codes that inflated their risk scores and caused Medicare overpayments.

Another enforcement trend under the umbrella of data reporting is Prescription Drug Event (PDE) data. A PDE is a record of a specific drug transaction which CMS uses to reconcile advance payments to a PDP sponsor against actual costs. At least one federal court has held that FCA liability arises when a PDP falsely certifies that it has submitted accurate and complete PDE data. In a case against CVS Caremark Corporation and its pharmacy benefits manager, SilverScript, the court held that “a PDE is a claim or demand for payment under the FCA” because it is a “prerequisite to obtaining additional payments and to reconcile the accuracy of any previous payments already made.” Therefore, PDE data that has been falsely certified as accurate by either the Part D sponsor or the sponsor’s subcontractor (like a pharmacy benefits manager) may give rise to an FCA claim.

Managed care plans’ exposure to liability continues to expand as CMS issues new regulations. A recent “60-day refund rule,” issued on May 19, 2014 for contract year 2015, requires MA organizations and PDPs to report and return overpayments within 60 days of having “identified” the existence of an overpayment. A proposed rule issued on May 12, 2014 recommends civil monetary penalties of $10,000 for each day that an MA organization or PDP fails to return overpayments.

In all of these ways, data misreporting exposes managed care plans to significant enforcement risks, including civil litigation and administrative sanctions. These entities should therefore keep a close watch on liability risks and develop strategies for staying out of the government’s line of fire.

ABOUT THE AUTHORS

John Kelly, Matt Curley and Shuchi Parikh are attorneys at Bass, Berry & Sims PLC.

This column is written for informational purposes only and should not be construed as legal advice.
t Priority Health in Michigan, about 24 patients with advanced cancers have gotten comprehensive genomic profiles of tumors since the managed care plan launched a testing program in October 2014. The aim? To give more information to physicians trying to help patients understand treatment options.

The cost? The genome tests cost $4,000 to $5,000, whereas it costs $7,000 to $15,000 per month for one drug therapy—and multiple drugs may be used, says John Fox, MD, Priority Health’s associate vice president of medical affairs. “We think there’s an unmet need, especially for rare, aggressive tumors... The goal is to get patients the optimal therapy the first time,” he says.

It’s been almost a dozen years since the Human Genome Project finished sequencing and mapping all human genes, allowing a first-time look at a person’s entire genetic blueprint. Since then, consensus is building on the promise of genetic testing and other technological advances to help individualize testing, prevention and treatment for better outcomes. But the road is bumpy as payers, health systems, hospitals and physicians in a fragmented delivery system face an overwhelming array of information to discuss with patients and act upon—if it is clinically actionable at all.

The aim of precision medicine—a term derided by some healthcare stakeholders as sounding more like marketing hype than science—is to develop more accurate diagnostic tools and therapies to help predict what will work best for the individual instead of using a one-size-fits-all approach.

That means not only performing genetic profiling to help treat cancers and other conditions, but also combining molecular information with environmental, behavioral and other data. Then comes interpretation and finding ways to overcome logistical and cost challenges—and handling issues ranging from patient privacy and consent to coding, electronic health records (EHRs) and coverage—to create a framework that allows its integration into healthcare delivery.

“I think it’s a real challenge for managed healthcare,” says Michael Millenson, president...
of Health Quality Advisors LLC and adjunct associate professor of medicine at Northwestern University. “In some cases, this can be curative of very deadly diseases, and how do you say, ‘We won’t pay for this?’ [But] those who pay for care have to understand how to make decisions and build the infrastructure as well.”

By building the infrastructure, such technology can be used to its fullest potential, Millenson says, adding, “And because it’s so expensive, that makes it even more important.” He notes that genetic testing is like any other clinical intervention: “It can be wonderful or not as effective as we hoped.”

Despite declining costs for analyzing a person’s genes, the cost of specialty therapies targeting specific genes or mutations is “high and climbing higher,” according to a New York Times story on April 27. It is a paradox that the Obama administration, even as it supports precision medicine, is trying to manage specialty medicine costs by seeking congressional permission for Medicare to negotiate prices with drug companies, the story said, quoting a Memorial Sloan Kettering Cancer Center official who said it “would be unfortunate if we make scientific progress and then price patients out of the drugs we develop through that progress.”

Daryl Pritchard, PhD, vice president of science policy for the Personalized Medicine Coalition (PMC) in Washington, D.C., describes precision medicine and accountable care as “the two big movers in healthcare reform”—and says how they will converge is a matter of

Continued on page 22
OFEV (nintedanib)—for the treatment of idiopathic pulmonary fibrosis (IPF)

- OFEV has been studied in approximately 1200 people with IPF across 3 clinical trials.
- 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).1-3
    - 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)

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.

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.

ONE CAPSULE, TWICE DAILY WITH FOOD

Not shown at actual size.

THE TOTALITY OF THE EVIDENCE DEMONSTRATES THAT OFEV SLOWS DISEASE PROGRESSION!4-7

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

SLOW THE PATH OF IPF PROGRESSION FOR YOUR MEMBERS
IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS (cont’d)

Gastrointestinal Disorders (cont’d)

Nausea and Vomiting (cont’d)

• Provided 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

• Co-administration 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. Co-administration 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.

OFEV® (nintedanib) capsules 150mg

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

Boehringer Ingelheim

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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 treatment of idiopathic pulmonary fibrosis (IPF).

Please see package insert for full Prescribing Information, including Patient Information.

ADVERSE REACTIONS:

The following adverse reactions are, in order of decreasing frequency of events (incidence), reported in at least 1 patient treated with OFEV and in 7% of patients treated with placebo:

- Gastrointestinal disorders:
  - Nausea
  - Vomiting
  - Abdominal pain
  - Diarrhea
  - Abdominal disorders
  - Metabolism and nutrition disorders:
    - Hypertension
  - Nervous system disorders:
    - Headache
  - Infections:
    - Weight decreased
  - Vascular disorders:
    - Hypertension

- Includes abdominal pain, abdominal symptoms, nausea, vomiting, diarrhea, abdominal disorders, and hypertension.

- Includes gastrointestinal disorders, including nausea, vomiting, abdominal pain, diarrhea, and abdominal disorders.

- Includes cardiac disorders, including hypertension.

- Includes gastrointestinal disorders, including diarrhea, nausea, vomiting, and abdominal pain.

- Includes metabolic and nutrition disorders, including hypertension.

- Includes cardiac disorders, including hypertension.

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 tolerance of OFEV. Management of drug interactions may require interruption, dose reduction, or discontinuation of therapy with OFEV. Coadministration with oral doses of a P-gp and CYP3A4 inhibitor, ketoconazole, 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 and these drugs may decrease exposure to nintedanib. Anticoagulants: Nintedanib is a VKORC1 inhibitor, and may increase the risk of bleeding. Monitor patients on full anticoagulant/therapy closely for bleeding and adjust.
subjects; no overall differences in safety were observed between subjects who were 65 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 ClCr) 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). Use enzyme and B-blocker Elevations: Advise patients that they will need to undergo liver function testing periodically. Advertise 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 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).
"We don’t know yet how to handle [the] data."
— Eric D. Green, MD, PhD, National Institutes of Health

Exploring precision medicine’s value

Since completion of the human genome project in 2003, it’s been a conversation—about how [personalized medicine] could revolutionize medicine," Pritchard says. “It’s the coalition’s sense that the conversation is changing from concept to reality. It’s no longer a question of whether it can be done, but instead, how can we do it, he says.

Pritchard is leading the coalition’s initiative into how to facilitate precision medicine’s adoption within healthcare delivery. He says PMC’s working group, which began in December 2014 and has about 15 academic health centers and 15 community hospital systems, hopes to identify a set of challenges, along with potential solutions and best practices, for publication in a peer-reviewed journal by the end of 2015.

Pritchard says the group, whose participants include Mayo Clinic, Inova Health System, Intermountain Healthcare, Mission Health, and Sutter Health, has identified five broad categories of challenges:

- Education and awareness of providers, consumers and payers;
- Institutional operations (how best to develop and integrate a precision-medicine system);
- Data management (how to collect and store information and incentivize its proper use);
- The decision-making process (understanding whether diagnostic tests are clinically actionable, how clinicians view tests’ perceived value, and how to offer support tools and involve patients in decision-making); and
- Ethical, legal and societal issues (how to obtain patient consent, deal with incidental findings and offer community support services).

PROMISING DEVELOPMENTS FOR SOME PATIENTS

The U.S. Department of Health and Human Services says the promise of precision medicine already has arrived for a small but growing number of patients: White blood cell counts returned to normal in eight of 10 people with one type of leukemia using a new drug that targets a specific gene. And genetic testing for HIV patients is helping doctors decide who will be helped by a new antiviral drug and who will experience harmful side effects.

Indeed, many local and regional providers, including Wake Forest Baptist Medical Center in Winston-Salem, North Carolina, tout precision medicine as rapidly advancing cancer care, allowing them to provide patients whose cancers aren’t responding to current treatment with more precise, targeted therapies.

A large research collaboration is underway between the Moffitt Cancer Center in Tampa, Florida, and Ohio State University’s Comprehensive Cancer Center. Called the Oncology Research Information Exchange Network, it aims to provide evidence to physicians of an individual’s best therapeutic options, including clinical trials, through data analysis and sharing. To date, 100,000-plus patients have agreed to participate by donating tissue; and four additional cancer centers joined the effort in February.

In an effort to jump start the process nationwide, President Obama unveiled a federal Precision Medicine Initiative in January 2015, putting $215 million into his proposed budget for fiscal year 2016. Of that, $130 million would build a volunteer database of 1 million Americans, a cohort expected to be large enough to move precision medicine from concept to reality. Another $70 million would go to the National Cancer Institute to scale up efforts to identify genetic markers for cancer and develop more...
effective treatment approaches. The remaining $15 million would fund issues related to regulation and to interoperability across secure health information technology systems.

“It's about establishing demonstrations on how best to implement and understand what’s effective,” says Eric D. Green, MD, PhD, director of the National Human Genome Research Institute at the National Institutes of Health (NIH). The effort’s initial focus is on cancer, which is “ready to go,” he says, “but with more robust research we think there will be more conditions.”

Green says there's a distinction between research and developing a scientific evidence base, and actual implementation. He explains that the federal research effort, through study of a large cohort, will serve as the basis for how to use individualized information.

