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DIABETES PRACTICE
OPTIONS™

Improving Patient Care Through Increased Practice Efficiency

NOVEMBER/DECEMBER 2012

CONTRIBUTORS

G. Keith Smith, MD

Robert E. Tucker, MD, MBA

EDITORIAL

Election Post-Script: Will Millions of Newly Insured Patients Deprive Docs of Choice?

By G. Keith Smith, MD, contributing editor

Whenever someone tells me they have a right to health care, I ask them, "From whom? From me?" This question exposes this "right" for the robbery that it is. Do you really want to exercise your right to health care on a physician who doesn't want any part of this bargain? What kind of care do you think you'll receive?

Years ago, I stopped doing cardiac anesthesia, as well over half of the patients were covered by Medicare and payment for my services was below what I thought acceptable ($285 for my last six-hour cardiac anesthetic). Soon thereafter I stopped dealing with Medicare and Medicaid altogether, as I increasingly saw myself as receiving money taken from my neighbors against their will.

Soon after, an angry cardiac surgeon, inconvenienced by my departure from the group of available cardiac anesthesiologists and with his finger in my face, told me he was going to see to it that I was forced to do these anesthetics, so as not to disrupt his schedule. I guess he thought he had a right to my services.

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EDITOR'S NOTE

Practice Options is pleased to announce the addition to its editorial board of G. Keith Smith, MD, and Michael West, MD, PhD. Dr. Smith is an anesthesiologist with the Surgery Center of Oklahoma in Oklahoma City and will be advising on the business of medicine. Dr. West is an endocrinologist with The Washington Endocrine Clinic, PLLC, in Washington, DC, and will be serving as the lead clinical editor for *Diabetes Practice Options*. Welcome aboard, Doctors.

—Rev DiCerto, *Practice Options* editor

STAFF

Editor
Rev DiCerto
845/398-5100
editor@premierhealthcare.com

Art Director
Meridith Feldman

Publisher
Premier Healthcare Resource, Inc.
150 Washington St.
Morristown, NJ 07960
973/682-9003; Fax: 973/682-9077
publisher@premierhealthcare.com

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This newsletter is published by Premier Healthcare Resource, Inc., Morristown, N.J.

EDITORIAL

I said, "Dr. X, I'll be happy to visit with the family before their loved one's surgery and inform them that I want no part of this and don't really want to be here, but someone is forcing me do this. Maybe you would like to wait for an anesthesiologist who wants to be part of this, because I certainly don't." The cardiac surgeon suddenly understood.

Now imagine this situation on a large scale. Angry mobs of folks waving their Obamacare insurance cards in the street, demanding free health care outside a closed and vacant doctor's office. In the wake of the 2012 presidential election, it seems likely that all the

G. Keith Smith, MD

elements of the Patient Protection and Affordable Care Act will be implemented, thereby flooding the health care system with millions of newly insured patients. This supposed right to health care cannot undo human nature and the myriad market forces at work to ensure that all parties involved in a transaction are willing participants. If government points its guns at the doctors to make them participate, I maintain that the health care that is delivered will be a different variety than the mobs expected. I don't know what it will be, but it won't be health care at all.

Physicians who have made or are in the process of making the transition to cash-based practices or concierge practices, embracing the principles of the free market and rejecting the old statist medical models, will paradoxically thrive in the dystopic new medical marketplace. Patients will become increasingly reliant on the remnant of physicians whose willingness to step out of the old model will save their medical practices and the lives of many of their patients. Patients seeing physicians with a gun in their ribs would do better to concentrate on wellness. ■

More information is available at
www.DiabetesOptions.net

DIABETES STRATEGY

Active Management Allows Practice to Improve Diabetes Outcomes

All providers find it challenging to help diabetes patients maintain blood glucose control. But at Southeast Texas Medical Associates (SETMA), providers have designed a coordinated, multifaceted set of initiatives that have prompted a steady 10-year decline in their patients' mean hemoglobin A1c (HbA1c). In 2001, mean HbA1c was 7.48; by 2011, it had fallen to 6.54.

SETMA has 36 providers including primary care physicians, specialists, nurse practitioners, and diabetes educators. "We have focused heavily on adopting strategies to improve our diabetes care," says James (Larry) Holly, MD, SETMA's CEO, adding that the practice currently treats more than 8,000 patients with diabetes. "Today, we are a Joslin Diabetes Center Affiliate, and all of our providers have earned National Committee for Quality Assurance (NCQA) recognition for excellence in diabetes care."

Components of SETMA's care model include using an electronic medical record (EMR) to track quality metrics and fill gaps in care; auditing care by population group; providing diabetes self-management education; ensuring that messaging stimulates patient empowerment; performing statistical analyses to identify areas for improvement; publicly reporting data by provider; and setting up a foundation to support the care of financially vulnerable patients.

Investing in Technology

The practice adopted an EMR in 1995. "We realized that the value of the EMR would not come from simply documenting patient encounters electronically, but rather would depend upon exploiting data integration and computation capacity to improve care and outcomes," Holly says.

In 1998, the practice designed a diabetes disease management tool, which is accessed through the EMR. The tool includes a suite of templates that guide providers in providing optimal diabetes care. The first template summarizes critical information such as the patient's vital signs, laboratory values, smoking status, and compliance with various care indicators. From this screen, the physician can access a series of templates that ensure that all aspects of diabetes care are provided.

The EMR also incorporates multiple diabetes data sets from organizations such as the Physician Consortium of Performance Improvement, the American Medical Association, the Centers for Medicare Services, the National Quality Forum, the Joslin Diabetes Center, NCQA, the Healthcare Effectiveness Data and Information Set, and the American Diabetes Association (ADA). "With the click of a button, providers can determine whether they have met all quality metrics for that patient, and if not, they can click on an automatic order for the necessary laboratory test or specialty referral," explains Holly.

Using a tool built into the EMR, SETMA's providers routinely generate the 12 Framingham risk scores to let each patient know what his or her cardiovascular, cerebrovascular, and other risks are. "Normally, it would take about 30 minutes to calculate these risk scores by hand, but because they are incorporated into the EMR, we can generate all of these scores in one second," says Holly. "By presenting these scores to patients, we encourage them to make a change that can improve their health in the near-term. For example, we might show a patient how much his risk score would improve if he lost just 10% of his body weight."

SETMA also uses statistical analyses to inform population-based quality improvement initiatives. In 2009, SETMA purchased a business intelligence software program, IBM Cognos, and modified it for health outcomes. "We wanted to analyze our diabetes care over time so we could identify patterns in outcomes," Holly explains. "We look for leverage points: where is the maximum opportunity to improve population health?" For example, several years ago the physicians discovered that many diabetes patients were losing control of their condition in October, November and December—not surprising, since these months include many holidays that involve eating. "Further analysis indicated that the patients who were losing control were being seen less frequently at the end of the year. In September, we wrote a letter to all of our diabetes patients and alerted them to this trend. We invited them to sign a

contract in which they agreed to come in at least twice during the final three months of the year to meet with a provider, to have their diabetes tested, and to maintain their exercise and diet. As a result, the end-of-year spike in mean HbA1c did not occur."

Improving Outcomes

In order to reduce patients' risk scores and improve diabetes outcomes, SETMA physicians realized that there were three lifestyle changes they wanted their patients to make. The practice designed a preventive health program, called the LESS initiative (Lose weight, Exercise, and Stop Smoking), to prompt these changes.

"Along with a sedentary lifestyle, even a small amount of excess weight can place a person at a higher risk of developing diabetes," says Holly. "And people with diabetes have such a high cardiovascular risk burden that smoking cessation is of critical importance to their health. But the good news is that we can meaningfully ameliorate this risk with lifestyle changes. We tell people, if you can lose even 10% of your body weight, your cardiovascular risk will decline significantly. This is a manageable goal and gives people hope."

The LESS initiative includes weight management, diabetes risk, and diabetes-specific exercise assessments along with a smoking cessation model for providers. At nearly every visit, nurses complete the LESS templates in the EMR. The nurse then prints a 10-15 page care plan for the patient that includes realistic weight management goals, a customized exercise "prescription," and smoking cessation strategies. Thanks in no small part to the LESS program, the average body mass index of patients has remained stable over the last 10 years, and nearly 3,000 patients have quit smoking. LESS has also been a factor in helping the practice reduce its average HbA1c levels.

Excellence in care quality has business benefits, including quality-based incentives paid by insurers.

Holly says it takes nurses less than 30 seconds to complete the tool. "This is a very effective way to deal with a set of complex lifestyle issues that many diabetes patients struggle with," he adds.

Empowering Patients

SETMA physicians also recognized that patient education and empowerment would be a critical factor in improving diabetes outcomes. In 2004, the practice adopted the ADA's diabetes self-management education program. "The program has two elements: medical nutrition therapy and diabetes self-management education," says Holly. "The program received ADA certification and has maintained it since 2005."

Diabetes patients are further empowered by messages that emphasize the practice's commitment to their health, as well as their own role in their care. "Everything—laboratory values, care goals, treatment steps—is thoroughly explained to patients, and providers tell them they should not leave the office unless they understand what they need to do to improve or maintain their health," explains Holly.

A poster in the waiting room depicts a baton, which represents the patient's care and treatment plan as it is transmitted from the provider to the patient. The poster illustrates that the patient must receive, understand, and assume responsibility for the plan if he or she is to carry it forward successfully. SETMA also developed what it calls the "Seven Stations" for diabetes treatment. These seven elements of success, which are described and displayed in framed posters hanging in the waiting room, help guide patients in their self-management efforts. The stations include self-monitoring of blood glucose; HbA1c control; the LESS initiative; the need for active self-management; the physician-patient partnership; care coordination and overcoming barriers to care; and the

Diabetes Management Tool Prompts Comprehensive Care

Southeast Texas Medical Associates (SETMA) created a comprehensive diabetes disease management tool to help physicians document care and prevent critical steps in diabetes care from falling through the cracks. The tool, accessed through the practice's electronic medial record offers a series of templates that prompt providers to collect and document data related to the patient's diabetes history, a review of diabetes systems, the diabetes care plan (i.e., meal requirements, laboratory/procedure orders, management steps, medications and doses, and education requirements), care management steps (i.e., HbA1c testing, eye care, foot care, lipid testing, flu shot, blood pressure monitoring, and urinalysis), various physical exams (e.g., foot, eye, nasopharynx, cardiovascular, neurological, motor, and cranial nerves), and patient compliance with various aspects of care such as medications, diet, exercise and education.

