Reporting Requirements

Chapter FastFACTS

1. **Patient safety organizations look at errors in aggregate to find causes and recommend solutions.**
2. **Reporting requirements for most physician offices are not yet in place.**
3. **Meeting quality standards can pay off—literally—for you and your practice.**
4. **The Physician Quality Reporting Initiative discusses 131 individual quality measures.**
5. **Information and tools are available to help provide quality care from the AMA, ACP, and others.**

How much do you know about reporting requirements? A good place to update what you know is the Patient Safety and Quality Improvement Act of 2005. That act authorized the Agency for Healthcare Research and Quality (AHRQ) to spearhead the establishment of patient safety organizations (PSOs)—public or private organizations with expertise in analyzing patient safety and hazards in healthcare. The goal was for PSOs to be the repository of reporting errors in order to develop insights into the underlying causes of patient safety events. According to the AHRQ's Website, "Communications with PSOs are protected to allay fears of increased risk of liability because of collection and analysis of patient safety events."

The initiative is only now getting started because it took time

Indications and usage

Levemir® is indicated for once- or twice-daily subcutaneous administration for the treatment of adult and pediatric patients with type 1 diabetes mellitus or adult patients with type 2 diabetes mellitus who require basal (long-acting) insulin for the control of hyperglycemia.

Important safety information

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

Hypoglycemia is the most common adverse effect of all insulin therapies, including Levemir®. As with other insulins, the timing of hypoglycemic events may differ among various insulin preparations. Glucose monitoring is recommended for all patients with diabetes. Levemir® is not to be used in insulin infusion pumps. Any change of insulin dose should be made cautiously and only under medical supervision. Concomitant oral antidiabetes treatment may require adjustment.

Inadequate dosing or discontinuation of treatment may lead to hyperglycemia and, in patients with type 1 diabetes, diabetic ketoacidosis. Levemir® should not be diluted or mixed with any other insulin preparations. Insulin may cause sodium retention and edema, particularly if previously poor metabolic control is improved by intensified insulin therapy. Dose and timing of administration may need to be adjusted to reduce the risk of hypoglycemia in patients being switched to Levemir® from other intermediate or long-acting insulin preparations. The dose of Levemir® may need to be adjusted in patients with renal or hepatic impairment.

Other adverse events commonly associated with insulin therapy may include injection site reactions (on average, 3% to 4% of patients in clinical trials) such as lipodystrophy, redness, pain, itching, hives, swelling, and inflammation.

*Whether these observed differences represent true differences in the effects of Levemir®, NPH insulin, and insulin glargine is not known, since these trials were not blinded and the protocols (eg, diet and exercise instructions and monitoring) were not specifically directed at exploring hypotheses related to weight effects of the treatments compared. The clinical significance of the observed differences in weight has not been established.

For your patients with type 2 diabetes,

start once-daily Levemir®

Levemir® helps patients with diabetes achieve their A1C goal.[2,3]

- 24-hour action at a once-daily dose[4,5]
- Provides consistent insulin absorption and action, day after day[4,6,7]
- Less weight gain[8]*

To access complimentary e-learning programs, visit novomedlink.com/Levemir

References: 1. Data on file. Novo Nordisk Inc, Princeton, NJ. **2.** Meneghini LF, Rosenberg KH, Koenen C, Meriläinen MJ, Lüddeke H-J. Insulin detemir improves glycaemic control with less hypoglycaemia and no weight gain in patients with type 2 diabetes who were insulin naive or treated with NPH or insulin glargine: clinical practice experience from a German subgroup of the PREDICTIVE study. *Diabetes Obes Metab*. 2007;9(3):418-427. **3.** Hermansen K, Davies M, Derezinski T, Ravn GM, Clauson P, Home P, for the Levemir Treat-to-Target Study Group. A 26-week, randomized, parallel, treat-to-target trial comparing insulin detemir with NPH insulin as add-on therapy to oral glucose-lowering drugs in insulin-naive people with type 2 diabetes. *Diabetes Care*. 2006;29(6):1269-1274. **4.** Klein O, Lynge J, Endahl L, Damholt B, Nosek L, Heise T. Albumin-bound basal insulin analogues (insulin detemir and NN344): comparable time-action profiles but less variability than insulin glargine in type 2 diabetes. *Diabetes Obes Metab*. 2007;9(3):290-299. **5.** Philis-Tsimikas A, Charpentier G, Clauson P, Ravn GM, Roberts VL, Thorsteinsson B. Comparison of once-daily insulin detemir with NPH insulin added to a regimen of oral antidiabetic drugs in poorly controlled type 2 diabetes. *Clin Ther*. 2006;28(10):1569-1581. **6.** Danne T, Endahl L, Haahr H, et al. Lower within-subject variability in pharmacokinetic profiles of insulin detemir in comparison to insulin glargine in children and adolescents with type 1 diabetes. Presented at: 43rd Annual Meeting of the European Association for the Study of Diabetes; September 17-21, 2007; Amsterdam, Netherlands. Abstract 0189. **7.** Heise T, Nosek L, Rønn BB, et al. Lower within-subject variability of insulin detemir in comparison to NPH insulin and insulin glargine in people with type 1 diabetes. *Diabetes*. 2004;53(6):1614-1620. **8.** Data on file. NDA21-536. Novo Nordisk Inc, Princeton, NJ.