“We don't know yet how to handle [the] data,” Green tells Managed Healthcare Executive. “I'm sure many health systems wouldn't want to do this right now because it isn't what they're poised to do.” But Green says it is reasonable to think about what will happen soon if pieces start falling into place. “We're poised to accelerate something that's going to be very powerful,” Green says. “...Today, if you have an acutely ill newborn in the NICU and that child is crashing and burning before your eyes—that child could have a genome sequencing in a matter of days. Because it's cheap compared to the care you're delivering and there's the potential for better treatment.”

Green foresees an increasing number of contexts for the use of genome sequencing: “I predict over the next five to 10 years, for the majority of cancers we will want to get genomic data on that tumor.”

As Congress decides whether to fund the federal Precision Medicine Initiative, an NIH advisory group expects to issue the implementation plan by about September, Green says. “If all goes well, we'll put out the first request for applications in September/October,” he says, noting this may occur even without assurances of money.

Separately, as part of a bipartisan effort to reform healthcare regulation, payment and delivery called the 21st Century Cures Initiative, the House Energy and Commerce Committee was set to introduce legislation during the week of April 27—after a year's worth of hearings—in which personalized medicine will play a significant role.

Meanwhile, private sector and state efforts are heating up. Among those initiatives ahead of the curve:

- Using $3 million in state start-up funds, the California Initiative to Advance Precision Medicine, a statewide collaboration led by the University of California at San Francisco (UCSF), was launched April 14 to spur public-private collaboration across California by building an infrastructure to advance precision medicine-oriented data, tools and applications. It will create two demonstration projects, inventory private and public precision-medicine projects in the state, and convene experts “to ensure the secure and fair exchange of data and knowledge,” state officials say.

- UCSF also is leading a public-private partnership...
Exploring precision medicine’s value

“I predict that in 10 to 15 years most of us will have our genome sequenced. [Geisinger] will just be ahead of the curve.”

— ANDY FAUCETT, GEISINGER HEALTH SYSTEM

that began in October 2014 with a $17 million, five-year award from the Department of Defense, analyzing data on thousands of patients that could lead to more precise diagnoses and patient-specific treatments, and better clinical trials, for traumatic brain injuries.

Blue Cross Blue Shield of Michigan and the University of Michigan Health System recently formed a statewide collaboration of physician organizations and laboratories to improve genetic testing practices. The Genetic Testing Resource and Quality Consortium wants to develop best practices that help medical professionals determine whether genetic testing should be used in common clinical scenarios and to decide which tests will be of most benefit.

In Pennsylvania, Geisinger Health System, an early adopter of EHRs, is involved in a large-scale, long-term genomic collaboration with a subsidiary of Regeneron Pharmaceuticals, Inc. Designed to identify genetic variants associated with human disease, the effort has sequenced the exomes of 31,000 people since its January 2014 launch; it intends to sequence about 250,000 more.

In a related move, Geisinger on April 14 opened its Precision Health Center housing clinical research space as well as a patient care center that includes a telemedicine genomics program. It is for Geisinger’s biobank participants, if researchers find something amiss with their genetic samples, as well as for patients outside its system who want another opinion on genetic testing.

INTEGRATED HEALTH SYSTEMS’ ROLE

When the Obama administration announced the Precision Medicine Initiative, federal officials said a key element is forging strong partnerships with the private sector. Specifically, they cited the role of “academic medical centers, researchers, foundations, privacy experts, medical ethicists, and medical product innovators” in helping to lay the foundation.

Yet, NIH’s Green describes it as “absolutely important” to include integrated health systems in the effort. “What Geisinger’s doing is what we’re interested in... This is a model for what we want to do on a much bigger national scale,” he says. He describes the need to partner with integrated health systems, genome companies and mobile health technology groups as vital because of interconnections.

When Geisinger was setting up its MyCode Community Health Initiative—a system-wide biobank to store blood and other samples for research use—it realized that, in many ways, its central Pennsylvania location was advantageous because of its stable population of large, multi-generational families. More than 50% of the program’s participants had used Geisinger for 20-plus years, and since Geisinger handles high-risk care, they likely stayed within its system for most treatments.

Andy Faucett, director of policy and education for Geisinger’s Office of the Chief Scientific Officer, says the health system started internally with its biobank “at a time when everyone was terrified about genetic information... We now know with sequencing, we’ll find things [that] people will want to know.” Thus, Geisinger has broadened its consent form so researchers can do “just about any type of studies on those samples,” from a single gene to an entire genome, he says.

Currently, MyCode and smaller participating biobanks have nearly 75,000 consents, of which there are about 50,000 samples already collected, he says. And the program is growing, adding 1,500 to 2,000 new consents per month. He cites a consent rate of up to 95%, depending on the clinic.

Working with Regeneron, Geisinger is sequencing 1,200 to 1,500 individuals weekly, Faucett says, describing it as likely the largest genome sequencing effort in the U.S. He explains it is not confined to cancer. “We have 20,000 genes, and we’re looking at all 20,000,” he says. “We’re not sequencing for specific targets... We want to take people with diabetes, obesity [and so on] and look for genetic indications... and we have permission to look at their active EHRs.”

Geisinger’s program is analyzing BRCA1 and BRCA2 (breast cancer), colon cancer,
anesthesia risk, and heart disease including sudden cardiac death, searching for known pathogenic changes to participants’ genes, he says. Geisinger expected to begin returning results in late April, notifying physicians first and then telling patients several days later under its open reports policy. “We anticipate 2% of individuals will have a positive finding—and each will have six to eight family members who carry the same change,” he says. Due to Regen-er’s high volume, genome sequencing costs less than the standard $4,000, but there are recruitment and storage costs for samples and data, he notes.

Several years ago, physician-led Geisinger “saw genomics as a major part of the future of medicine” and pushed ahead on its genomics work, Faucett says, adding, “I predict that in 10 to 15 years most of us will have our genome sequenced, [Geisinger] will just be ahead of the curve.”

He estimates that Geisinger, with its infra-structure, logistics, and consent forms in place, is “probably two-plus years ahead” of the federal initiative. He says Geisinger hopes to participate in the federal effort’s public-private partnerships, and has offered advice since its inception.

Institutions interested in precision medicine must invest in it, looking at everything from staffing levels to determining how to put information into EHRs in a user-friendly format, Faucett says, adding, “We’ve hired a lot of genetic counselors and we’re rapidly building our team.”

Moreover, Geisinger is in active discussions with payers, Faucett says. “We have our own payer arm—Geisinger Health Plan—and we’re trying to gather the right information to show them [i.e., other payers] that [genetic testing] would be beneficial and cost-effective to do.”

MICHIGAN BUILDS ON A COLLABORATIVE APPROACH

In Michigan, David Share, MD, MPH, the Michigan Blues’ senior vice president of Value Partnerships, describes the genetic testing collaboration as building on nearly two dozen statewide collaborative efforts over the years. A hybrid community practice and hospital-based initiative, it is extending its reach to primary care specialists, genetic counselors, pathologists and other provider types across Michigan.

“We’re on the verge of this explosion of more information and potential costs,” Share says. He cites a pressing need for a knowledge base in a current environment with “a plethora of information about genetic testing and a paucity of understanding.” Despite long-term potential, there now is “much more uncertainty than certainty,” he says. “It’s tough for an expert to keep up, impossible for the generalist.”

Share worries about some tech firms’ push toward broad genetic testing. “Once you do ‘shot gun’ testing [on people not at risk], then you’re more likely to get misleading information, like mutations with no clinical significance,” he says.

“Within Tier 1, we pay all the time, don’t pay, or, like with BRCA1, we pay if we make sure it’s warranted…”

— DAVID FINLEY, MD, CIGNA CORP.

The genetic testing quality consortium is working to pull together expertise in Michigan and provide tools to clinicians to guide their practices, he says. Recruitment of providers is expected to continue into the fall, followed by information gathering and development of clinical guidelines.

“We expect to start with about 10 to 15 communities of practitioners,” then grow statewide, he says, stressing the effort “isn’t for the Blues to determine coverage. The goal here is not to control anybody, but to gain knowledge so people can make better choices.”

In making its own coverage determinations on all genetic testing, not only breast cancer, the Michigan Blues has contracted with a company of genetic testing experts to guide the insurer “in sifting through clinical evidence on which tests offer meaningful help in treatment,” Share says.

“Other health plans are establishing contracts with companies that will do a panel of hundreds of tests for $1,500, and it sounds like a bargain,” Share says. “But then you’re drinking from a fire hose, taking in huge amounts of information…” He says this could result in too much data that is not necessarily actionable, perhaps worrisome to patients, and likely to snowball into unneeded tests. “If you test ev-
For patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy

Otezla was evaluated in 2 multicenter, double-blind, placebo-controlled trials of similar design. Patients with moderate to severe plaque psoriasis (N = 1257) were randomized 2:1 to Otezla 30 mg or placebo twice daily for 16 weeks, after a 5-day titration. Inclusion criteria: Age ≥18 years, BSA involvement ≥10%, sPGA ≥3, PASI score ≥12, candidates for phototherapy or systemic therapy. PASI-75 response at week 16 (primary endpoint): Study 1: Otezla 33% vs placebo 5% (P < 0.0001); Similar PASI-75 response was achieved in Study 2.

BSA, body surface area; PASI, Psoriasis Area and Severity Index; sPGA, static Physician Global Assessment.

IMPORTANT SAFETY INFORMATION

Contraindications

Otezla® (apremilast) is contraindicated in patients with a known hypersensitivity to apremilast or to any of the excipients in the formulation.

Warnings and Precautions

Depression: Treatment with Otezla is associated with an increase in adverse reactions of depression. During clinical trials, 1.3% (12/920) of patients treated with Otezla reported depression compared to 0.4% (2/506) on placebo; 0.1% (1/1308) of Otezla patients discontinued treatment due to depression compared with none on placebo (0/506). Depression was reported as serious in 0.1% (1/1308) of patients exposed to Otezla, compared to none in placebo-treated patients (0/506). Suicidal behavior was observed in 0.1% (1/1308) of patients on Otezla, compared to 0.2% (1/506) on placebo. One patient treated with Otezla attempted suicide; one patient on placebo committed suicide.

Carefully weigh the risks and benefits of treatment with Otezla for patients with a history of depression and/or suicidal thoughts/behavior, or in patients who develop such symptoms while on Otezla. Patients, caregivers, and families should be advised of the need to be alert for the emergence or worsening of depression, suicidal thoughts or other mood changes, and they should contact their healthcare provider if such changes occur.