Providers can also review diagnostic criteria, screening criteria, important diabetes concepts, evidence-based clinical recommendations, medication lists, and the patient's blood sugar history. Finally, providers can print the diabetes care plan and education materials related to various subjects to distribute to the patient.

The diabetes disease management tool's templates are available for viewing at www.setma.com/Tutorial_Diabetes.cfm. —DJN

principles of a medical home.

As of 2008, SETMA reports 250 quality metrics on its website by provider name. "Although physicians were initially concerned about public reporting of data, they now realize that this gives all of us motivation for improving care," Holly says. "We empower our patients to review our quality and expect excellent care."

Ongoing Initiatives

Focus on best practices is a critical feature of the practice. "Each month, we close our office for half a day and discuss our diabetes care performance data and best practices," Holly says. "In this way, quality improvement does not occur in a blameful or punitive environment. It has become a natural and ongoing discussion."

Diabetes prevention is another key focus at SETMA. "Because the best strategy in diabetes care is to prevent its onset," asserts Holly, "we developed a diabetes prevention program." The program includes algorithms that guide how often patients should be screened for diabetes. "Patients with prediabetes are placed in a special treatment program that helps us reverse the course of the disease."

SETMA's most recent diabetes care enhancement was to become a patient-centered medical home (PCMH). "In 2010 we received formal recognition as a PCMH by both NCQA and the Accreditation Association for Ambulatory Health Care," says Holly. "This required us to develop a very robust plan of care for our patients with diabetes. We give them a document at the end of the visit that includes their data, goals, and assessments, with instructions and educational materials to help them participate successfully in their own care." As a PCMH, SETMA also offers a team approach to diabetes care, with diabetes educators, nutritionists, and endocrinologists on staff.

"The program received ADA certification and has maintained it since 2005."

—James Holly, MD, CEO, Southeast Texas Medical Associates

The practice is also sensitive to ethnic disparities. "We evaluate the HbA1c status of our African-American patients to ensure that they receive the same quality of care and exhibit the same outcomes as our Caucasian patients," says Holly, noting that other ethnic minorities are not heavily represented in the practice. Over time, the practice has virtually eliminated racial disparities in diabetes and hypertension outcomes.

"We also considered whether some patients faced financial barriers to care by analyzing different populations and insurance products," Holly continues. "We worked with our major HMO to eliminate copays for our patients, some of whom might find even a $5 copay to be a barrier." Notably, in 2008 SETMA created a foundation that the practice funds with $500,000 annually; the foundation pays for medications, surgeries, and copayments to non-SETMA physicians on behalf of financially vulnerable patients, thereby improving outcomes for that vulnerable population.

"Each year we have seen significant improvements in our diabetes outcomes, indicating that the initiatives we were adopting were having a meaningful impact," says Holly. He notes that excellence in care quality has business benefits, including quality-based incentives paid by insurers; the practice is currently building an accountable care organization, which should hopefully create additional financial benefits. "But our real reward is not monetary, it is improving the lives of the people we serve. That sounds corny, but it really is what motivates us."

Holly says that all practices can improve their diabetes outcomes if they have passion and vision. "Small practices can pursue joint initiatives, or see what kind of assistance insurance companies can offer," he notes, adding that physicians can "help themselves" to anything they want from the SETMA website (www.setma.com). "If they use SETMA's initiatives to improve the care of their own patients, that's reward enough for us." ■

—Reported and written by Deborah J. Neveleff, in North Potomac, Md.

Wireless Glucometers Enhance Care Quality

Always interested in trying new technological enhancements, the physicians at Southeast Texas Medical Associates (SETMA) now encourage patients to use a wireless glucometer manufactured by TelCare (www.telcare.com). "Patients do their glucometer checks at home as usual," explains James Holly, MD, SETMA's CEO. "The glucometer then automatically reports their blood glucose values to our EMR [electronic medical record system] via a wireless connection."

Using the EMR, the physicians can view and analyze all of their patients' data, meaning that they don't have to manually download meters or review paper logbooks. The EMR allows physicians to quickly identify which patients are out of their acceptable glucose range or are not adhering to glucose testing.

This technology allows the physicians to display time series data in graphic form and observe daily averages and trends. "This enables us to conduct surveillance of our patients' health, even when they are not here for a visit," says Holly.

—DJN

PRACTICE MANAGEMENT

Take All Practice Members' Needs Into Account When Creating a Retirement Plan

By Robert E. Tucker, MD, MBA

Employer-sponsored retirement plans are an important benefit provided in most medical practices. When the practice employs individuals of varying ages, income levels, and educational backgrounds, the plan must be carefully structured to treat all participants fairly. Recent regulations have added to the record keeping and potentially expose plans to greater scrutiny. Physicians must be aware of the steps they can take to minimize their liability while creating a sound investment environment for all employees. These steps include working with professionals to provide plan design, administration and investment management.

Complying With Regulations

One of the advantages of practicing medicine within the structure of a corporation is the ability to create efficient benefit plans, including retirement plans. However, if the corporation employs individuals other than a single physician, federal regulations mandate that retirement plan provisions be applied fairly across all classes of employees. Complying with these regulations can place an administrative burden on the physician-owner and staff, and can create unexpected sources of liability for those involved in the administration of the plan. Fortunately, steps can be taken to reduce the liability of the plan sponsors by properly structuring and funding the plan, ensuring adequate record keeping, and providing investment opportunities suitable to participants with a broad range of investment knowledge and risk tolerance.

The initial setup of the retirement plan provides the best opportunity to create a fully compliant environment. The advice of a retirement plan consultant is crucial. It can come from an attorney, accountant, or plan administration consultant, but the advisor should be free to recommend the most appropriate model and service providers without potential conflicts of interest. It may also not be best to bundle all of the required services with a single source. While the structure necessarily is based on the desires of the income-earners of the practice—namely, its physicians—it's important to keep in mind that, because benefits are also provided to non-physicians, all administrative and funding costs must be carefully analyzed to make the plan as efficient as possible. The plan should have the flexibility to meet the needs of highly compensated individuals of different ages, particularly if there is a desire to maximize contributions. As the ages and income levels of the participants become more diverse, it becomes more likely that an off-the-shelf solution will not be satisfactory.

With the demise of guaranteed pensions, and the uncertainty over the availability of Social Security in the future, employees are being asked to take a more active role in their retirement saving by participating in 401(k) and similar deferral plans. In anticipation of increased scrutiny of retirement plan information by employees, the Department of Labor has issued new regulations under the Employee Retirement Income Security Act (ERISA) designed to provide plan sponsors and plan participants with additional information about their accounts. It is hoped that having this information will empower the participants to become better educated and make more intelligent decisions. The regulations, however, will also provide participants with the information to question decisions made on their behalf by the plan sponsors, particularly in the face of poor investment performance.

A compliant retirement plan can provide all participants with a degree of control over their retirement income.

ERISA regulations now mandate that all fees paid by a plan be "reasonable," and that these fees be disclosed not only to the plan sponsors, but to the

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Robert E. Tucker, MD, MBA is vice president at Plancorp, LLC (www.plancorp.com), a fee-based wealth management firm in St. Louis County, Missouri. Having practiced orthopedic hand surgery for 25 years and participating in a variety of administrative and medical business roles, he is in a unique position to understand the current medical environment and to help physicians structure their financial activities to create a path to financial independence.

For your patients with type 2 diabetes who need more than A1C control, choose Levemir® (insulin detemir [rDNA origin] injection)

24/7 GLUCOSE CONTROL

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Low rates of hypoglycemia

In 1 study, approximately 45% of patients in each treatment arm achieved A1C <7% with no hypoglycemic events within the last 4 weeks of observation.[1]

- A single major hypoglycemic event was reported in the 70-90 mg/dL group; no major hypoglycemic events in the 80-110 mg/dL group
- Minor hypoglycemia rates were 5.09 (70-90 mg/dL) and 3.16 (80-110 mg/dL) per patient-year*

From a 20-week, randomized, controlled, multicenter, open-label, parallel-group, treat-to-target trial using a self-titration algorithm in insulin-naive patients with type 2 diabetes, A1C ≥7% and ≤9% on OAD therapy randomized to Levemir® and OAD (1:1) to 2 different fasting plasma glucose (FPG) titration targets (70-90 mg/dL [n=121] or 80-110 mg/dL [n=122]). At study end, in the 80-110 mg/dL group, 55% of patients achieved goal (A1C <7%) with A1C decrease of 0.9%. The mean A1C was 7%.[1]

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Indications and Usage

Levemir® (insulin detemir [rDNA origin] injection) is indicated to improve glycemic control in adults and children with diabetes mellitus.

Important Limitations of Use:
Levemir® is not recommended for the treatment of diabetic ketoacidosis. Intravenous rapid-acting or short-acting insulin is the preferred treatment for this condition.

Important Safety Information

Levemir® is contraindicated in patients hypersensitive to insulin detemir or one of its excipients.

Do not dilute or mix Levemir® with any other insulin solution, or use in insulin infusion pumps. Do not administer Levemir® intravenously or intramuscularly because severe hypoglycemia can occur.

Hypoglycemia is the most common adverse reaction of insulin therapy, including Levemir®. The timing of hypoglycemia usually reflects the time action profile of the administered insulin formulations. Glucose monitoring is essential for all patients receiving insulin therapy. Any changes to an insulin regimen should be made cautiously and only under medical supervision.

Needles and Levemir® FlexPen® must not be shared.

Severe, life-threatening, generalized allergy, including anaphylaxis, can occur with insulin products, including Levemir®. Adverse reactions associated with Levemir® include hypoglycemia, allergic reactions, injection site reactions, lipodystrophy, rash and pruritus. Careful glucose monitoring and dose adjustments of insulin, including Levemir®, may be necessary in patients with renal or hepatic impairment.

Levemir® has not been studied in children with type 2 diabetes, and in children with type 1 diabetes under the age of six.

Please see brief summary of Prescribing Information on adjacent page.

Needles are sold separately and may require a prescription in some states.

*Minor=SMPG <56 mg/dL and not requiring third-party assistance.

† Intended as a guide. Lower acquisition costs alone do not necessarily reflect a cost advantage in the outcome of the condition treated because other variables affect relative costs. Formulary status is subject to change.