Weight Decrease: Body weight loss of 5-10% occurred in 12% (96/814) of patients treated with Otezla and in 5% (19/382) of patients treated with placebo. Body weight loss of ≥10% occurred in 2% (16/784) of patients treated with Otezla compared to 1% (3/382) of patients treated with placebo. Monitor body weight regularly; evaluate unexplained or clinically significant weight loss, and consider discontinuation of Otezla.

Drug Interactions: Apremilast exposure was decreased when Otezla was co-administered with rifampin, a strong CYP450 enzyme inducer; loss of Otezla efficacy may occur. Concomitant use of Otezla with CYP450 enzyme inducers (eg, rifampin, phenobarbital, carbamazepine, phenytoin) is not recommended.

Adverse Reactions

Adverse reactions reported in ≥5% of patients were (Otezla%, placebo%): diarrhea (17, 6), nausea (17, 7), upper respiratory tract infection (9, 6), tension headache (8, 4), and headache (6, 4).

Use in Specific Populations

Pregnancy and Nursing Mothers: Otezla is Pregnancy Category C; it has not been studied in pregnant women. Use during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known whether apremilast or its metabolites are present in human milk. Caution should be exercised when Otezla is administered to a nursing woman.

Renal Impairment: Otezla dosage should be reduced in patients with severe renal impairment (creatinine clearance less than 30 mL/min); for details, see Dosage and Administration, Section 2, in the Full Prescribing Information.

OTZEZA® (apremilast) tablets, for oral use

The following is a Brief Summary; refer to Full Prescribing Information for complete product information.

INDICATIONS AND USAGE
OTZEZA® (apremilast) is indicated for the treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

CONTRAINDICATIONS
OTZEZA is contraindicated in patients with a known hypersensitivity to apremilast or to any of the excipients in the formulation [see Adverse Reactions (6.7)].

WARNINGS AND PRECAUTIONS
Depression: Treatment with OTZEZA is associated with an increase in adverse reactions of depression. Before using OTZEZA in patients with a history of depression and/or suicidal thoughts or behavior prescribers should carefully weigh the risks and benefits of treatment with OTZEZA in such patients. Patients, their caregivers, and families should be advised of the need to be alert for the emergence or worsening of depression, suicidal thoughts or other mood changes, and if such changes occur to contact their healthcare provider. Prescribers should carefully evaluate the risks and benefits of continuing treatment with OTZEZA if such events occur. During the 0 to 16 week placebo-controlled period of the 3 controlled clinical trials, 1.3% (12/920) of patients treated with OTZEZA reported depression compared to 0.4% (2/506) treated with placebo. During the clinical trials, 0.1% (1/1308) of patients treated with OTZEZA discontinued treatment due to depression compared with none in placebo-treated patients (0/506). Depression was reported as serious in 0.1% (1/1308) of patients exposed to OTZEZA, compared to none in placebo-treated patients (0/506). Instances of suicidal behavior have been observed in 0.1% (1/1308) of patients while receiving OTZEZA, compared to 0.2% (1/506) in placebo-treated patients. In the clinical trials, one patient treated with OTZEZA attempted suicide while one who received placebo committed suicide.

Weight Decrease: During the controlled period of the trials in psoriasis, weight decrease between 5%-10% of body weight occurred in 12% (96/784) of patients treated with OTZEZA compared to 5% (19/382) treated with placebo. Weight decrease of ≥10% of body weight occurred in 2% (16/784) of patients treated with OTZEZA 30 mg twice daily compared to 1% (3/382) patients treated with placebo. Patients treated with OTZEZA should have their weight monitored regularly. If unexplained or clinically significant weight loss occurs, weight loss should be evaluated, and discontinuation of OTZEZA should be considered.

Drug Interactions: Co-administration of strong cytochrome P450 450 enzyme inducers, rifampin, resulted in a reduction of systemic exposure of apremilast, which may result in a loss of efficacy of OTZEZA. Therefore, the use of cytochrome P450 450 enzyme inducers (e.g., rifampin, phenobarbital, carbamazepine, phenytoin) with OTZEZA is not recommended [see Drug Interactions (7.1) and Clinical Pharmacology (12.3)].

ADVERSE REACTIONS

Clinical Trials Experience in Psoriasis: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trial of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice. Diarrhea, nausea, and upper respiratory tract infection were the most commonly reported adverse reactions. The most common adverse reactions leading to discontinuation for patients taking OTZEZA were nausea (1.6%), diarrhea (1.0%), and headache (0.8%). The proportion of patients with psoriasis who discontinued treatment due to any adverse reaction was 6.1% for patients treated with OTZEZA 30 mg twice daily and 4.1% for placebo-treated patients.

Table 3: Adverse Reactions Reported in ≥1% of Patients on OTZEZA and With Greater Frequency Than in Patients on Placebo; up to Day 112 (Week 16)

<table>
<thead>
<tr>
<th>Preferred Term</th>
<th>Placebo (N=506) n (%)</th>
<th>OTZEZA 30 mg BID (N=920) n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea</td>
<td>32 (6)</td>
<td>160 (17)</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>31 (6)</td>
<td>84 (9)</td>
</tr>
<tr>
<td>Headache</td>
<td>21 (4)</td>
<td>75 (8)</td>
</tr>
<tr>
<td>Headache</td>
<td>19 (4)</td>
<td>55 (6)</td>
</tr>
<tr>
<td>Abdominal pain*</td>
<td>11 (2)</td>
<td>39 (4)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>35 (7)</td>
<td>155 (17)</td>
</tr>
<tr>
<td>Tension headache</td>
<td>24 (4)</td>
<td>78 (8)</td>
</tr>
<tr>
<td>vomiting</td>
<td>8 (2)</td>
<td>35 (4)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>9 (2)</td>
<td>29 (3)</td>
</tr>
</tbody>
</table>

Table 3: Adverse Reactions Reported in ≥1% of Patients on OTZEZA and With Greater Frequency Than in Patients on Placebo; up to Day 112 (Week 16)

<table>
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<tr>
<th>Preferred Term</th>
<th>Placebo (N=506) n (%)</th>
<th>OTZEZA 30 mg BID (N=920) n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dyspepsia</td>
<td>6 (1)</td>
<td>29 (3)</td>
</tr>
<tr>
<td>Decrease appetite</td>
<td>5 (1)</td>
<td>26 (3)</td>
</tr>
<tr>
<td>Insomnia</td>
<td>4 (1)</td>
<td>21 (2)</td>
</tr>
<tr>
<td>Back pain</td>
<td>4 (1)</td>
<td>20 (2)</td>
</tr>
<tr>
<td>Migraine</td>
<td>5 (1)</td>
<td>19 (2)</td>
</tr>
<tr>
<td>Frequent bowel movements</td>
<td>1 (0)</td>
<td>17 (2)</td>
</tr>
<tr>
<td>Depression</td>
<td>2 (0)</td>
<td>12 (1)</td>
</tr>
<tr>
<td>Bronchitis</td>
<td>2 (0)</td>
<td>12 (1)</td>
</tr>
<tr>
<td>Tooth abscess</td>
<td>0 (0)</td>
<td>10 (1)</td>
</tr>
<tr>
<td>Folliculitis</td>
<td>0 (0)</td>
<td>9 (1)</td>
</tr>
<tr>
<td>Sinus headache</td>
<td>0 (0)</td>
<td>9 (1)</td>
</tr>
</tbody>
</table>

Two subjects treated with OTZEZA experienced serious adverse reaction of abdominal pain.

Severe worsening of psoriasis (rebound) occurred in 0.3% (4/1184) patients following discontinuation of treatment with OTZEZA (apremilast).

DRUG INTERACTIONS

Strong CYP 450 Inducers: Apremilast exposure is decreased when OTZEZA is co-administered with strong CYP450 inducers (such as rifampin) and may result in loss of efficacy [see Warnings and Precautions (5.3) and Clinical Pharmacology (12.3)].

USE IN SPECIFIC POPULATIONS

Pregnancy: Pregnancy Category C. OTZEZA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Pregnancy Exposure Registry: There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to OTZEZA during pregnancy. Information about the registry can be obtained by calling 1-877-311-8972.

Nursing Mothers: It is not known whether OTZEZA or its metabolites are present in human milk. Because many drugs are present in human milk, caution should be exercised when OTZEZA is administered to a nursing woman. Pediatric use: The safety and effectiveness of OTZEZA in pediatric patients less than 18 years of age have not been established.

OVERDOSAGE

In case of overdose, patients should seek immediate medical help. Patients should be managed by symptomatic and supportive care should there be an overdose.

Manufactured for: Celgene Corporation, Summit, NJ 07901

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Pat. http://www.celgene.com/therapies

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Based on APRP1.003 OTZ_PsO_HCP_BSw.003 09_2014
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Continued from page 25

everyone with a broad panel—that’s a lot more expensive than targeting where it’s needed,” Share says. If a physician does 100 blood tests, five to eight may be slightly elevated or low, “but that may be just normal variation,” he explains.

Share anticipates more efficient use of resources and savings if there is “intelligent evidence-based testing and treatment,” and people who don’t benefit from genetic tests don’t get them. Ultimately, he says, “We think we’ll deliver much more care to the community” with the initiative.

**CIGNA PROCEEDS CAUTIOUSLY**

Cigna Corp. considers coverage for genetic testing—ranging from sequencing a single gene, such as BRCA, to multigene panels looking at five, 10 or 20 genes, to full genome sequencing—in the same way the managed care organization makes other coverage decisions, says David Finley, MD, Cigna’s national medical officer for enterprise affordability. “Do scientific studies prove an association with beneficial health outcomes? That’s the standard we use to cover anything, including multigene panels,” he says.

Finley says there is no question that BRCA testing, which identifies genes linked to a greater risk for developing breast and ovarian cancers, is tied to beneficial health outcomes. By contrast, he says, “There might be multi-gene panels that companies sell, saying, ‘If you look at something like BRCA, you could look at other things’...but there’s no evidence that this further testing leads to beneficial health outcomes.”

Cigna’s approach is to look at each individual test and hold it up to the basic standard, explains Finley. In addition to BRCA, Tier 1 genetic tests are those performed for such illnesses as cystic fibrosis, colon cancer, and various neonatal conditions; and they have sufficient volume to merit their own CPT codes. In general, Finley says, Cigna pays for Tier 1 tests “because they’ve been around for awhile, they’re well understood, they’re not abused...and we wouldn’t achieve anything by managing these tests.”

“Within Tier 1, we pay all the time, don’t pay, or, like with BRCA1, we pay if we make sure it’s warranted [based on personal and family cancer history] and that patient gets genetic counseling” prior to testing, Finley says.

For Cigna, Tier 2 essentially consists of 10 CPT codes, each of which has five to 250 different genetic tests based on how resource-intensive they are, he says. If it’s “high intensity, and we don’t know what it’s for, we don’t cover” the genetic tests. He notes, for example, that tests for Alzheimers, and some cholesterol and lipid tests, are not clinically actionable.

Another category is pharmacogenetics tests that show whether an individual will metabolize a drug in a different way due to genetic mutation. Finley notes that Cigna’s policy is not to cover a test for how a person metabolizes Coumadin, an anticoagulant, because it doesn’t change or affect how a patient would be treated and monitored. “But we cover other pharmacogenetic testing,” he adds.

With respect to genetic testing of tumor tissues, Finley says that Cigna covers tests including OncotypeDX, a multigene panel. Some women with breast cancer may have one or two lymph nodes positive and, while they may not fall within the guidelines for chemotherapy, they may be advised to get chemotherapy if this test were to show they are at higher risk of recurrence, he explains.

Given these various categories, Finley says, “If someone says, ‘Do you cover precision/personalized medicine?’ I would say, ‘What do you mean?’ Right now, I think there’s more information out there than the medical community knows what to do with...and I think we need to be careful.”

Finley says the volume of genetic testing is increasing. Cigna saw “a marked increase” after actress Angelina Jolie had a double mastectomy to prevent breast cancer after a positive BRCA test in 2013, “and that increase has been maintained,” he says.

**NARROWING DOWN RISK FACTORS**

As for preventive efforts, some firms are marketing products measuring an individual’s genetic risk of certain diseases. Chief executive officer Prakash Menon of BaseHealth, says his firm’s health assessment platform analyzes a person’s genetic, lifestyle, medical and environmental factors to calculate risks for 40 of the most complex diseases, including Type 2 diabetes and stroke. It isn’t a direct-to-patient model; data go to physicians who walk through patients’ assessments, set up action plans and track progress. It works with wearable fitness and other devices to get patient information directly into the platform.

In April, the California-based firm added to its stand-alone platform for physicians, introducing a bundle of technology and services that
Exploring precision medicine’s value

allows its products to be integrated into hospitals’ existing systems. Menon says BaseHealth’s current focus is primarily on medium-sized regional medical centers handling around 20,000 patient visits annually, and concierge physician groups.

BaseHealth also is in discussions about offering its product at a per-member-per-month rate to plans trying to manage high-risk members and to differentiate themselves by offering wellness platforms, he says. “We will talk with ACOs [accountable care organizations] when the time is right,” he adds.

BaseHealth’s platform doesn’t require a $4,000 full genome sequencing, Menon says; instead, it uses genome typing based on a saliva sample for about $200. “We don’t make money on it; it’s just a cost pass-through to the lab,” he says. The monthly cost per patient, including monitoring, is about $9.75.

Education is a strong component of BaseHealth’s product. If the patient has 20 risk factors, for example, the physician may want to consider a narrower focus. “You’ve got to make this personalized,” says Hossein Fakhrai-Rad, BaseHealth founder and chief scientific officer. “And within those two or three [risk factors], you may just focus on blood pressure...so the patient doesn’t get overwhelmed.

“We’ve been commercializing for the last eight months,” Menon says, citing a dramatic increase of interest in the past four to five months. “When we started, it was harder to explain...but I think now everybody gets it,” he says. “The challenges...are just trying to fit it into business models that work.”

VALUE OF SPECIALIZED TREATMENTS

With more treatment breakthroughs and rising use of specialty pharmaceuticals, the question is how to ascribe value, says Dan Renick, RPh, president of Precision for Value, a unit of Precision for Medicine, a specialized services firm supporting next-generation drug development and commercialization. He says this value proposition is especially daunting when plans may incur significant costs now but derived benefits may take years, perhaps after affected individuals dis-enroll.

“Precision medicine in the face of limited resources necessitates evidence generation that supports the value of therapeutic breakthroughs,” says Renick, a former Humana Inc. pharmacy executive. He works with managed-care divisions of pharmaceutical companies as they attempt to define products’ value for plans, often starting with baseline models that health plans then utilize with data on their specific populations and geographies.

Unlike therapies for asthma, chronic obstructive pulmonary disease and other chronic conditions that foster short-term benefits by avoiding emergency-room visits and hospitalizations, Renick says a costly hepatitis C treatment may avoid a liver transplant many years from now. “Plans ask, ‘How can I pay such a huge cost upfront and perhaps not derive value later on?’” he says.

To illustrate his work, Renick, while declining to discuss specifics, cites use of a highly specialized therapy that greatly reduces hospitalizations. While modestly higher in price than standard therapy, the new therapy may be provided at home at much lower costs since the standard requires an infusion center. “So you recognize the new formulation offers value beyond what previously existed in the market...If you solely look at the price, you may overlook value,” he says. “In that case, we supported the [pharmaceutical] client to effectively analyze the evidence and communicated the total value proposition to payers.”

Renick distinguishes between making new therapies available in the plan formulary and actively letting drug makers talk to physicians. “As integrated delivery systems become payers, they actively advocate for the use of that product...because they’re bearing risk within their systems,” he says. It begins with broad formulary acceptance, he says, “then you go to integrated delivery systems that may more actively move patients to newer therapies to take advantage of the costs of lower administration.”

“Precision medicine in the face of limited resources necessitates evidence generation that supports the value of therapeutic breakthroughs.”

— DAN RENICK, RPH, PRECISION FOR VALUE

Judy Packer-Tursman is a freelance writer in Washington, D.C.
Google changes health search rules

Mayo Clinic info featured in box when consumers receive search results  by JUDY PACKER-TURSMAN

Given that one in 20 Google searches is for health-related information, Google, Inc. recently decided to try something new. In February, the global technology firm, in partnership with Mayo Clinic, launched a Web health-search product that it says is giving U.S. consumers “a better place to start” in finding reliable, vetted online information on health conditions such as concussion and measles.

Industry experts assert that Google’s still-evolving product, while perhaps a “useful first pass,” won’t replace nurse advice lines or other information tools used by managed care organizations for members. Some MCOs, including Cigna Corp., also tout their own online information sources as offering increasingly sophisticated information on local provider costs and quality directly related to members’ coverage and geography.

But such efforts, even for national MCOs, are by their nature more limited than massive Google’s efforts—and may come later in the information-seeking process.

Conservatively, Google, which posted $66 billion in revenue for 2014, gets several billion hits a month from consumers seeking health information—even before they approach their physicians or other providers in their insurers’ networks. Studies by Pew Research Center and others indicate that about eight in 10 consumers seeking health-related information begin with a search engine.

“A thread that runs through all this is consumer trust,” says Harry Greenspun, MD, director of the Deloitte Center for Health Solutions in Washington, D.C., the consulting firm’s research arm whose scope of work includes regular consumer surveys. “...It’s very common for people to do Web searches for information, but they bring the information to someone they trust more.”

Among consumers seeking health information, there is “real skepticism once you [look beyond] government agencies and organizations that are specifically aligned around a particular disease,” Greenspun says. Payers, pharma and employers—those entities trying to send the most information to consumers—actually rank at the lowest level of trust, especially amid privacy concerns, he says.

Against this backdrop, he says the jury is still out on consumer information partnerships among technology firms, healthcare companies and other businesses, viewed with varying levels of trust. “Just because you create this, doesn’t mean consumers are...
going to use it....Mayo already has this data on its website,” Greenspun says.

Consumers’ “needs haven’t changed much,” he says, but their expectations have risen considerably. “Millenials in particular want to get information the way they want to get it,” Greenspun says. “If someone has a question, they’ll want it answered on the device, in the moment....So the question will be whether health plans are serving consumers in the ways they want to be served.”

The bottom line for health plans? “Plans need to understand what their consumers want,” Greenspun says. “Consumers may or may not use this kind of thing [i.e., the Google/Mayo search product]. If they don’t trust this information, they may just do what they’d do anyway—and call a nurse advice line [or another source]...But it could be important because the first call that you make will often determine your ultimate outcome and the cost.” A person with neck pain, for example, might call a primary care physician, a neurosurgeon, an orthopedist, a chiropractor or a massage therapist, he says.

“The real lesson here for plans is that disruptions are everywhere, and there are lots and lots of traditional and nontraditional players [partnering with each other]—and they’re jumping into healthcare and challenging traditional business practices,” Greenspun tells Managed Healthcare Executive.

“In an era where consumers are becoming more powerful, organizations that can meet consumers’ needs better are likely going to erode existing business models...disruption is the new norm now.”

**NOT TRYING TO REPLACE MEDICAL ADVICE**

In its new health-search venture, Google is using Knowledge Graph, a Google app that provides more than a list of Web pages related to a search. Included next to page links is boxed information on typical symptoms and treatments, details on how common the condition is, who it affects, whether it is contagious, and so on, sometimes accompanied by medical illustrations.

Google’s Prem Ramaswami, the product manager directing the health initiative, told Managed Healthcare Executive in an exclusive interview that Google has been interested in health searches since its inception. Google wants to help users by “providing an introductory framework from which you can have a really useful conversation” with your physician, he says.

In general, Google wanted to better understand the health space, according to Ramaswami, and to build a database of health-related information similar to what it has done in other fields. He says the effort evolved from the idea of looking at a condition’s basic symptoms to consideration of other matters, such as its prevalence, in order to “take users down a safe path.”

Ramaswami explains that Google “crowd-sourced information,” paying more than 150 medical doctors across the U.S. to review materials and to give Google “prevalence ratings,” such as whether asthma always presents with a cough. Google also has medical doctors on staff who review information, he says, explaining Google is aware that “getting health information wrong can have really bad impacts.”

Eight in 10 consumers seeking health-related information begin with a search engine.
“We are in uncharted territory...so we hired a medical director on staff to implement the process,” he says, adding that the information-vetting process with 150 doctors is ongoing. He explains the idea is to present “the medical gestalt,” and not the latest information on cutting-edge research. For example, doctors vetting information on Ebola determined that a rapid test for Ebola, while FDA-approved, is not yet commonly used, so this test isn’t included in Google’s “knowledge graph.”