On your iPhone®
Scan the QR code to download the NovoDose™ app to know how to optimally dose Levemir®

Levemir® FlexPen®
insulin detemir (rDNA origin) injection

References: 1. Blonde L, Merilainen M, Karwe V, Raskin P; TITRATE™ Study Group. Patient-directed titration for achieving glycaemic goals using a once-daily basal insulin analogue: an assessment of two different fasting plasma glucose targets - the TITRATE™ study. *Diabetes Obes Metab.* 2009;11(6):623-631. **2.** Data on file. Novo Nordisk Inc, Princeton, NJ.

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LEVEMIR® (insulin detemir [rDNA origin] injection)

Rx ONLY

BRIEF SUMMARY. Please consult package insert for full prescribing information.

INDICATIONS AND USAGE: LEVEMIR® is indicated to improve glycemic control in adults and children with diabetes mellitus. Important Limitations of Use: LEVEMIR® is not recommended for the treatment of diabetic ketoacidosis. Intravenous rapid-acting or short-acting insulin is the preferred treatment for this condition.

CONTRAINDICATIONS: LEVEMIR® is contraindicated in patients with hypersensitivity to LEVEMIR® or any of its excipients. Reactions have included anaphylaxis.

WARNINGS AND PRECAUTIONS: Dosage adjustment and monitoring: Glucose monitoring is essential for all patients receiving insulin therapy. Changes to an insulin regimen should be made cautiously and only under medical supervision. Changes in insulin strength, manufacturer, type, or method of administration may result in the need for a change in the insulin dose or an adjustment of concomitant anti-diabetic treatment. As with all insulin preparations, the time course of action for LEVEMIR® may vary in different individuals or at different times in the same individual and is dependent on many conditions, including the local blood supply, local temperature, and physical activity. **Administration:** LEVEMIR® should only be administered subcutaneously. Do not administer LEVEMIR® intravenously or intramuscularly. The intended duration of activity of LEVEMIR® is dependent on injection into subcutaneous tissue. Intravenous or intramuscular administration of the usual subcutaneous dose could result in severe hypoglycemia. Do not use LEVEMIR® in insulin infusion pumps. Do not dilute or mix LEVEMIR® with any other insulin or solution. If LEVEMIR® is diluted or mixed, the pharmacokinetic or pharmacodynamic profile (e.g., onset of action, time to peak effect) of LEVEMIR® and the mixed insulin may be altered in an unpredictable manner. **Hypoglycemia:** Hypoglycemia is the most common adverse reaction of insulin therapy, including LEVEMIR®. The risk of hypoglycemia increases with intensive glycemic control. Patients must be educated to recognize and manage hypoglycemia. Severe hypoglycemia can lead to unconsciousness or convulsions and may result in temporary or permanent impairment of brain function or death. Severe hypoglycemia requiring the assistance of another person or parenteral glucose infusion, or glucagon administration has been observed in clinical trials with insulin, including trials with LEVEMIR®. The timing of hypoglycemia usually reflects the time-action profile of the administered insulin formulations. Other factors such as changes in food intake (e.g., amount of food or timing of meals), exercise, and concomitant medications may also alter the risk of hypoglycemia. The prolonged effect of subcutaneous LEVEMIR® may delay recovery from hypoglycemia. As with all insulins, use caution in patients with hypoglycemia unawareness and in patients who may be predisposed to hypoglycemia (e.g., the pediatric population and patients who fast or have erratic food intake). The patient's ability to concentrate and react may be impaired as a result of hypoglycemia. This may present a risk in situations where these abilities are especially important, such as driving or operating other machinery. Early warning symptoms of hypoglycemia may be different or less pronounced under certain conditions, such as longstanding diabetes, diabetic neuropathy, use of medications such as beta-blockers, or intensified glycemic control. These situations may result in severe hypoglycemia (and, possibly, loss of consciousness) prior to the patient's awareness of hypoglycemia. **Hypersensitivity and allergic reactions:** Severe, life-threatening, generalized allergy, including anaphylaxis, can occur with insulin products, including LEVEMIR®. **Renal Impairment:** No difference was observed in the pharmacokinetics of insulin detemir between non-diabetic individuals with renal impairment and healthy volunteers. However, some studies with human insulin have shown increased circulating insulin concentrations in patients with renal impairment. Careful glucose monitoring and dose adjustments of insulin, including LEVEMIR®, may be necessary in patients with renal impairment. **Hepatic Impairment:** Non-diabetic individuals with severe hepatic impairment had lower systemic exposures to insulin detemir compared to healthy volunteers. However, some studies with human insulin have shown increased circulating insulin concentrations in patients with liver impairment. Careful glucose monitoring and dose adjustments of insulin, including LEVEMIR®, may be necessary in patients with hepatic impairment. **Drug interactions:** Some medications may alter insulin requirements and subsequently increase the risk for hypoglycemia or hyperglycemia.

ADVERSE REACTIONS: The following adverse reactions are discussed elsewhere: Hypoglycemia; Hypersensitivity and allergic reactions. Clinical trial experience: Because clinical trials are conducted under widely varying designs, the adverse reaction rates reported in one clinical trial may not be easily compared to those rates reported in another clinical trial, and may not reflect the rates actually observed in clinical practice. The frequencies of adverse reactions (excluding hypoglycemia) reported during LEVEMIR® clinical trials in patients with type 1 diabetes mellitus and type 2 diabetes mellitus are listed in Tables 1-4 below. See Tables 5 and 6 for the hypoglycemia findings.

Table 1: Adverse reactions (excluding hypoglycemia) in two pooled clinical trials of 16 weeks and 24 weeks duration in adults with type 1 diabetes (adverse reactions with incidence ≥ 5%)

	LEVEMIR®, % (n = 767)	NPH, % (n = 388)
Upper respiratory tract infection	26.1	21.4
Headache	22.6	22.7
Pharyngitis	9.5	8.0
Influenza-like illness	7.8	7.0
Abdominal Pain	6.0	2.6

Table 2: Adverse reactions (excluding hypoglycemia) in a 26-week trial comparing insulin aspart + LEVEMIR® to insulin aspart + insulin glargine in adults with type 1 diabetes (adverse reactions with incidence ≥ 5%)

	LEVEMIR®, % (n = 161)	Glargine, % (n = 159)
Upper respiratory tract infection	26.7	32.1
Headache	14.3	19.5
Back pain	8.1	6.3
Influenza-like illness	6.2	8.2
Gastroenteritis	5.6	4.4
Bronchitis	5.0	1.9

Table 3: Adverse reactions (excluding hypoglycemia) in two pooled clinical trials of 22 weeks and 24 weeks duration in adults with type 2 diabetes (adverse reactions with incidence ≥ 5%)

	LEVEMIR®, % (n = 432)	NPH, % (n = 437)
Upper respiratory tract infection	12.5	11.2
Headache	6.5	5.3

Table 4: Adverse reactions (excluding hypoglycemia) in a 26-week clinical trial of children and adolescents with type 1 diabetes (adverse reactions with incidence ≥ 5%)

	LEVEMIR®, % (n = 232)	NPH, % (n = 115)
Upper respiratory tract infection	35.8	42.6
Headache	31.0	32.2
Pharyngitis	17.2	20.9
Gastroenteritis	16.8	11.3
Influenza-like illness	13.8	20.9
Abdominal pain	13.4	13.0
Pyrexia	10.3	6.1
Cough	8.2	4.3
Viral infection	7.3	7.8
Nausea	6.5	7.0
Rhinitis	6.5	3.5
Vomiting	6.5	10.4

Hypoglycemia: Hypoglycemia is the most commonly observed adverse reaction in patients using insulin, including LEVEMIR®. Tables 5 and 6 summarize the incidence of severe and non-severe hypoglycemia in the LEVEMIR® clinical trials. Severe hypoglycemia was defined as an event with symptoms consistent with hypoglycemia requiring assistance of another person and associated with either a blood glucose below 50 mg/dL or prompt recovery after oral carbohydrate, intravenous glucose or glucagon administration. Non-severe hypoglycemia was defined as an asymptomatic or symptomatic plasma glucose < 56 mg/dL (<50 mg/dL in Study A and C) that was self-treated by the patient. The rates of hypoglycemia in the LEVEMIR® clinical trials (see Section 14 for a description of the study designs) were comparable between LEVEMIR®-treated patients and non-LEVEMIR®-treated patients (see Tables 5 and 6).

Table 5: Hypoglycemia in Patients with Type 1 Diabetes

		Study A Type 1 Diabetes Adults 16 weeks In combination with insulin aspart		Study B Type 1 Diabetes Adults 26 weeks In combination with insulin aspart		Study C Type 1 Diabetes Adults 24 weeks In combination with regular insulin		Study D Type 1 Diabetes Pediatrics 26 weeks In combination with insulin aspart	
		Twice-Daily LEVEMIR®	Twice-Daily NPH	Twice-Daily LEVEMIR®	Once-Daily Glargine	Once-Daily LEVEMIR®	Once-Daily NPH	Once- or Twice Daily LEVEMIR®	Once- or Twice Daily NPH
Severe hypoglycemia	Percent of patients with at least 1 event (n/total N)	8.7 (24/276)	10.6 (14/132)	5.0 (8/161)	10.1 (16/159)	7.5 (37/491)	10.2 (26/256)	15.9 (37/232)	20.0 (23/115)
	Event/patient/year	0.52	0.43	0.13	0.31	0.35	0.32	0.91	0.99
Non-severe hypoglycemia	Percent of patients (n/total N)	88.0 (243/276)	89.4 (118/132)	82.0 (132/161)	77.4 (123/159)	88.4 (434/491)	87.9 (225/256)	93.1 (216/232)	95.7 (110/115)
	Event/patient/year	26.4	37.5	20.2	21.8	31.1	33.4	31.6	37.0

Table 6: Hypoglycemia in Patients with Type 2 Diabetes

		Study E Type 2 Diabetes Adults 24 weeks In combination with oral agents		Study F Type 2 Diabetes Adults 22 weeks In combination with insulin aspart	
		Twice-Daily LEVEMIR®	Twice-Daily NPH	Once- or Twice Daily LEVEMIR®	Once- or Twice Daily NPH
Severe hypoglycemia	Percent of patients with at least 1 event (n/total N)	0.4 (1/237)	2.5 (6/238)	1.5 (3/195)	4.0 (8/199)
	Event/patient/year	0.01	0.08	0.04	0.13
Non-severe hypoglycemia	Percent of patients (n/total N)	40.5 (96/237)	64.3 (153/238)	32.3 (63/195)	32.2 (64/199)
	Event/patient/year	3.5	6.9	1.6	2.0

Insulin Initiation and Intensification of Glucose Control: Intensification or rapid improvement in glucose control has been associated with a transitory, reversible ophthalmologic refraction disorder, worsening of diabetic retinopathy, and acute painful peripheral neuropathy. However, long-term glycemic control decreases the risk of diabetic retinopathy and neuropathy. *Lipodystrophy:* Long-term use of insulin, including LEVEMIR®, can cause lipodystrophy at the site of repeated insulin injections. Lipodystrophy includes lipohypertrophy (thickening of adipose tissue) and lipoatrophy (thinning of adipose tissue), and may affect insulin adsorption. Rotate insulin injection sites within the same region to reduce the risk of lipodystrophy. *Weight Gain:* Weight gain can occur with insulin therapy, including LEVEMIR®, and has been attributed to the anabolic effects of insulin and the decrease in glucosuria. *Peripheral Edema:* Insulin, including LEVEMIR®, may cause sodium retention and edema, particularly if previously poor metabolic control is improved by intensified insulin therapy. *Allergic Reactions: Local Allergy:* As with any insulin therapy, patients taking LEVEMIR® may experience injection site reactions, including localized erythema, pain, pruritis, urticaria, edema, and inflammation. In clinical studies in adults, three patients treated with LEVEMIR® reported injection site pain (0.25%) compared to one patient treated with NPH insulin (0.12%). The reports of pain at the injection site did not result in discontinuation of therapy. Rotation of the injection site within a given area from one injection to the next may help to reduce or prevent these reactions. In some instances, these reactions may be related to factors other than insulin, such as irritants in a skin cleansing agent or poor injection technique. Most minor reactions to insulin usually resolve in a few days to a few weeks. *Systemic Allergy:* Severe, life-threatening, generalized allergy, including anaphylaxis, generalized skin reactions, angioedema, bronchospasm, hypotension, and shock may occur with any insulin, including LEVEMIR®, and may be life-threatening. *Antibody Production:* All insulin products can elicit the formation of insulin antibodies. These insulin antibodies may increase or decrease the efficacy of insulin and may require adjustment of the insulin dose. In phase 3 clinical trials of LEVEMIR®, antibody development has been observed with no apparent impact on glycemic control. **Postmarketing experience:** The following adverse reactions have been identified during post approval use of LEVEMIR®. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Medication errors have been reported during post-approval use of LEVEMIR® in which other insulins, particularly rapid-acting or short-acting insulins, have been accidentally administered instead of LEVEMIR®. To avoid medication errors between LEVEMIR® and other insulins, patients should be instructed always to verify the insulin label before each injection.

More detailed information is available upon request.

For information about LEVEMIR® contact:
Novo Nordisk Inc.,
100 College Road West
Princeton, NJ 08540
1-800-727-6500
www.novonordisk-us.com

Manufactured by:
Novo Nordisk A/S
DK-2880 Bagsvaerd, Denmark

Revised: 1/2012

0212-00007333-1 2/2012

novo nordisk®

Levemir®
insulin detemir (rDNA origin) injection

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participants as well. As a result, participants must receive compliant quarterly statements showing the holdings and performance of their accounts and also the fees and costs paid either directly or indirectly for the management of the plan, including investment advice, transaction costs, and internal costs of any mutual funds held in the plan.

Structuring Your Plan

To maintain a plan that is fully compliant, think of the plan as a stool supported by three legs. The first is an administrator: an individual or organization that monitors enrollment, calculates the appropriate contributions, and coordinates the distribution of reports and assists in plan distributions. A competent administrator will keep abreast of changing regulations and recommend necessary changes in the plan design, as well as recommend methods of maximizing contributions to highly compensated participants. The second leg is the record keeper, whose job is to account for the plan assets and process the contributions. The administration and record keeping can be bundled and provided by the same company. However, using independent third-party administrators and record keepers provides additional checks and balances.

The final leg is the investment manager. In this area, plan sponsors can delegate administrative tasks and offload liability. An advisor who acts as a "3(38) fiduciary" can assume fiduciary responsibility for the investment choices, rather than simply make suggestions for which the plan sponsors are responsible. The plan sponsor should consider working with such an investment advisor who has the expertise to make investment recommendations and the ability to assume fiduciary responsibility for their selection.

Physicians must be aware of the steps they can take to minimize their liability while creating a sound investment environment for all employees.

The implementation of the new regulations provides a perfect opportunity to review your plan structure and the investment opportunities offered. Because the investment fiduciaries have the responsibility of making decisions on other people's investments, they must make available choices appropriate for themselves and for others. Participants should have access to low-cost investments (e.g., no-load mutual funds) that can be combined into portfolios that allow for varying tolerances to investment risk. Index or asset class mutual funds that can track the performance of the securities markets and can be combined into model portfolios of varying degrees of risk are ideal choices for these models. The proper advisor can build the model portfolios and provide historic information on their performance and education of their appropriateness for individuals in different life situations.

The creation of a compliant retirement plan can provide all participants with a degree of control over their retirement income and will be seen by employees as a valuable benefit and an incentive to remain employed by the practice. Taking the analogy of the three-legged stool into consideration, a retirement plan can be built that accomplishes these goals while minimizing liability to the plan sponsors and administrative burden to the practice. ■

Check for These Things When Establishing a Retirement Plan in Your Practice

Even in a small practice with only a few employees, an employer-sponsored retirement plan must take the needs of all participants into consideration. It makes sense, and is actually encouraged by the Department of Labor, that the plan sponsors delegate responsibilities to qualified advisors who can also assume much of the liability. Keep in mind the following when establishing or reviewing your plan:

- Have the sponsors clearly documented what they are trying to accomplish with the plan?
- Has there been a professional review of how to accomplish the goals most efficiently?
- Has an investment manager been selected who can serve as a section 3(38) fiduciary, and who can provide investments that are inexpensive to own, are assembled into model risk-based portfolios, and are suitable for participants of various ages, incomes, and educational levels?
- Have a record keeper and an administrator been selected who can provide Department of Labor compliant reports, consult on the plan structure, and allow access to a variety of administrative reports by appropriate staff and to detailed account information by all participants?
- Are there resources available to educate the plan participants and provide administrative support to the staff?
- Can all of this be done at reasonable cost and in such a way as to minimize the burden on the practice's staff?
- Are the various providers free from conflicts of interest?

—RET

ORGANIZATIONAL OPTIONS

Strategic Partnerships Help Health Care Organizations Transition Toward ACO Model

Health care institutions are increasingly pressured to provide quality patient care at a lower cost. While the Obama administration has proposed accountable care organizations (ACOs) as a potential vehicle for reaching those goals, jumping directly from a predominantly fee-for-service model to a full-fledged ACO is not always feasible. Some health care organizations are experimenting with their own transitional models of shared accountability, including partnerships with other health care organizations to pool their resources. "When doctors and other health care providers can work together to coordinate patient care, patients receive higher quality care, and we all see lower costs," according to the Centers for Medicare & Medicaid Services (CMS). In theory, such partnerships would streamline access to patient information and lead to better patient care coordination.

Inova Health System, a not-for-profit health care system based in Falls Church, Va., will soon be putting this theory to the test. In June 2012, Inova partnered with Aetna, a major national health care benefits provider based in Hartford, Conn., to establish Innovation Health Plans, a jointly owned health plan serving Northern Virginia, including more than 1.1 million residents currently served by Inova. The new co-branded health insurance plan is a separate corporate entity from either corporation that will be licensed first in Virginia as a preferred provider organization and also as a health maintenance organization. It is scheduled to roll out starting on January 1, 2013.

Pooling Assets

"This is the opportunity for a major provider system and insurer to get together and do some things that haven't been done before," says Kylanne Green, Inova's executive president of health services. While not considered a CMS/Medicare ACO in the strict legal sense, Innovation Health Plans aims to hold members more accountable for care in terms of quality, satisfaction, and costs associated with delivering care.

"We plan to do that in a couple of ways," says Green. "First of all, [having] a better relationship with an insurer actually facilitates access to care in the right setting, with the right people taking care of the patient. So, the closer relationship [Inova] has with the insurer, the better and more appropriate access patients and physicians have. A closer relationship between the payer and the provider facilitates things going more smoothly. That's one way access and the patient experience are better. We also have many years' worth of data available through Aetna—not just about patients, but about the providers—that we can use in order to analyze how to make the quality of the product better. If you have the right care delivered in the right time, we believe that can lower costs."

"The organization we created gives the physicians an opportunity to be active participants in our mission, vision, and goal-setting," says Vera Dvorak, MD, Inova's medical director for care management. "Having access to credible data gives them the opportunity to create a new pathway, to create new quality indicators, because now they are becoming the owners of the [utilization] data."

The most important thing Innovation Health Plans offers is access to patient information across the continuum of care, according to Dvorak. Physicians will have answers at their fingertips to such questions as:

- What happened to the patient in the emergency room?
- What happened to the patient in the ambulatory setting?
- What services were provided in the hospital?
- Was the patient under the care of the transitional case managers?
- Was the patient referred to a didactic learning center?

"Having this knowledge about what happened to the patient in the continuum of care is a powerful tool for making assessments and for ordering

appropriate tests," says Dvorak. "We are finding that physicians are becoming part of the creation. Putting physicians in the middle of Inova and Aetna to be the decision-makers in the care of the patient is a welcome opportunity for them. The goal is to provide patient-centered medical records."

Patients will also be more engaged in their own care, as the new health plan will allow them access to important health care information, such as laboratory results. "We are truly creating a collaborative model of care, with the patient being central to all of it," says Dvorak.

Sharing Accountability

The foundation of Innovation Health Plans is shared accountability, according to Green. "The physicians are accountable for what happens, and they may be accountable to different goals than before," she says. "The health system is accountable to the physician—to assist them by providing the support tools and the care in our institution that physicians need to treat their patients. [Inova and Aetna] are accountable to the people we serve. Insurance companies provide the infrastructure and resources they have—data and information, as well as economic resources to help build systems."

"Our anticipation is that with the accountability of the physicians and others, we will quickly move to a model that's more performance-based."

— Kylanne Green, Inova Health System, Falls Church, Va.

Although the model is currently fee-for-service, physicians will be part of the network, and they are currently engaged in establishing quality and performance indicators. "They know there will be rewards if they actually do what they set out to do," says Dvorak. "They will create their own pay-for-performance model." The ultimate goal is to reward physicians for quality care.

"Part of what makes this different from what we had before is that we're asking our physicians to establish what they believe performance should be—be it performance with respect to patient satisfaction, quality, or financial performance," says Green.