Google thought about who provides accurate health information and is a well-known brand, then asked Mayo Clinic to be a partner. Ramaswami says. Google approached Mayo on the new health-search product, he says, “but Mayo has also approached us for years about how to be a partner.”

According to Ramaswami, Google presents health information to Mayo—“Here’s a condition and here are all the facts and prevalence”—and asks Mayo to tell Google if it is “missing anything along the way.” He says there are space constraints for information since Google’s app is designed for a mobile phone; but even though the source line is listed as “Mayo and others,” with a hyperlink to Mayo’s website, he says other resources are listed under “Learn more.”

Mayo Clinic has been “an excellent partner so far,” Ramaswami says, but he stresses that Google is working with others on reviewing health information. Each of the facts in the knowledge graphs has been reviewed, on average, “by 11.1” medical doctors, he says. He describes it as a rigorous process: “We really spent a lot of time to make sure a lot of eyes are on these graphs.”

Ramaswami says the health product partnership “makes good sense” for both parties, and that Google is keeping its options open with respect to future initiatives. “We view this as an initial foray into health, and there’s a lot more we want to do over time,” he says. For example, Google may do more with its information for people doing searches on prescription drugs, expanding on materials it compiled on Lipitor and other drugs a couple of years ago, he says.

Thus far, Google has completed information for about 400 health conditions, and wants “to add more conditions and make the graph more applicable,” Ramaswami says. Google wants to make this health information available globally over time, he adds, noting that medical care isn’t as accessible in some parts of the world as it is in the U.S., and some conditions are rare in the U.S. but not elsewhere.

Ramaswami says Google, through its constant monitoring of Web searches, “knows what people are looking for on a daily basis,” and its completed information on 400 conditions represents a significant portion of what is being searched for. “Google has tried to build prevalence information...and just because it’s rare doesn’t mean people aren’t looking for it a lot,” he says, citing Ebola as an example.

Just prior to Google’s launch of information on measles, vaccination was in the news because of a recent outbreak in the U.S., he says. To “disseminate good health,” he says Google’s measles description is: “A viral infection that’s serious for small children but is easily preventable by a vaccine.”

Overall, Google is getting good feedback on its new health-search product from users, Ramaswami says. He notes this is the first time that Google is building user graphs using experts, and some physicians are telling the company that they want to be able to print out the materials for patients.

A ‘FIRST PASS’

Broadly speaking, some healthcare industry insiders say Google’s new product, as an effort at promoting more transparency in healthcare, is welcome. But others voice concerns.

“I think a lot remains to be seen,” says Caitlin Morris, health system transformation program director at Families USA, a healthcare consumer advocacy group.

In general, Morris says that, while she isn’t sure the Google/Mayo initiative will prove to
be of great benefit to consumers, “any sort of effort to direct consumers to more validated, more useful information is a good one.” Such direct access to validated information reduces problems associated with finding less credible information, she says. But she notes that Google and Mayo are businesses, so their venture “can be perceived as an ad—which doesn’t mean it’s not a credible service.”

Moreover, Morris says the way in which health information is presented can bias consumers—and “what it selects to display can have real consequences for folks,” especially with respect to treatments. Thus, she says, people must understand the Google health search “is very superficial and a first pass at information, and not a replacement for a conversation with a doctor.”

As for whether Google’s product could replace other consumer health-information tools, Morris says: “I wouldn’t see it as a credible replacement for tools that health plans provide to support consumers outside of the doctor’s office, like nurse help lines...which respond to individual needs.”

**CIGNA’S HEALTH INFO TOOL**

Cigna spokesman Joe Mondy says Google’s venture into improving health searches could be helpful. “As a principle, we think all forms of transparency are important,” he says. “When Google says they want to provide tools, we say, ‘Come on in.’”

But Mondy notes that Google has “been in the game in fits and starts with various partners,” whereas Cigna has spent the past 15 years steadily improving its information tool in its role as a health-service provider for millions of customers.

Cigna offers its own online information tool—myCigna.com—to 14 million-plus consumers, including members and their families, he says. It has evolved from a network provider directory and now offers in-depth quality and cost information on network physicians; pharmacy drug-cost comparisons; information on MRIs and other procedures, including hospital charges and pricing ranges; and other data for comparison shopping. Data are updated in batch work on a weekly basis, he says, and quality measures are vetted with network physicians before approaching consumers with the tool.

Cigna also uses Google maps and color-coded pins to show doctors’ ratings and locations, he notes.

The insurer has “virtually 100% saturation” of medical members registering to use myCigna, he says, “and the number of visits is dramatically rising, particularly on the app side.”

In 2014, Cigna had 28 million customer visits to its professional search engine, Mondy says. While the plan offers cost and quality information on 110 medical and dental procedures comprising almost all of its claims (up from 80 procedures in 2014), he says, about 8 million hits were related to three procedures: colonoscopy, MRI and mammography. Cigna also offers pricing information on 60,000 pharmacies.

Cigna added the capability to perform cost analysis to its mobile app in 2014 and had 3 million app visits last year, says Mondy. It may begin “anticipatory computing” (monitoring what members are looking at and anticipating what else they might be interested in) in the next few years, he adds.

“You could start there [i.e., with a Google search], then go to myCigna to see what doctors and hospitals specifically charge according to your plan, determine how much money is available in your Health Savings Account, get real-time information on where you are with your deductible and your co-insurance,” Mondy says. “[Ours] is a very precise tool that does the math for you.”

“We want to make consumers more proactive and better partners in their care,” Mondy concludes, echoing Google’s Ramaswami.

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“We view this as an initial foray into health, and there’s a lot more we want to do over time.”

PREM RAMASWAMI, GOOGLE
n a move that is sending waves throughout the country, late last year California tax authorities revoked Blue Shield of California’s tax-exempt status. The Franchise Tax Board hasn’t commented on the exact reasons for this revocation although some observers have speculated it may be related to high reserves, executive salaries similar to that of for-profit insurers, or the perception that it is not fulfilling its mission as a non-profit. Blue Shield believes it meets the requirements for a state income tax exemption and has challenged the Franchise Tax Board’s decision.

Ironically, the question arises, are non-profit plans at a competitive disadvantage or a competitive advantage?

David Ford, principal of The Health Commons Group and former chief executive officer of non-profit insurer, CareOregon, Woodland, Washington, says there are advantages and disadvantages to having such status. “An advantage is that they don’t have to pay the same taxes as a for-profit, so they can take the income and use it to grow, become innovative, and restructure the fundamental business,” he says.

In addition, non-profits have a distinct marketing advantage as consumers like the idea of their health plans not being in business to “make money” per se, but rather to provide access to care. Ford was quick to point out, however, that, “These are people’s perceptions, which may not necessarily be true.” Health plan providers may prefer doing business with non-profits because non-profits reinvest income in the community instead of distributing it to shareholders, some believe.

But non-profits have a disadvantage when it comes to having capital and access to capital. “For-profits have virtually unlimited access to capital when stock prices rise,” Ford says. “When they deliver good returns, they get more investors. For-profits don’t have as many regulatory issues to deal with, either, and are freer in their marketing practices. They can be more innovative in investing money to make money.”

By having more sources of capital, for-profit plans have better buying capabilities to acquire companies. “If a purchase is a fair price and the organization has earnings, it is an economical way to buy value, whereas non-profit plans have to use cash because they don’t have any other currency available,” explains Bill Copeland, U.S. Life Sciences and Health Care Leader, Deloitte, Philadelphia, Pennsylvania. “In a competitive environment where there is a race to build capabilities around analytics, consumerism, and value-based care, non-profits are at a slight disadvantage, especially if they’re not at scale. Ultimately, the for-profit plans have a greater degree of flexibility in accomplishing goals compared to the non-profits.”

Affordable Care Act is a game changer

Before the Affordable Care Act (ACA) of 2012, non-profit versus for-profit status didn’t seem as significant because the business of providing health insurance hadn’t changed much in decades. But now, under the ACA, millions of uninsured Americans are now insured. “ACA created a market for individuals, it expanded government programs, it put a premium on making products more affordable, and it placed a mandate around paying providers based on outcomes, not just fee for service,” Copeland says. “All of these things introduced many new concepts to health plans such as consumerism, innovative payment methodologies, analytics, and
more choices in convenience to make them more affordable. As a result, technology and business processes—and other things health plans have perfected over the years—have had to change.”

Consequently, Copeland predicts increased pressure on smaller, underperforming non-profit plans to either consolidate with other plans to create a bigger plan or discover a different way to secure capabilities, or they risk becoming non-competitive and becoming impaired. For-profit plans see this as opportunity to grow by acquiring non-profits.

According to a Deloitte report, the ACA has leveled the playing field by requiring all health plans to accept individuals with pre-existing conditions and provide coverage at community-rated prices. It will be harder for the single-state Blues to differentiate themselves and compete purely on their not-for-profit status and charitable investments in the community through health and wellness. This is not to suggest that the single-state Blues should give up their mission, the report states. Their non-profit status and investment in their communities continue to be valued by many consumers, employers, and regulators. The ACA provisions, though, have narrowed the differences among health plans and the single-state Blues may now need additional ways to distinguish themselves in the market.

**Will more plans become for-profits?**

Although a state cannot force a plan to convert to a for-profit, it can encourage it to do so and states do levy some control over plans. “If you look at conversions of the past, they benefited from what the plan was trying to do and what the state thought was a good solution for its financial woes,” Copeland says.

When Empire Blue Cross and Blue Shield converted to a for-profit plan, the sale’s proceeds benefitted both the foundation as well as some state initiatives that needed funding—which is typical, Copeland says.

Horizon Blue Cross and Blue Shield of New Jersey have explored converting to for-profit plans, including a potential sale to Wellpoint, but the state plan couldn’t agree on fair market value and some other special provisions, so the plan didn’t convert. “So there are cases of this working and instances where it didn’t work,” Copeland says.

John Santilli, MBA, partner, Access Market Intelligence, Trumbull, Connecticut, predicts that market forces—including implementation of the ACA, continued consolidation of health insurers, and an increase of reserves by Blues Plans—may drive some non-profit Blues plans to convert to for-profit status or consider merging with other Blues plans to strengthen their market share. Also, a number of Blues plans have created non-Blues licensed subsidiaries or are creating affiliations and joint ventures with other Blues Plans or other health organizations to extend their market reach.

**The future of non-profits**

So what is the future of non-profits like Blue Shield that have large cash reserves but are hampered by regulations that dictate how they can spend them?