"There will be financial integration at the point that we are mature enough to understand that we have the data we need, we have the information that we can disseminate, and we have the buy-in of the physicians and other caregivers to what it is they want to measure," says Green. "So while initially it's going to look like a fee-for-service model, our anticipation is that with the accountability of the physicians

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CMS Programs Can Help Practices Transition to ACO Model

The Centers for Medicare & Medicaid Services (CMS) recognizes that transition to an accountable care organization (ACO) is not easy, and that health care organizations may vary in their stage of readiness, as well as in organization size, type, and infrastructure. CMS has, therefore, proposed different options geared to gradually ease practices out of the traditional fee-for-service based health care paradigm while maintaining, and eventually enhancing, patient care. These include:

- **Partnerships for Patients.** Supports the efforts of clinicians to safely coordinate patients' transitions from hospitals to other settings; shares proven methods of reducing in-hospital harm and preventing hospital readmission.
- **Bundled Payments for Care Improvements.** Allows for use of any one of four bundled payment systems, giving providers control and flexibility regarding which conditions to bundle, how health care delivery is structured, and how payments are allocated.
- **Comprehensive Primary Care Initiative.** A monthly fee is given to primary care practices to help patients with chronic disease adhere to long-term care plans, to give patients around-the-clock access to important health care information, to facilitate the delivery of preventive care, to help patients engage in self-care, and to facilitate coordination among primary care doctors and specialists.
- **Federally Qualified Health Center (FQHC) Advanced Primary Care Practice.** Evaluates clinicians' effectiveness in coordinating and improving care for Medicare patients.
- **Medicare Shared Savings Program.** Clinicians who meet patient care quality standards may share in any savings they earn for the Medicare program.
- **Advance Payment ACO model.** Provides aid to physician-owned or rural practices that need it to set up an ACO-supportive infrastructure.
- **Pioneer ACO model.** Studies organizations experienced in providing integrated care across the continuum to demonstrate the benefits of highly coordinated care.
- **Financial models to support state efforts to integrate care for Medicare/Medicaid enrollees.** Test a capitated model and a managed fee-for-service model to see if they can better align the financing of Medicare and Medicaid programs.

For more information, visit http://tinyurl.com/9ah67pr.

—SC

With the power of a GLP-1 receptor agonist

Help adult patients grab type 2 diabetes by the roots.

Powerful A1C reductions -0.8% to -1.5%*
—Lowered FPG and PPG

Increased beta-cell function
—Improves insulin secretion

Low rate of hypoglycemia

May reduce weight
—Victoza® is not indicated for the management of obesity, and weight change was a secondary end point in clinical trials

To hear what patients are saying and why Victoza® is the #1 prescribed GLP-1 agonist by endocrinologists,† visit **VictozaPro.com/Voices**.

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VICTOZA®
liraglutide (rDNA origin) injection

Indications and usage

Victoza® is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Because of the uncertain relevance of the rodent thyroid C-cell tumor findings to humans, prescribe Victoza® only to patients for whom the potential benefits are considered to outweigh the potential risk. Victoza® is not recommended as first-line therapy for patients who have inadequate glycemic control on diet and exercise.

In clinical trials of Victoza®, there were more cases of pancreatitis with Victoza® than with comparators. Victoza® has not been studied sufficiently in patients with a history of pancreatitis to determine whether these patients are at increased risk for pancreatitis while using Victoza®. Use with caution in patients with a history of pancreatitis.

Victoza® is not a substitute for insulin. Victoza® should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.

The concurrent use of Victoza® and insulin has not been studied.

Important safety information

Liraglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures in both genders of rats and mice. It is unknown whether Victoza® causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as human relevance could not be ruled out by clinical or nonclinical studies. Victoza® is contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Based on the findings in rodents, monitoring with serum calcitonin or thyroid ultrasound was performed during clinical trials, but this may have increased the number of unnecessary thyroid surgeries. It is unknown whether monitoring with serum calcitonin or thyroid ultrasound will mitigate human risk of thyroid C-cell tumors. Patients should be counseled regarding the risk and symptoms of thyroid tumors.

If pancreatitis is suspected, Victoza® should be discontinued. Victoza® should not be re-initiated if pancreatitis is confirmed.

When Victoza® is used with an insulin secretagogue (e.g. a sulfonylurea) serious hypoglycemia can occur. Consider lowering the dose of the insulin secretagogue to reduce the risk of hypoglycemia.

Renal impairment has been reported postmarketing, usually in association with nausea, vomiting, diarrhea, or dehydration, which may sometimes require hemodialysis. Use caution when initiating or escalating doses of Victoza® in patients with renal impairment.

There have been no studies establishing conclusive evidence of macrovascular risk reduction with Victoza® or any other antidiabetic drug.

The most common adverse reactions, reported in ≥5% of patients treated with Victoza® and more commonly than in patients treated with placebo, are headache, nausea, diarrhea, and anti-liraglutide antibody formation. Immunogenicity-related events, including urticaria, were more common among Victoza®-treated patients (0.8%) than among comparator-treated patients (0.4%) in clinical trials.

Victoza® has not been studied in type 2 diabetes patients below 18 years of age and is not recommended for use in pediatric patients.

Victoza® should be used with caution in patients with hepatic impairment.

Please see brief summary of Prescribing Information on adjacent page.

*Victoza® 1.2 mg and 1.8 mg when used alone or in combination with OADs.
†IMS Health Inc. LifeLink Longitudinal Prescription Database (LRx)™, April 2010-March 2011. Patients new to a GLP-1 agonist regimen from a previous regimen without a GLP-1 agonist.

1111-00006038-1 January 2012

Victoza® (liraglutide [rDNA origin] injection)

Rx Only

BRIEF SUMMARY. Please consult package insert for full prescribing information.

WARNING: RISK OF THYROID C-CELL TUMORS: Liraglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures in both genders of rats and mice. It is unknown whether Victoza® causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as human relevance could not be ruled out by clinical or nonclinical studies. Victoza® is contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Based on the findings in rodents, monitoring with serum calcitonin or thyroid ultrasound was performed during clinical trials, but this may have increased the number of unnecessary thyroid surgeries. It is unknown whether monitoring with serum calcitonin or thyroid ultrasound will mitigate human risk of thyroid C-cell tumors. Patients should be counseled regarding the risk and symptoms of thyroid tumors *[see Contraindications and Warnings and Precautions]*.

INDICATIONS AND USAGE: Victoza® is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. **Important Limitations of Use:** Because of the uncertain relevance of the rodent thyroid C-cell tumor findings to humans, prescribe Victoza® only to patients for whom the potential benefits are considered to outweigh the potential risk. Victoza® is not recommended as first-line therapy for patients who have inadequate glycemic control on diet and exercise. In clinical trials of Victoza®, there were more cases of pancreatitis with Victoza® than with comparators. Victoza® has not been studied sufficiently in patients with a history of pancreatitis to determine whether these patients are at increased risk for pancreatitis while using Victoza®. Use with caution in patients with a history of pancreatitis. Victoza® is not a substitute for insulin. Victoza® should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings. The concurrent use of Victoza® and insulin has not been studied.

CONTRAINDICATIONS: Victoza® is contraindicated in patients with a personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).

WARNINGS AND PRECAUTIONS: Risk of Thyroid C-cell Tumors: Liraglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors (adenomas and/or carcinomas) at clinically relevant exposures in both genders of rats and mice. Malignant thyroid C-cell carcinomas were detected in rats and mice. A statistically significant increase in cancer was observed in rats receiving liraglutide at 8-times clinical exposure compared to controls. It is unknown whether Victoza® will cause thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as the human relevance of liraglutide-induced rodent thyroid C-cell tumors could not be determined by clinical or nonclinical studies *[see Boxed Warning, Contraindications]*. In the clinical trials, there have been 4 reported cases of thyroid C-cell hyperplasia among Victoza®-treated patients and 1 case in a comparator-treated patient (1.3 vs. 0.6 cases per 1000 patient-years). One additional case of thyroid C-cell hyperplasia in a Victoza®-treated patient and 1 case of MTC in a comparator-treated patient have subsequently been reported. This comparator-treated patient with MTC had pre-treatment serum calcitonin concentrations >1000 ng/L suggesting pre-existing disease. All of these cases were diagnosed after thyroidectomy, which was prompted by abnormal results on routine, protocol-specified measurements of serum calcitonin. Four of the five liraglutide-treated patients had elevated calcitonin concentrations at baseline and throughout the trial. One liraglutide and one non-liraglutide-treated patient developed elevated calcitonin concentrations while on treatment. Calcitonin, a biological marker of MTC, was measured throughout the clinical development program. The serum calcitonin assay used in the Victoza® clinical trials had a lower limit of quantification (LLOQ) of 0.7 ng/L and the upper limit of the reference range was 5.0 ng/L for women and 8.4 ng/L for men. At Weeks 26 and 52 in the clinical trials, adjusted mean serum calcitonin concentrations were higher in Victoza®-treated patients compared to placebo-treated patients but not compared to patients receiving active comparator. At these timepoints, the adjusted mean serum calcitonin values (~ 1.0 ng/L) were just above the LLOQ with between-group differences in adjusted mean serum calcitonin values of approximately 0.1 ng/L or less. Among patients with pre-treatment serum calcitonin below the upper limit of the reference range, shifts to above the upper limit of the reference range which persisted in subsequent measurements occurred most frequently among patients treated with Victoza® 1.8 mg/day. In trials with on-treatment serum calcitonin measurements out to 5-6 months, 1.9% of patients treated with Victoza® 1.8 mg/day developed new and persistent calcitonin elevations above the upper limit of the reference range compared to 0.8-1.1% of patients treated with control medication or the 0.6 and 1.2 mg doses of Victoza®. In trials with on-treatment serum calcitonin measurements out to 12 months, 1.3% of patients treated with Victoza® 1.8 mg/day had new and persistent elevations of calcitonin from below or within the reference range to above the upper limit of the reference range, compared to 0.6%, 0% and 1.0% of patients treated with Victoza® 1.2 mg, placebo and active control, respectively. Otherwise, Victoza® did not produce consistent dose-dependent or time-dependent increases in serum calcitonin. Patients with MTC usually have calcitonin values >50 ng/L. In Victoza® clinical trials, among patients with pre-treatment serum calcitonin <50 ng/L, one Victoza®-treated patient and no comparator-treated patients developed serum calcitonin >50 ng/L. The Victoza®-treated patient who developed serum calcitonin >50 ng/L had an elevated pre-treatment serum calcitonin of 10.7 ng/L that increased to 30.7 ng/L at Week 12 and 53.5 ng/L at the end of the 6-month trial. Follow-up serum calcitonin was 22.3 ng/L more than 2.5 years after the last dose of Victoza®. The largest increase in serum calcitonin in a comparator-treated patient was seen with glimepiride in a patient whose serum calcitonin increased from 19.3 ng/L at baseline to 44.8 ng/L at Week 65 and 38.1 ng/L at Week 104. Among patients who began with serum calcitonin <20 ng/L, calcitonin elevations to >20 ng/L occurred in 0.7% of Victoza®-treated patients, 0.3% of placebo-treated patients, and 0.5% of active-comparator-treated patients, with an incidence of 1.1% among patients treated with 1.8 mg/day of Victoza®. The clinical significance of these findings is unknown. Counsel patients regarding the risk for MTC and the symptoms of thyroid tumors (e.g. a mass in the neck, dysphagia, dyspnea or persistent hoarseness). It is unknown whether monitoring with serum calcitonin or thyroid ultrasound will mitigate the potential risk of MTC, and such monitoring may increase the risk of unnecessary procedures, due to low test specificity for serum calcitonin and a high background incidence of thyroid disease. Patients with thyroid nodules noted on physical examination or neck imaging obtained for other reasons should be referred to an endocrinologist for further evaluation. Although routine monitoring of serum calcitonin is of uncertain value in patients treated with Victoza®, if serum calcitonin is measured and found to be elevated, the patient should be referred to an endocrinologist for further evaluation. **Pancreatitis:** In clinical trials of Victoza®, there were 7 cases of pancreatitis among Victoza®-treated patients and 1 case among comparator-treated patients (2.2 vs. 0.6 cases per 1000 patient-years). Five cases with Victoza® were reported as acute pancreatitis and two cases with Victoza® were reported as chronic pancreatitis. In one case in a Victoza®-treated patient, pancreatitis, with necrosis, was observed and led to death; however clinical causality could not be established. One additional case of pancreatitis has subsequently been reported in a Victoza®-treated patient. Some patients had other risk factors for pancreatitis, such as a history of cholelithiasis or alcohol abuse. There are no conclusive data establishing a risk of pancreatitis with Victoza® treatment. After initiation of Victoza®, and after dose increases, observe patients carefully for signs and symptoms of pancreatitis (including persistent severe abdominal pain, sometimes radiating to the back and which may or may not be accompanied by vomiting). If pancreatitis is suspected, Victoza® and other potentially suspect medications should be discontinued promptly, confirmatory tests should be performed and appropriate management should be initiated. If pancreatitis is confirmed, Victoza® should not be restarted. Use with caution in patients with a history of pancreatitis. **Use with Medications Known to Cause Hypoglycemia:** Patients receiving Victoza® in combination with an insulin secretagogue (e.g., sulfonylurea) may have an increased risk of hypoglycemia. In the clinical trials of at least 26 weeks duration, hypoglycemia requiring the assistance of another person for treatment occurred in 7 Victoza®-treated patients and in two comparator-treated patients. Six of these 7 patients treated with Victoza® were also taking a sulfonylurea. The risk of hypoglycemia may be lowered by a reduction in the dose of sulfonylurea or other insulin secretagogues *[see Adverse Reactions]*. **Renal Impairment:** Victoza® has not been found to be directly nephrotoxic in animal studies or clinical trials. There have been postmarketing reports of acute renal failure and worsening of chronic renal failure, which may sometimes require hemodialysis in Victoza®-treated patients *[see Adverse Reactions]*. Some of these events were reported in patients without known underlying renal disease. A majority of the reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration *[see Adverse Reactions]*. Some of the reported events occurred in patients receiving one or more medications known to affect renal function or hydration status. Altered renal function has been reversed in many of the reported cases with supportive treatment and discontinuation of potentially causative agents, including Victoza®. Use caution when initiating or escalating doses of Victoza® in patients with renal impairment. **Macrovascular Outcomes:** There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with Victoza® or any other antidiabetic drug.

ADVERSE REACTIONS: Clinical Trials Experience: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The safety of Victoza® was evaluated in a 52-week monotherapy trial and in five 26-week, add-on combination therapy trials. In the monotherapy trial, patients were treated with Victoza® 1.2 mg daily, Victoza® 1.8 mg daily, or glimepiride 8 mg daily. In the add-on to metformin trial, patients were treated with Victoza® 0.6 mg, Victoza® 1.2 mg, Victoza® 1.8 mg, placebo, or glimepiride 4 mg. In the add-on to glimepiride trial, patients were treated with Victoza® 0.6 mg, Victoza® 1.2 mg, Victoza® 1.8 mg, placebo, or rosiglitazone 4 mg. In the add-on to metformin + glimepiride trial, patients were treated with Victoza® 1.8 mg, placebo, or insulin glargine. In the add-on to metformin + rosiglitazone trial, patients were treated with Victoza® 1.2 mg, Victoza® 1.8 mg or placebo. *Withdrawals:* The incidence of withdrawal due to adverse events was 7.8% for Victoza®-treated patients and 3.4% for comparator-treated patients in the five controlled trials of 26 weeks duration or longer. This difference was driven by withdrawals due to gastrointestinal adverse reactions, which occurred in 5.0% of Victoza®-treated patients and 0.5% of comparator-treated patients. The most common adverse reactions leading to withdrawal for Victoza®-treated patients were nausea (2.8% versus 0% for comparator) and vomiting (1.5% versus 0.1% for comparator). Withdrawal due to gastrointestinal adverse events mainly occurred during the first 2-3 months of the trials. Tables 1, 2 and 3 summarize the adverse events reported in ≥5% of Victoza®-treated patients in the six controlled trials of 26 weeks duration or longer.

Table 1: Adverse events reported in ≥5% of Victoza®-treated patients or ≥5% of glimepiride-treated patients: 52-week monotherapy trial

	All Victoza® N = 497	Glimepiride N = 248
Adverse Event Term	(%)	(%)
Nausea	28.4	8.5
Diarrhea	17.1	8.9
Vomiting	10.9	3.6
Constipation	9.9	4.8
Upper Respiratory Tract Infection	9.5	5.6
Headache	9.1	9.3
Influenza	7.4	3.6
Urinary Tract Infection	6.0	4.0
Dizziness	5.8	5.2
Sinusitis	5.6	6.0
Nasopharyngitis	5.2	5.2
Back Pain	5.0	4.4
Hypertension	3.0	6.0

Table 2: Adverse events reported in ≥5% of Victoza®-treated patients and occurring more frequently with Victoza® compared to placebo: 26-week combination therapy trials

Add-on to Metformin Trial			
	All Victoza® + Metformin N = 724	Placebo + Metformin N = 121	Glimepiride + Metformin N = 242
Adverse Event Term	(%)	(%)	(%)
Nausea	15.2	4.1	3.3
Diarrhea	10.9	4.1	3.7
Headache	9.0	6.6	9.5
Vomiting	6.5	0.8	0.4
Add-on to Glimepiride Trial			
	All Victoza® + Glimepiride N = 695	Placebo + Glimepiride N = 114	Rosiglitazone + Glimepiride N = 231
Adverse Event Term	(%)	(%)	(%)
Nausea	7.5	1.8	2.6
Diarrhea	7.2	1.8	2.2

Constipation	5.3	0.9	1.7
Dyspepsia	5.2	0.9	2.6
Add-on to Metformin + Glimepiride			
	Victoza® 1.8 + Metformin + Glimepiride N = 230	Placebo + Metformin + Glimepiride N = 114	Glargine + Metformin + Glimepiride N = 232
Adverse Event Term	(%)	(%)	(%)
Nausea	13.9	3.5	1.3
Diarrhea	10.0	5.3	1.3
Headache	9.6	7.9	5.6
Dyspepsia	6.5	0.9	1.7
Vomiting	6.5	3.5	0.4

Add-on to Metformin + Rosiglitazone		
	All Victoza® + Metformin + Rosiglitazone N = 355	Placebo + Metformin + Rosiglitazone N = 175
Adverse Event Term	(%)	(%)
Nausea	34.6	8.6
Diarrhea	14.1	6.3
Vomiting	12.4	2.9
Decreased Appetite	9.3	1.1
Anorexia	9.0	0.0
Headache	8.2	4.6
Constipation	5.1	1.1
Fatigue	5.1	1.7

Table 3: Treatment-Emergent Adverse Events in 26 Week Open-Label Trial versus Exenatide (Adverse events with frequency ≥5% and occurring more frequently with Victoza® compared to exenatide are listed)

	Victoza® 1.8 mg once daily + metformin and/or sulfonylurea N = 235	**Exenatide 10 mcg twice daily + metformin and/or sulfonylurea** N = 232
Preferred Term	(%)	(%)
Diarrhea	12.3	12.1
Dyspepsia	8.9	4.7
Constipation	5.1	2.6