As a mission-based non-profit, Steve Shivinsky, vice president of corporate communications, Blue Shield of California, San Francisco, California, says the company will keep its focus on providing all Californians access to high-quality, affordable care, being a good corporate citizen, and being a good steward of its resources and the company. “We will continue to limit our net income to 2% of revenue, and to give excess funds back to our customers and the community,” he says. “We will continue to provide robust support to the Blue Shield of California Foundation’s efforts to improve the health safety net and address domestic violence. And we will continue to advocate for public policy that benefits the public, as we have done for many years.”

Shivinsky says Blue Shield believes it meets the requirements...
for a state income tax exemption and has challenged the Franchise Tax Board’s decision. “If the decision is upheld, we will pay the taxes we owe, as we always have,” he says.

Regardless of the decision, Blue Shield will remain a non-profit, Shivinsky says. “This best allows us to pursue our mission,” he says. “If we converted to a for-profit, our first responsibility would be to return profits to shareholders or other owners. We have no interest in that path.”

In fact, Shivinsky points out that in 2011, Blue Shield of California voluntarily capped its net income at 2% of revenue, and returned amounts over that to its customers and the community. “We are the only major health plan in America to maintain such a voluntary cap, giving back $560 million since the program’s adoption,” he says.

In addition, Blue Shield’s pending $1.2 billion acquisition of CareFirst—which has more than 500,000 members primarily in Medicaid managed-care plans, as well as some under Medicare—would expand its offerings into the Medicaid program for the first time, an important step in advancing its mission. The acquisition should be complete in the third quarter of this year.

According to Ford, “Virtually every large non-profit insurer is under the same pressures which Blue Shield of California faces to adapt to new market conditions—California is just a very visible example.” The question is, how are non-profits going to deal with this adaptation despite having big reserves yet having limitations on how those reserves can be spent because of their historic tax-exempt status?

Ford believes it would be wise for non-profits to channel excess reserves into premium reductions, which is what ACA was designed to do. “One reason for non-profit status is to provide access to healthcare at affordable rates,” he says. “Another reason for tax-exemption is to use reserves and future profitability to ‘invest forward’ into the community delivery system, as well, and to improve care and the cost of care in the future. This is called the ‘triple aim.’ If plans can actually and visibly accomplish this, regulators will be happy.”

In states with a significant amount of rural areas, non-profits could invest in establishing providers in those areas, pay to set up telemedicine networks, subsidize high-priced pharmaceutical drugs, and/or pay for the treatment of rare and costly diseases, Ford suggests.

We know now that many causes for severe disease are socially caused, which result in expensive late stage medical costs, such as Adverse Childhood Experiences (ACEs). “These social causes for disease are not addressed within the structure of our current medical system,” Ford says. “If non-profit insurers could redeploy their reserves and profits toward improving the community population’s health by addressing these social determinates of health, the non-profit insurers could preserve their tax-exemption by demonstrating a genuine social and public benefit to justify continuing this tax advantage.”

Challenges ahead
With the passage of the ACA, Ford believes non-profit health plans need to reinvent themselves. “The pressure is on to demonstrate to state regulators—who are always looking for tax revenue—what is different (good and socially beneficial) about them and how they will benefit their respective states,” he says.

In addition, as a result of ACA, non-profits need to figure out how to provide guaranteed access for everyone. And as they add members, non-profits will need to set aside reserves to cover claims. “Non-profit plans have to approach additional investors—hospitals, providers, and so forth, to get that money, but may not succeed,” Ford predicts. “Difficult, yes, but even though they have an opportunity to grow 30 percent (a provision of ACA), they may not be able to do so as a result of insufficient capital access unless they reinvent themselves fundamentally and quickly.”

Santilli expects that Blues plans will find the health insurance market more competitive going forward. “They may experience some erosion of their market share, although they are well positioned historically and generate ample revenue to fund initiatives to compete effectively,” he says.

The bottom line is that emerging growth opportunities and business challenges are driving fundamental shifts to the health plan market. Now, more than ever, gaining a competitive edge requires achieving new levels of operating efficiency, demonstrating value, and offering improved affordability, product flexibility, and service responsiveness. Traditional business models are no longer sufficient, and many health plans are taking steps to diversify their product and service offerings, modify care and payment arrangements with providers, and improve their interfaces with consumers in ways they hope will differentiate them from competitors.

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There may be a light at the end of the tunnel in the fight against opioid addiction. A 2013 report from the Centers for Disease Control and Prevention (CDC) indicates that the number of deaths from prescription pain relievers dropped 5% in 2012, the first decline since 1999. This is in contrast to a three-fold increase in the United States from 2001 to 2011, according to the National Center for Health Statistics.

The Department of Health & Human Services is taking steps to address the opioid problem through an initiative that focuses on:

- Providing training and education and updated guidelines to help health professionals make informed prescribing decisions;
- Increasing the use of naloxone, a medication used to counter the effects of excessive use of opioids; and
- Expanding the use of medication-assisted treatment that combines medication with counseling and behavioral therapies to treat substance abuse disorders.

One of the other drivers behind the decrease in deaths from prescription pain relievers may be the shift of hydrocodone-containing combination products from Schedule III of the Controlled Substances Act to the more tightly regulated Schedule II by the Drug Enforcement Administration (DEA), effective Oct. 6, 2014. DEA stated that the change affects several hundred brand-name and generic hydrocodone combination products, including cough suppressants that are currently marketed in the United States.

According to DEA, the rescheduling serves to alert prescribers, pharmacists, and others to the potential for addiction and highlights the need for careful monitoring and evaluation of use of the combination drugs.

Prescriptions for hydrocodone combination products that were written before October 6 may include refills, but not if they were dispensed after April 8, 2015. Prescriptions for Schedule II controlled substances are only allowed for 30 days maximum.

**Unreported medications**

The Millennium Research Institute, a research, education and advocacy organization focused on toxicology, pharmacy and pain and practice management, conducted a study on the role of urine in drug testing in addiction treatment. In 51.5% of samples, liquid chromatography tandem mass spectrometry testing revealed the presence of unreported prescription medications or illicit drugs, while immunoassay tests showed clinical false positive and false negative results.

Steve Passik, MD, vice president of clinical research and advocacy for Millennium Health, a health solutions company based in San Diego, says the enhanced information from the mass spectrometry tool presents...
opportunities in the clinical setting to intervene when relapses occur. It not only indicates that opioids have been taken, but goes a step farther to reveal the presence of unreported or illicit prescription medications. “The information can be put into a prescriber’s hand in 24 hours,” he adds.

Passik is not unaware of the difficulty balancing less abuse with ensuring that patients who need prescription controlled substances have access when necessary. He supports the move toward the use of opioids with abuse-deterrent features.

**Cross-checks**

Jo-Ellen Abou Nader, senior director of drug waste solutions for Express Scripts, a PBM headquartered in St. Louis, Mo., says it’s easy for members to slip through identification for abusing prescription controlled substances —just by paying cash or using a drug card. Express Scripts uses predictive modeling to assist in finding these individuals.

If it finds that a member may be abusing prescription drugs, it reaches out to prescribers to verify drugs doses, to identify if the controlled substances are medically necessary to determine whether physicians have seen the patient in their office and if they have established a medication use agreement or contract with their patients spelling out a course of treatment.

The PBM’s ability to cross-check both medical and pharmacy data is a boon to detection and prevention. Nader says that it is important to get as much data as possible including doctor claims for office visits and multiple visits to the emergency room for drugs.

Express Scripts also communicates with pharmacies to verify that they actually filled and dispensed prescriptions. Nader says that electronic prescribing of controlled substances (EPCS) can help detect valid prescriptions and prevent doctor shopping but will not have much effect if physicians and patients are in collusion.

“You have to look at the big picture,” Nader says, “not just claims but also doses and combinations of drugs taken by members.” She agrees with Passik that the difficulty in solving abuse of prescription controlled substances lies with creating a balance between not locking in patients with long-term pain or cancer against too many prescriptions.

**Role of e-prescribing**

Ken Whittemore, senior vice president of professional and regulatory affairs for Surescripts, a health information network based...
in Arlington, Va., advocates for e-prescribing because he says it eliminates chances of tampering with prescriptions made possible by hand-written ones.

In 2008, the Minnesota Legislature enacted an e-prescribing mandate to improve quality outcomes and efficiency in healthcare. The mandate required prescribers, pharmacists and pharmacies and pharmacy benefit managers to be e-prescribing by Jan. 1, 2011.

New York’s I-STOP law for e-prescribing changes the way prescription drugs are distributed and tracked. It requires most prescribers to consult the Prescription Monitoring Program (PMP) Registry when writing prescriptions for Schedule II, III, and IV controlled substances. The PMP Registry provides practitioners with direct, secure, real-time access to view dispensed controlled substance prescription histories for their patients.

New York also recently extended the implementation of mandatory EPCS for another year, until March 27, 2016; however, e-prescribing of both controlled and non-controlled substances is already permissible in New York.

According to Surescripts, 70% of pharmacies are able to receive electronic prescriptions for controlled substances, while only 6% of prescribers are ready to e-prescribe. That served as an impetus for Surescripts to develop a step-by-step video guide and tools to educate prescribers about EPCS.

Whitemore says that because more requirements exist for providers than pharmacists to deploy e-prescribing, the former are not moving forward as quickly.

“E-prescribing is not always popular with doctors,” he adds. Surescripts expects to increase the number of electronic prescriptions of controlled substances in 2015 by 400% over last year. At press time, EPCS was legal in 48 states and the District of Columbia.

High-risk patients
Kathy Starner, principal health outcomes researcher for Prime Therapeutics, a PBM based in St. Paul, Minn., says the PBM is not doing anything that unusual in terms of clinical programs addressing prescription controlled substance abuse and fraud, but that Prime does stand out in one way: It measures the success of programs and shares results with others.

Prime Therapeutics developed a controlled substance score that identifies high-risk users. By analyzing the scores, the PBM found a significant association between scores and health outcomes, including hospitalization and emergency room visits, drug costs and total cost of care.

“There is a linear relationship...
between higher scores and more utilization, which leads to higher costs. It is important to identify members with high scores and intervene,” she says.

In a study, Prime examined the number of claims, prescribers of the drugs and pharmacies dispensing them, as well as the rate of use of controlled substances, of 11 million commercial plan members over three months of claims. Prime then looked at 1 million members who had a score of 2.5 or higher and had been enrolled continuously during 2012 and 2013, and found that a one point increase in a score is associated with:

- Higher total cost of $1,488.
- Higher controlled substance drug cost of $235.
- Increase in hospitalization rate of 0.9%.
- Increase in emergency room visit rate of 1.5%.