Gastrointestinal adverse events: In the five clinical trials of 26 weeks duration or longer, gastrointestinal adverse events were reported in 41% of Victoza®-treated patients and were dose-related. Gastrointestinal adverse events occurred in 17% of comparator-treated patients. Events that occurred more commonly among Victoza®-treated patients included nausea, vomiting, diarrhea, dyspepsia and constipation. In a 26-week study of Victoza® versus exenatide, both in combination with metformin and/or sulfonylurea overall gastrointestinal adverse event incidence rates, including nausea, were similar in patients treated with Victoza® and exenatide. In five clinical trials of 26 weeks duration or longer, the percentage of patients who reported nausea declined over time. Approximately 13% of Victoza®-treated patients and 2% of comparator-treated patients reported nausea during the first 2 weeks of treatment. In a 26 week study of Victoza® versus exenatide, both in combination with metformin and/or sulfonylurea, the proportion of patients with nausea also declined over time. *Immunogenicity:* Consistent with the potentially immunogenic properties of protein and peptide pharmaceuticals, patients treated with Victoza® may develop anti-liraglutide antibodies. Approximately 50-70% of Victoza®-treated patients in the five clinical trials of 26 weeks duration or longer were tested for the presence of anti-liraglutide antibodies at the end of treatment. Low titers (concentrations not requiring dilution of serum) of anti-liraglutide antibodies were detected in 8.6% of these Victoza®-treated patients. Sampling was not performed uniformly across all patients in the clinical trials, and this may have resulted in an underestimate of the actual percentage of patients who developed antibodies. Cross-reacting anti-liraglutide antibodies to native glucagon-like peptide-1 (GLP-1) occurred in 6.9% of the Victoza®-treated patients in the 52-week monotherapy trial and in 4.8% of the Victoza®-treated patients in the 26-week add-on combination therapy trials. These cross-reacting antibodies were not tested for neutralizing effect against native GLP-1, and thus the potential for clinically significant neutralization of native GLP-1 was not assessed. Antibodies that had a neutralizing effect on liraglutide in an *in vitro* assay occurred in 2.3% of the Victoza®-treated patients in the 52-week monotherapy trial and in 1.0% of the Victoza®-treated patients in the 26-week add-on combination therapy trials. Among Victoza®-treated patients who developed anti-liraglutide antibodies, the most common category of adverse events was that of infections, which occurred among 40% of these patients compared to 36%, 34% and 35% of antibody-negative Victoza®-treated, placebo-treated and active-control-treated patients, respectively. The specific infections which occurred with greater frequency among Victoza®-treated antibody-positive patients were primarily nonserious upper respiratory tract infections, which occurred among 11% of Victoza®-treated antibody-positive patients; and among 7%, 7% and 5% of antibody-negative Victoza®-treated, placebo-treated and active-control-treated patients, respectively. Among Victoza®-treated antibody-negative patients, the most common category of adverse events was that of gastrointestinal events, which occurred in 43%, 18% and 19% of antibody-negative Victoza®-treated, placebo-treated and active-control-treated patients, respectively. Antibody formation was not associated with reduced efficacy of Victoza® when comparing mean HbA_{1c} of all antibody-positive and all antibody-negative patients. However, the 3 patients with the highest titers of anti-liraglutide antibodies had no reduction in HbA_{1c} with Victoza® treatment. In clinical trials of Victoza®, events from a composite of adverse events potentially related to immunogenicity (e.g. urticaria, angioedema) occurred among 0.8% of Victoza®-treated patients and among 0.4% of comparator-treated patients. Urticaria accounted for approximately one-half of the events in this composite for Victoza®-treated patients. Patients who developed anti-liraglutide antibodies were not more likely to develop events from the immunogenicity events composite than were patients who did not develop anti-liraglutide antibodies. *Injection site reactions:* Injection site reactions (e.g., injection site rash, erythema) were reported in approximately 2% of Victoza®-treated patients in the five clinical trials of at least 26 weeks duration. Less than 0.2% of Victoza®-treated patients discontinued due to injection site reactions. *Papillary thyroid carcinoma:* In clinical trials of Victoza®, there were 6 reported cases of papillary thyroid carcinoma in patients treated with Victoza® and 1 case in a comparator-treated patient (1.9 vs. 0.6 cases per 1000 patient-years). Most of these papillary thyroid carcinomas were <1 cm in greatest diameter and were diagnosed in surgical pathology specimens after thyroidectomy prompted by findings on protocol-specified screening with serum calcitonin or thyroid ultrasound. *Hypoglycemia:* In the clinical trials of at least 26 weeks duration, hypoglycemia requiring the assistance of another person for treatment occurred in 7 Victoza®-treated patients (2.6 cases per 1000 patient-years) and in two comparator-treated patients. Six of these 7 patients treated with Victoza® were also taking a sulfonylurea. One other patient was taking Victoza® in combination with metformin but had another likely explanation for the hypoglycemia (this event occurred during hospitalization and after insulin infusion) (Table 4). Two additional cases of hypoglycemia requiring the assistance of another person for treatment have subsequently been reported in patients who were not taking a concomitant sulfonylurea. Both patients were receiving Victoza®, one as monotherapy and the other in combination with metformin. Both patients had another likely explanation for the hypoglycemia (one received insulin during a frequently-sampled intravenous glucose tolerance test, and the other had intracranial hemorrhage and uncertain food intake).

Table 4: Incidence (%) and Rate (episodes/patient year) of Hypoglycemia in the 52-Week Monotherapy Trial and in the 26-Week Combination Therapy Trials

	Victoza® Treatment	**Active Comparator**	**Placebo Comparator**
Monotherapy	**Victoza®** (N = 497)	**Glimepiride** (N = 248)	**None**
Patient not able to self–treat	0	0	—
Patient able to self–treat	9.7 (0.24)	25.0 (1.66)	—
Not classified	1.2 (0.03)	2.4 (0.04)	—
Add-on to Metformin	**Victoza® + Metformin** (N = 724)	**Glimepiride + Metformin** (N = 242)	**Placebo + Metformin** (N = 121)
Patient not able to self–treat	0.1 (0.001)	0	0
Patient able to self–treat	3.6 (0.05)	22.3 (0.87)	2.5 (0.06)
Add-on to Glimepiride	**Victoza® + Glimepiride** (N = 695)	**Rosiglitazone + Glimepiride** (N = 231)	**Placebo + Glimepiride** (N = 114)
Patient not able to self–treat	0.1 (0.003)	0	0
Patient able to self–treat	7.5 (0.38)	4.3 (0.12)	2.6 (0.17)
Not classified	0.9 (0.05)	0.9 (0.02)	0
Add-on to Metformin + Rosiglitazone	**Victoza® + Metformin + Rosiglitazone** (N = 355)	**None**	**Placebo + Metformin + Rosiglitazone** (N = 175)
Patient not able to self–treat	0	—	0
Patient able to self–treat	7.9 (0.49)	—	4.6 (0.15)
Not classified	0.6 (0.01)	—	1.1 (0.03)
Add-on to Metformin + Glimepiride	**Victoza® + Metformin + Glimepiride** (N = 230)	**Insulin glargine + Metformin + Glimepiride** (N = 232)	**Placebo + Metformin + Glimepiride** (N = 114)
Patient not able to self–treat	2.2 (0.06)	0	0
Patient able to self–treat	27.4 (1.16)	28.9 (1.29)	16.7 (0.95)
Not classified	0	1.7 (0.04)	0

In a pooled analysis of clinical trials, the incidence rate (per 1,000 patient-years) for malignant neoplasms (based on investigator-reported events, medical history, pathology reports, and surgical reports from both blinded and open-label study periods) was 10.9 for Victoza®, 6.3 for placebo, and 7.2 for active comparator. After excluding papillary thyroid carcinoma events *[see Adverse Reactions]*, no particular cancer cell type predominated. Seven malignant neoplasm events were reported beyond 1 year of exposure to study medication, six events among Victoza®-treated patients (4 colon, 1 prostate and 1 nasopharyngeal), no events with placebo and one event with active comparator (colon). Causality has not been established. **Laboratory Tests:** In the five clinical trials of at least 26 weeks duration, mildly elevated serum bilirubin concentrations (elevations to no more than twice the upper limit of the reference range) occurred in 4.0% of Victoza®-treated patients, 2.1% of placebo-treated patients and 3.5% of active-comparator-treated patients. This finding was not accompanied by abnormalities in other liver tests. The significance of this isolated finding is unknown. **Post-Marketing Experience:** The following additional adverse reactions have been reported during post-approval use of Victoza®. Because these events are reported voluntarily from a population of uncertain size, it is generally not possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Gastrointestinal: nausea, vomiting and diarrhea sometimes resulting in dehydration *[see Warnings and Precautions]*. Renal and Urinary Disorders: increased serum creatinine, acute renal failure or worsening of chronic renal failure, which may sometimes require hemodialysis *[see Warnings and Precautions]*.

OVERDOSAGE: In a clinical trial, one patient with type 2 diabetes experienced a single overdose of Victoza® 17.4 mg subcutaneous (10 times the maximum recommended dose). Effects of the overdose included severe nausea and vomiting requiring hospitalization. No hypoglycemia was reported. The patient recovered without complications. In the event of overdosage, appropriate supportive treatment should be initiated according to the patient's clinical signs and symptoms.

More detailed information is available upon request.

For information about Victoza® contact: Novo Nordisk Inc., 100 College Road West, Princeton, New Jersey 08540, 1–877-484-2869

Date of Issue: May 18, 2011 **Version: 3**

Manufactured by: Novo Nordisk A/S, DK-2880 Bagsvaerd, Denmark

novo nordisk®

VICTOZA®
liraglutide (rDNA origin) injection

Continued from page 12

and others, we will quickly move to a model that's more performance-based. And it will be performance-based in several realms—not just patient satisfaction and quality. It will be performance-based in terms of the cost of care, and how well individuals are helped to manage their illness. It is my anticipation that the physicians will be very able to begin to establish those metrics pretty quickly, once they have the information they need."

Some health care organizations are experimenting with their own transitional models of shared accountability, including partnerships with other health care organizations to pool their resources.

Broadening an Electronic Platform

In preparation for the 2013 launch, Inova and Aetna are currently working on putting new electronic systems in place. "Inova has invested a lot of time and effort in a new system called Epic, which is going to be the electronic platform for all of our clinical care," says Green. "It includes electronic medical records, financial and demographic information, and clinical information."

Inova intends to make the electronic platform available to all in-network physicians who want to be part of it. "The limits of the law require that physicians must pay for some of the operations and the hardware," says Green. "We intend to be able to offer physicians in Northern Virginia, through the network, the sort of support in the systems that is admissible by law. We can actually provide operational support for about 85%. That's a big help for physician practices."

Since many physicians already have their own electronic practice management systems in place, another goal of Inova's is to introduce an electronic platform that can integrate with physician members' existing systems. "For the past five months, on the information tech side, we've gone out to physicians in the community to understand what they use to operate," says Green. "That has been part of the network we're building, which is different and distinct from the health plan itself. The intention is that Aetna, which already has a broad-based national network, will continue to have a network in Northern Virginia. It will be Inova's role to develop a network alongside that, that has the capabilities to go further in terms of clinical integration—support for integration and data sharing."

One of Inova's roles in this partnership is to work with community physicians to establish a network that will spend more time analyzing and measuring patient satisfaction. As a stipulation of membership in Innovation Health Plans, physicians, hospitals, and other health care facilities must agree to continuous improvement in the patient experience, which will be objectively measured.

"We have an advisory council of physicians who are going to establish what those objectives should be, so it will not just be Inova that's involved in that," says Green. "Physicians will help drive that as well. It's evolving at this point." ■

—Reported and written by Stacy Clapp, in Orangeburg, N.Y.

Pressures, Opportunities Motivated Formation of ACO-Like Provider

Innovation Health Plans, a new health plan serving Northern Virginia, will begin rolling out on January 1, 2013. Jointly owned by Hartford, Conn.-based health benefits provider Aetna and Inova Health System, a not-for-profit health care system based in Falls Church, Va., the new organization will serve patients in Northern Virginia, including more than 1.1 million residents currently served by Inova. While Innovation Health Plans is not technically an ACO, it will hold its providers more accountable for the quality and costs associated with delivering care than a traditional fee-for-service provider.