Prime’s earlier research indicated that there was a 1.4 point reduction in members’ controlled substance scores when prescribers received letters about their patients with higher scores. Starner says the majority of prescribers found the letters useful.

**State monitoring**

Medicare Part D does not permit prescription drug plans or Medicare Advantage prescription drug plans to limit patients with a history of abuse to one prescriber and/or pharmacy. Bills have been presented to change this scenario.

On the other hand, 46 state Medicaid agencies currently operate lock-in programs that prevent recipients from obtaining excessive quantities of prescription drugs. Program design varies widely between states in terms of defining high-risk controlled substance use, the scope of actual lock-in restrictions and length of program enrollment. In addition, there is a lack of peer-reviewed literature evaluating the design and effectiveness of Medicaid lock-in programs.

Every state but Missouri has established Prescription Drug Monitoring Programs (PDMPs), which maintain statewide electronic databases of prescriptions dispensed for controlled substances. The programs help identify drug abuse and diversion and prescription drug-addicted individuals to enable intervention and treatment; educate individuals about abuse; inform public health initiatives; support legitimate use of controlled substances; and confirm for prescribers that a drug is being used for a legitimate medical condition.

Information includes a patient’s personal information, the name of the medical practitioner doing the prescribing, the dispenser, the type of medication and the dosage. Medical practitioners are then encouraged—and in some states, such as Kentucky, required—to access this information from the electronic database, prior to writing a prescription for a potentially addictive drug.

At first Passik says the monitoring programs offered little value but now that they are moving to real time, he considers them to be more effective—especially in conjunction with urine drug testing. He points out that each state determines if it will operate a monitoring program, including how often data are collected, who can access the data, when it can be accessed and whether communication can cross state lines.

In light of a study revealing that care providers in the highest prescribing state wrote almost three times as many opioid painkiller prescriptions per person as those in the lowest prescribing state, a July 2014 CDC brief makes recommendations to states about PDMPs. The report suggests that these different patterns arise from disagreement in different parts of the country over when to use prescription painkillers and how much to prescribe.

The CDC recommends that states increase use of their monitoring programs by making data available in real time, ensuring that all prescribers for all controlled substances use the program and that prescribers receive alerts when problems are identified. It also recommends that healthcare providers use the drug monitoring programs to identify patients who might be misusing prescription drugs.

**Abuse-deterrents**

In early April, the U.S. Food and Drug Administration issued a final guidance to help drug manufacturers develop opioid drug products with potential abuse deterrent properties. The guidelines recommend how manufacturers should conduct studies that demonstrate the drugs are abuse deterrent.

The California State Legislature introduced a bill recently that facilitates doctors in prescribing “abuse-deterrent formulation” opioids in place of traditional ones to reduce the use of narcotics.

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APPLE REVS UP CLINICAL RESEARCH

Participants flock to provide data for trials via iPhones by DONNA MARBURY

When Apple, Inc., announced the MyHeart Counts mobile app at a tech industry event in March, Alan Yeung, MD, said he hoped 1,000 people would download it. Built on the open source Apple ResearchKit platform, the app collects data for research studies.

By the next day, more than 10,000 people had signed up, and to date there are more than 36,000 participants.

“I didn’t know people were that eager to sign up for research,” says Yeung, medical director of Stanford Cardiovascular Health, who is leading the MyHeart Counts efforts. The MyHeart Counts app collects fitness data from iPhones and wearable fitness devices connected to iPhones over a seven-day period in order to assess cardiovascular disease risk. Stanford is already looking at ways to capitalize on the initial success. “Now there’s tremendous interest from other faculty who deal with other disease states and health issues to produce an app, and no data is shared with them. The ResearchKit technology uses the new Watson Health Cloud by IBM to stay HIPAA-compliant.

Expanding the research pool
The possibility of large-scale research that would include people who are interested in their health but who wouldn’t normally engage with a research institution was Apple’s goal in developing the technology. Analysts predict that the April launch of the Apple Watch coupled with the ResearchKit platform could give the technology company leverage to boost and sustain interest in the wearable technology market. In a press release, Apple states that ResearchKit apps have more than 60,000 users combined.

“IOS apps already help millions of customers track and improve their health. With hundreds of millions of iPhones in use around the world, we saw an opportunity for Apple to have an even greater impact by empowering people to participate in and contribute to medical research,” said Jeff Williams, Apple’s senior vice president of operations in a press release. “ResearchKit gives the scientific community access to a diverse, global population and more ways to collect data than ever before.”

As of July 2014, there are 1.2 million apps available in Apple’s App Store—nearly 100,000 of them are health and fitness related, according to the 2014 mHealth App Developer Economics study.

For Yeung, ResearchKit allows for a broader perspective on the relationship between fitness, nutrition and patient behavior. One question that many want to know is: How accurate is the data from mobile devices?

A report in the February Journal of the American Medical Association states that smartphones are imperfect devices, but better than wearable activity trackers when it comes to tracking important healthcare information. The accessibility that smartphones offer over costly wearables is also an advantage to researchers. However, Yeung points out that no form of research is perfect.

“The objective was to find out how active people are. With traditional research, there are recall
issues, and people often overestimate their activity level. Wearables provide real time data,” says Yeung, who adds that medical researchers are able to get a clearer, more accurate picture of how behavior affects health outcomes. “When people are inactive or the phone is inactive, there’s no data. So in a sense, no data can be more accurate than data from recall.”

To launch the platform, Apple limited the use of the technology to just a few, prominent medical research organizations that focused on some of the nation’s most costly health issues. Currently, there are only five apps available that use the ResearchKit platform:

- Stanford’s MyHeart Counts;
- Share the Journey, developed by the University of California, Los Angeles and Sage Bionetworks to track breast cancer symptoms after treatment;
- GlucoSuccess, a Massachusetts General Hospital app that studies pre-diabetes and diabetes behavior;
- Parkinson mPower, a partnership between Sage Bionetworks, University of Rochester and Beijing Institute of Geriatrics that allows people with Parkinson disease to track their symptoms; and
- Asthma Health, developed by Mount Sinai Medical Center, helps asthma patients to personalize and analyze their treatment.

Tracking asthma

The technology of ResearchKit removes barriers such as geography and time that limits participants, says Yu-Feng Yvonne Chan, MD, PhD, FACEP, director of personalized medicine and digital health and assistant professor of genetics and genomic sciences at the Icahn School of Medicine at Mount Sinai in New York City, which is collecting the Asthma Health mobile app research. Mount Sinai, Weill Cornell Medical College, and LifeMap Solutions developed the app to help participants self-manage the disease as well as track symptom patterns. The app combines a user’s GPS cell phone data with information about a city’s air quality to help participants avoid areas that might trigger symptoms.

“The quantity of data, both subjective (patient reported) and objective/real time monitoring (through devices, environmental sources, etc.) as well as the rate of acquisition of this data are quite remarkable,” says Chan. “Study participants may also feel a greater sense of freedom and control in how their data is collected and their role in this research process,” she adds.

But Chan notes that the approach isn’t without concerns. The novelty of ResearchKit apps could fade, in the same way that some critics believe that wearable technology activity trackers, including Jawbone and Fitbit, could be a fad. Nearly one-third of wearable technology users stopped using their device in six months, according to a July 2014 whitepaper by Endeavor Partners.

“We are mindful of this factor and have worked closely with our technology partners on user interaction and user experience to ensure that the app is user-friendly. However, at the end of the day, this is a research app and is not designed to be entertaining,” Chan says. “We hope that, over time, the utility and impact of using the app (i.e., improved asthma control, better quality of life, and fewer unexpected medical visits) will keep users engaged. Our early engagement and retention numbers look fairly promising.”

Future uses

Currently, Yeung says that no private health plans or organizations are involved with the mobile app, and no data on pay is being collected. He says his team is looking for ways to broaden its reach by expanding to Android platforms and social media to provide health and wellness coaching, and spark competition between users.

Chan says that her team plans to publish their data in peer-reviewed journals and present findings at conferences. “Assuming our hypothesis is correct and that the usage of our app is associated with improved health outcomes for our patients, we hope that it becomes a standard tool for patients to better care for their asthma,” Chan says.
A significant and growing performance gap exists between dual eligible and non-dual eligible members that cannot be attributed to a health plan’s quality of service, a new study has found. “An Investigation of Medicare Advantage Dual Eligible Member-Level Performance on the Centers for Medicare and Medicaid Services (CMS) Five-Star Quality Measures” from Inovalon is the largest-ever analysis of dual eligible member data. Results show that the presence of low education, low income, and other social and demographic factors associated with poverty not only affects a person’s health and health-related outcomes, it also affects how a person scores on measures of health plan performance, independent of plan characteristics. Dual eligible beneficiaries are individuals who qualify for coverage from both Medicare and Medicaid.

The study’s objective, according to Inovalon, was to identify and quantify the clinical, sociodemographic and community risk factors most associated with the worst-observed outcomes for a majority of Medicare measures used to assess the performance of Medicare Advantage (MA) health plans in delivering quality of care. “This is an important, groundbreaking analysis of data not previously achievable in the industry,” said Christie Teigland, Ph.D., director of statistical research at Inovalon and principal investigator of the study. “Previous studies have shown that plans specializing in care of low-income Medicare beneficiaries generally scored lower on the Centers for Medicare and Medicaid Five-Star Quality Rating System than plans serving a healthier, more-educated population with higher income. However, studies to date have not determined whether these findings are a result of poor plan performance or enrollee characteristics such as sociodemographic status-related factors, or a combination of both.”

Results showed that a significant association exists between dual eligible status and lower performance on specific Part C and D measure Star ratings. They validate the integral role that income, race/ethnicity, and gender play on the HEDIS and CMS Part D measures used in the Five-Star rating system, according to Inovalon.

As evidenced by this analysis, the gap has widened in reported Star ratings for 2012 and 2013 compared to previous findings. When scored by either the Charlson Comorbidity Index or CMS MA risk score, dual eligible members were found to be consistently more complex to manage.

Additionally, examination of 80 CMS MA contracts indicated that dual eligible members performed worse on nine of the 10 Star measures that were investigated.