"Our efforts started long before the [Patient Protection and Affordable Care Act] was actually a law, in response to pressures and opportunities," says Inova's Executive President of Health Services Kylanne Green. "Even in Northern Virginia, which is a very fortunate community, there were significant pressures associated with the escalation of cost and the toll that took, predominantly on employers and employees—working people. At the same time, there were new ways of thinking in the provider communities, including physicians, Inova, and payers, that allowed the opportunity [for us] to develop a new plan. Things needed to change, and we needed to work together differently."

"Health care costs are rising faster than any other segment of the economy," says Green. "While we have the potential to deliver great quality health care in the United States, there is fragmentation that prevents us from doing the things we should be able to do in the quality realm. That's been a challenge in Northern Virginia as much as it has been elsewhere. So, to the extent that we can, [we want to] use and share our information, establish common goals and agree to work toward them, and have platforms to assist us in doing that." —SC

CAPITAL IDEAS

Common CPA Advice on Asset Protection Can Leave Physicians Exposed

By David B. Mandell, JD, MBA, and Carole C. Foos, CPA

Many financial advisors are surprised when they realize how few physicians have gotten any advice or direction on asset protection from their certified public accountants (CPAs). Physicians should ask themselves whether their CPAs have helped them shield their assets from unnecessary exposure. Most likely they haven't.

Unfortunately, even when doctors do get asset protection advice from their accountants, that advice is often plain wrong. Common bad advice from CPAs ranges from "You don't need to worry about asset protection, you have insurance," to "Why create a professional corporation for protection? It's not worth the expense," to "Just put the assets in your spouse's name. That will protect you."

David Mandell, JD, MBA, is an attorney and principal of the financial consulting firm OJM Group (www.ojmgroup.com), where **Carole C. Foos, CPA** works as a tax consultant. They can be reached at 877-656-4362.

Going Beyond Insurance

While experienced financial advisors strongly advocate property and casualty (P&C) insurance as part of a physician's asset protection plan, an insurance policy is 50 pages long for a reason. There are a variety of exclusions in such plans that most doctors never take the time to read, let alone understand. This is true for personal policies—like homeowner's, car, and even umbrella insurance—as well as for business policies, the most important of which for physicians is medical malpractice insurance.

Even if a physician's policy does cover the risk in question, there are still risks of a malpractice claim going beyond coverage limits (malpractice judgments do periodically exceed traditional $1/3 million coverage), strict liability, and bankruptcy of the insurance company. In any of these cases, the practice could be left with the sole responsibility for the loss. Lastly, even if all of the practice's losses are within coverage limits, it may see its future premiums skyrocket.

For these reasons, it is unwise to rely solely on insurance for protection of a medical practice, especially when many asset protection techniques actually will save physicians taxes and help them build retirement wealth.

By choosing to use a "disregarded" status for a solely owned LLC, the doctor may also pay more taxes on his or her income every year than if he or she chose a different tax status.

Form a Professional Corporation

Many physicians over the years have followed their accountants' advice that they don't need to form a professional corporation (PC). The main justification for such advice seems to be the expense and the additional paperwork involved. It costs $1,000 or so to create a PC, which works out to a few hundred dollars per year, and a PC requires the filing of an additional tax return and the keeping of minutes and other legal documentation. It is troubling that physicians often follow this bad advice, while almost no other sophisticated businessperson would. It is unlikely that any other owner of a significant business would allow that business to operate in their own name.

When a physician fails to use a PC or other similar entity (PA, PLLC) to run a practice, he or she exposes all his or her personal wealth to any claim against the practice. While CPAs are quick to point out that a PC will not protect a doctor's assets from malpractice anyway, they ignore all liability risks created by employees that the physician might have nothing do with.

For example, an employee might be involved in a car accident when driving for the business; or a patient might slip and fall in the office, or be involved in a car accident in the parking lot. If implemented correctly, the PC would protect the physician's personal wealth against all of these potential liabilities and more. Without a PC in place, all of his or her personal wealth would be vulnerable.

For this kind of protection, the small cost and paperwork associated with forming a PC are worthwhile. In fact, most CPAs have such an entity in place, and nearly 100% of solo attorneys use one. Why is a PC not considered appropriate protection for small medical practices? Of course it is!

Avoid the 'Disregarded Entity'

Related to the mistaken advice that a physician should avoid using a PC is the more common misguidance for solo physicians to create a professional entity, but to choose to have the entity taxed as a "disregarded entity" by the IRS. A sole-owned corporation or LLC can elect not to be treated as a separate entity with its own employer identification number (EIN) but, instead, to be treated as a "disregarded entity" using the social security number of the sole owner (the physician). CPAs recommend this approach as a cost-saving measure, saving the cost of a simple tax return, perhaps $1,000 per year. But in using this strategy, the physician incurs the same risk as having no legal entity at all. A lawsuit against the practice could "pierce the corporate veil" and attack all of the doctor's personal assets, even if he or she was uninvolved in the activity that created liability.

Physicians often follow this bad advice, while almost no other sophisticated businessperson would. It is unlikely that any other owner of a significant business would allow that business to operate in their own name.

While subjecting all of the physician's personal assets to these types of risks to save $1,000 per year is bad enough, this advice is also detrimental from a tax perspective. By choosing to use a "disregarded" status for a solely owned LLC, the doctor may also pay more taxes on his or her income every year than if he or she chose a different tax status. Typically the "S" tax status would be preferable in such situations.

Thus, this bad advice is wrong on two levels, both in terms of asset protection and tax liability. Nevertheless, in the last six months, advisors at OJM Group have worked with two successful solo physicians who had been following their CPAs' advice to register their practices as disregarded entities. If physicians with over $1 million of annual income and significant net worth can get such poor advice from their advisors, anyone can.

In today's risky financial environment, asset protection should clearly be part of any physician's financial plan. It is unfortunate that so many doctors are often tripped up by poor advice from accountants. Physicians should be on guard for such poor advice and seek out advisors well versed in these matters to be part of their team and to work with their CPAs.■

Putting Assets in a Spouse's Name Can Leave Them Vulnerable

A common piece of bad advice CPAs give physicians about asset protection is that assets in a doctor's spouse's name cannot be touched. Financial advisors see many physicians who have put their assets in the name of the non-physician spouse and assume those assets are protected from lawsuits against the physician. To see how this legal interpretation is wrong, simply ask the following:

- Whose income was used to purchase the asset?
- Has the physician used the asset at any time?
- Does the physician have any control over the asset?
- Has the physician benefited from "the spouse's assets" in any way?

If the answer is "yes" to any of these questions, most courts will find that at least half of the value of the contested assets will be exposed to the claims against the doctor. In community property states, 100% of the value may be exposed, as a community asset.

Another good litmus test is for the physician to ask the CPA what he or she thinks will happen in the event of a divorce if the advice to put all the assets in the spouse's name is followed. He or she will likely say that the court would treat these assets as joint because the physician and spouse are still treating them as joint (living in the house, spending the accounts, paying the taxes). The court understands that the physician hasn't really given the assets to the spouse. Most likely this is the way the court would treat the assets for creditor purposes, as well.

—DBM, CCF

PRACTICE MANAGEMENT NEWS

Survey: Majority of Clinicians View Electronic Exchange of Health Information Positively

Survey results released October 3 reveal that 78% of responding clinicians believe the electronic exchange of health information will improve the quality of patient care and aid them in coordinating care, meeting the demands of new care models, and participating in third-party reporting and incentive programs. The American College of Physicians (ACP; www.acponline.org), the Bipartisan Policy Center, and Doctors Helping Doctors Transform Health Care analyzed 527 responses in the report "Clinician Perspectives on Electronic Health Information Sharing for Transitions of Care."

Challenges remain for the widespread electronic exchange of health information. More than 70% of clinicians surveyed identified lack of interoperability, lack of infrastructure, and the cost of setting up and maintaining interfaces and exchanges as major barriers preventing clinicians from exchanging information.

Additional findings include:

- Access to medication lists and laboratory and imaging test results are commonly recognized as high priorities for transitions of care.
- Timeliness of information is important.
- When updating the electronic health record (EHR) with information received from an external source, clinicians prefer to be able to choose the information they want integrated.

The survey was fielded by AmericanEHR Partners, founded by ACP and Cientis Technologies; the American Association of Medical Directors of Information Systems; the American College of Surgeons; and the American Academy of Pediatrics. Respondents are predominantly primary care providers in practice settings that include 10 physicians or less and who are EHR users.

NCQA Releases Updated Physician and Hospital Quality Certification Program

The National Committee for Quality Assurance (NCQA; www.ncqa.org) in September released the latest version of its Physician and Hospital Quality (PHQ) Certification program, which evaluates how well health plans and other organizations measure and report the quality and cost of physicians and hospitals. The new certification encourages greater participation from more organizations. It also provides more guidance to plans that create physician measurement programs based on cost and quality.

The updated standards and guidelines move the review process from the organization level to the program level. With this new approach, NCQA calls for organizations to be transparent about their cost and efficiency, even when small population sizes or lack of measures make it hard to gauge quality.

For more information about PHQ or to request an application, visit http://tinyurl.com/c2tq32b.

Survey Examines Physician Morale, Perspectives on State of U.S. Health Care

Patients are likely to experience increasing challenges in accessing care if current physician practice pattern trends continue, according to a survey of practicing physicians released in September. The research was commissioned by The Physicians Foundation (www.physiciansfoundation.org).

Physicians are working fewer hours, seeing fewer patients, and limiting access to their practices in light of changes to the medical practice environment, according to the report, "A Survey of America's Physicians: Practice Patterns and Perspectives." The report estimates that if these patterns continue, 44,250 full-time-equivalent physicians will be lost from the workforce in the next four years. Over the next one to three years, more than 50% of physicians will cut back on patients seen, work part-time, switch to concierge medicine, retire, or take other steps likely to reduce patient access, the report says.

Cited rising operating costs, time constraints and diminishing reimbursement, 52% of physicians have limited the access of Medicare patients or are planning to do so, while 26% have already closed their practices to Medicaid patients, the survey shows.

The survey, fielded online by Merritt Hawkins for The Physicians Foundation, is based on responses from 13,575 physicians across the United States. To access the full survey, which also examines issues of physician morale and physicians' opinions regarding health care cost drivers, visit http://tinyurl.com/cmfvfgm.

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