Further, the study found that multivariate analyses controlling for demographics, socioeconomic characteristics, and severity of illness confirm dual members consistently underperform in eight of the 10 measures investigated. According to Inovalon, this is an important finding demonstrating a significant performance gap exists between dual eligible and non-dual eligible members even after adjusting for other important socioeconomic and clinical risk factors. It suggests that the Five-Star rating system, in its current state, may penalize MA plans serving a high proportion of dual eligible beneficiaries. Lower Star ratings result in lower incentive payments and may lead to reduced services to dual eligibles, suggesting a need for further research into the benchmarking and refinement of Star quality measures to assure fair comparisons of performance across MA plans serving different populations.
Health Management

populations, says Inovalon. The findings demonstrated that dual eligible members enrolled in MA plans have significantly lower-quality scores, but the less positive outcomes for those members does not appear to be due to the quality of care provided by a health plan, according to Teigland. "Instead, the increased prevalence of poor outcomes is due to a variety of clinical, sociodemographic and community resource factors, such as living in a high poverty area or an area with a shortage of primary care physicians," she says.

The study used member-level MA data extracted from Inovalon’s Medical Outcomes Research for Effectiveness and Economics Registry (MORE² Registry). The MORE² Registry provides visibility into the medical utilization of more than 98 million unique and de-identified individuals nationwide covering more than 3.1 billion member-months of data from 2002 through September of 2013.

Within this study, from the 11.8 million MA enrollees present within the MORE² Registry, Inovalon identified 1,335,709 enrollees in 2011 (16.6% dual eligible) and 1,605,644 enrollees in 2012 (16.2% dual eligible) from 80 individual CMS contracts who met the study inclusion criteria. Rates for nine Star measures were calculated independently for the dual and non-dual eligible members and then within each of those groups, stratifying by various demographic, clinical, and socioeconomic characteristics. In addition, a tenth measure—Plan All-Cause Readmission Rate (PCR)—was calculated using the National Committee for Quality Assurance (NCQA) risk adjustment model for MA members age 65 and older, which controls for chronic conditions and factors impacting likelihood of readmission.

“There is long-standing research that shows a person’s income, level of education, and other social demographic factors affect a person’s overall health and use of healthcare services when they are sick,” says Rich Bringewatt, president, National Health Policy Group, Special Needs Plan (SNP) Alliance. “As a result, individuals who are in low socioeconomic circumstances have factors that negatively affect their care and their outcomes compared to individuals in higher socioeconomic circumstances.”

The SNP Alliance is a national group of specialty health care plans and programs exclusively focused on improving SNP and Medicare-Medicaid Plan policy and performance.

“This study provides insight for plans, providers and other managed care executives about what some of these factors are and opens up options for how to more efficiently and effectively improve health outcomes for these disadvantaged persons,” says Bringewatt. “It is critical that public reporting of plan performance take these factors into account. It is also imperative that agencies that provide financial incentives or penalties associated with a plan’s performance rating account for these factors as well. Otherwise, plans that specialize in the care of people who are poor may be unintentionally penalized by quality measurement programs.”

This research can be used to help guide future measure development efforts to improve the validity, reliability and usefulness of performance measures, according to Teigland, and "also help guide the development of methods that help plans address the adverse effects of low income, low education, and other social and community factors associated with poverty."
The term "super utilizer" has become shorthand for patients with multiple chronic conditions who access care frequently, resulting in the highest cost to public health and uncompensated care. They’ve typically not had regular healthcare membership and may have one, or even all, of a group of common chronic conditions such as diabetes, cardiovascular disease, obesity, asthma, and Chronic Obstructive Pulmonary Disease.

In addition, many are homeless, have literacy issues, low or no income, and lack transportation and family support. They may have been incarcerated, suffer from substance abuse or alcoholism, and nearly all are burdened with some form of mental illness.

It’s no surprise, then, that managing super utilizers is a challenge. The good news is that the creation of the Affordable Care Act (ACA) has led to community-based approaches like health homes that appear to be making inroads.

The health home solution
In 2010, the Medicaid Health Home State Plan Option was created under the ACA to provide “a way for states to finance intensive care management,” for Medicaid beneficiaries with chronic conditions, says Kathy Moses, senior program officer for the Center for Health Care Strategies (CHCS).

“It’s a simple formula: If a patient has two or more chronic conditions as defined by the state, patients enrolled in Medicaid can receive care coordination through a health home,” says Moses. There is not always a brick and mortar home involved, she adds. “It’s a concept, not necessarily a physical place.”

Incarceration link
States can use the health home concept to address specific areas that contribute to high utilization of hospital and emergency department services. Rachel Davis, senior program officer who oversees the Complex Care Innovation Lab, describes how some health homes in New York state are addressing incarceration issues. “There are a high number of super utilizers in New York who are involved with the criminal justice system, and that’s really challenging,” says Davis. In many states, including New York, people who have been incarcerated for more than 30 days lose their Medicaid benefits, making it
difficult for them to maintain continuity of care, she explains. “They get discouraged, they don’t have their Medicaid status turned on when they’re released, and they may or may not have medicines they need. This can lead to a variety of problems, including not being able to access needed medications or doctors in a timely fashion after release. Davis notes that it’s “not unusual to see these individuals show up in the emergency room a few days or weeks after they are released from jail or prison due to this lack of coverage.”

In response to this challenge, Maimonides Health Center in Brooklyn hired a staffer to liaise with Rikers Island, which is the entry point for most incarcerated people in New York City, Davis explains. Any time one of their health home members shows up in the Rikers database, an electronic alert is sent to the Maimonides health home. The alert lets the staff person know that the health home needs to step in and start coordinating with the member and jail staff to ensure that the incarcerated member’s medical needs are met. The health home also works with jail staff to create a discharge plan for the member, including working to reinstate Medicaid benefits upon release.

In another scenario, Davis describes how a health home staff person works in a probation office. “Anytime a probation officer thinks their client is a good fit for health home services, they can walk them across the hallway and connect them to the health home’s representative and get them enrolled in the [Medicaid] program,” she says.

**Engagement a hurdle**

Finding patients with chronic conditions and engaging them in health home programs is often the biggest challenge, says Moses, who adds it’s unlikely that patients with no phone, transportation or computer access will engage on their own. With some health homes posting only a 20% engagement rate, Moses says states need to do more than leave it to chance that people will actively participate. In addition, the health home team’s initial efforts must be focused on showing eligible patients how health home services can be beneficial.

To bring more people into care, Davis says that a number of health homes are turning to non-traditional health workers. “Individuals who are hired from within the community to be peers or community health workers can be very successful in engaging patients. They share lived experiences with the patients, and can connect with them about the challenges they’ve faced and how they have worked to overcome them,” she notes.

There is often a high level of mistrust of the healthcare system among health home eligible individuals, and these non-traditional healthcare workers can be better at connecting with patients and gaining their trust, says Davis.

**Coordinating care**

Prior to the ACA and Medicaid health homes, “care management systems were often organized around specific conditions such as HIV or mental health, which could lead to fragmentation,” Davis says. “New York saw an opportunity in health homes to look at the patient holistically, rather than divvying them up by condition. This is really an evolution of the original disease management concept.”

Now they’re finding more clues to the already complex super utilizer profile. “One of the more interesting things that come across our radar is there is evidence that these folks as children or young adults experienced some kind of physical, sexual or social trauma, and there is very good evidence that this kind of trauma in childhood plays a role in adult health outcomes,” says Davis.

Adds Moses, “There are probably opportunities for commercial insurers to learn from innovative efforts being implemented to help high-cost, high-need populations in publicly financed care.”

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Barbara Hesselgrave is a freelance writer in Baltimore, Maryland.
A WIN FOR COMPETITION

Supreme Court’s denial of antitrust immunity will aid innovation

The American system of healthcare delivery, management and insurance is in a state of dynamic change and many of the most innovative developments aimed at efficiency, quality and cost savings are originating with managed care organizations (MCOs). Too often, innovation is met by what the economist Milton Friedman called “the tyranny of the status quo”—the resistance of entrenched guilds to allow productive competition. For occupants of MCO C-Suites faced with such resistance, there is good news both from the Supreme Court of the United States and the Federal Trade Commission (FTC).

Recently, the Supreme Court held that the North Carolina Dental Board was not insulated from federal antitrust liability under the so-called “state action” doctrine when it engaged in anticompetitive conduct to restrain non-dentists from performing teeth whitening services. The Court reaffirmed that state action antitrust immunity for professional board regulatory actions has two prerequisites: the actions must be conducted under “active state supervision,” and they must follow a “clearly articulated state policy” to displace competition.

Although the North Carolina case involved a dental board’s attempt to restrict activities of non-dentists, the Court’s opinion has broader implications for how states regulate and “actively supervise” both professional boards in the healthcare sector, and also other state programs requiring active state supervision—such as certificate of public advantage regulations or other innovative “ACO”-like structures that are being sanctioned by states. This decision also illustrates how an individual or entity, subject to perceived over-regulation by a professional board, might mount a defense by scrutinizing whether the board meets the “state action” requirements to be insulated from liability for anticompetitive regulatory actions.

Shortly after the Court’s opinion was released, FTC Chairwoman Edith Ramirez issued a statement making clear that the FTC will continue to scrutinize arrangements where market participants act as regulators that are unsupervised by the state: “Today, the Supreme Court affirmed the Federal Trade Commission’s position in recognizing that a state may not give private market participants unsupervised authority to suppress competition even if they act through a formally designated ‘state agency,’” she wrote. “We are pleased with the Supreme Court’s recognition that the antitrust laws limit the ability of market incumbents to suppress competition through state professional boards.”

The FTC has continued to manifest its authority in this area with respect to other state boards, e.g., in Texas, and the limitation on anticompetitive state action enunciated by the Supreme Court is proving an effective weapon. Often regulatory boards act for protectionist reasons without a clearly articulated state policy to allow anticompetitive conduct. However, even where there is a clearly articulated policy (which was assumed in the North Carolina case), the board in question must be actively supervised by the state itself. The supervision rule “stems from the recognition that where a private party is engaging in anticompetitive activity, there is a real danger that he is acting to further his own interests, rather than the governmental interests of the State.”

The North Carolina case provides a potentially useful weapon to MCOs offering innovative services that might not be well received by state boards composed of competitors looking to preserve their economic place. Novel MCOs, ACOs, and other new players in the field who might find themselves subject to over-regulation or exclusion should be poised to benefit from this statement of the law and should take heart in the potential assistance of the FTC and other federal antitrust regulators.

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