Please see brief summary of Prescribing Information on adjacent page.

135155-R1 November 2008

novo nordisk®

Levemir®

insulin detemir (rDNA origin) injection

Levemir®

insulin detemir (rDNA origin) injection

Rx ONLY
BRIEF SUMMARY. Please see package insert for prescribing information.

INDICATIONS AND USAGE
LEVEMIR is indicated for once- or twice-daily subcutaneous administration for the treatment of adult and pediatric patients with type 1 diabetes mellitus or adult patients with type 2 diabetes mellitus who require basal (long acting) insulin for the control of hyperglycemia.

CONTRAINDICATIONS
LEVEMIR is contraindicated in patients hypersensitive to insulin detemir or one of its excipients.

WARNINGS
Hypoglycemia is the most common adverse effect of insulin therapy, including LEVEMIR. As with all insulins, the timing of hypoglycemia may differ among various insulin formulations.

Glucose monitoring is recommended for all patients with diabetes.

LEVEMIR is not to be used in insulin infusion pumps.

Any change of insulin dose should be made cautiously and only under medical supervision. Changes in insulin strength, timing of dosing, manufacturer, type (e.g., regular, NPH, or insulin analogs), species (animal, human), or method of manufacture (rDNA versus animal-source insulin) may result in the need for a change in dosage. Concomitant oral antidiabetic treatment may need to be adjusted.

PRECAUTIONS
General
Inadequate dosing or discontinuation of treatment may lead to hyperglycemia and, in patients with type 1 diabetes, diabetic ketoacidosis. The first symptoms of hyperglycemia usually occur gradually over a period of hours or days. They include nausea, vomiting, drowsiness, flushed dry skin, dry mouth, increased urination, thirst and loss of appetite as well as acetone breath. Untreated hyperglycemic events are potentially fatal.

LEVEMIR is not intended for intravenous or intramuscular administration. The prolonged duration of activity of insulin detemir is dependent on injection into subcutaneous tissue. Intravenous administration of the usual subcutaneous dose could result in severe hypoglycemia. Absorption after intramuscular administration is both faster and more extensive than absorption after subcutaneous administration.

LEVEMIR should not be diluted or mixed with any other insulin preparations (see PRECAUTIONS, Mixing of Insulins).

Insulin may cause sodium retention and edema, particularly if previously poor metabolic control is improved by intensified insulin therapy.

Lipodystrophy and hypersensitivity are among potential clinical adverse effects associated with the use of all insulins.

As with all insulin preparations, the time course of LEVEMIR action may vary in different individuals or at different times in the same individual and is dependent on site of injection, blood supply, temperature, and physical activity.

Adjustment of dosage of any insulin may be necessary if patients change their physical activity or their usual meal plan.

Hypoglycemia
As with all insulin preparations, hypoglycemic reactions may be associated with the administration of LEVEMIR. Hypoglycemia is the most common adverse effect of insulins. Early warning symptoms of hypoglycemia may be different or less pronounced under certain conditions, such as long duration of diabetes, diabetic nerve disease, use of medications such as beta-blockers, or intensified diabetes control (see PRECAUTIONS, Drug Interactions).

Such situations may result in severe hypoglycemia (and, possibly, loss of consciousness) prior to patients' awareness of hypoglycemia.

The time of occurrence of hypoglycemia depends on the action profile of the insulins used and may, therefore, change when the treatment regimen or timing of dosing is changed. In patients being switched from other intermediate or long-acting insulin preparations to once- or twice-daily LEVEMIR, dosages can be prescribed on a unit-to-unit basis; however, as with all insulin preparations, dose and timing of administration may need to be adjusted to reduce the risk of hypoglycemia.

Renal Impairment
As with other insulins, the requirements for LEVEMIR may need to be adjusted in patients with renal impairment.

Hepatic Impairment
As with other insulins, the requirements for LEVEMIR may need to be adjusted in patients with hepatic impairment.

Injection Site and Allergic Reactions
As with any insulin therapy, lipodystrophy may occur at the injection site and delay insulin absorption. Other injection site reactions with insulin therapy may include redness, pain, itching, hives, swelling, and inflammation. Continuous rotation of the injection site within a given area may help to reduce or prevent these reactions. Reactions usually resolve in a few days to a few weeks. On rare occasions, injection site reactions may require discontinuation of LEVEMIR.

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.

Systemic allergy: Generalized allergy to insulin, which is less common but potentially more serious, may cause rash (including pruritus) over the whole body, shortness of breath, wheezing, reduction in blood pressure, rapid pulse, or sweating. Severe cases of generalized allergy, including anaphylactic reaction, may be life-threatening.

Intercurrent Conditions
Insulin requirements may be altered during intercurrent conditions such as illness, emotional disturbances, or other stresses.

Information for Patients
LEVEMIR must only be used if the solution appears clear and colorless with no visible particles. Patients should be informed about potential risks and advantages of LEVEMIR therapy, including the possible side effects. Patients should be offered continued education and advice on insulin therapies, injection technique, life-style management, regular glucose monitoring, periodic glycosylated hemoglobin testing, recognition and management of hypo- and hyperglycemia, adherence to meal planning, complications of insulin therapy, timing of dosage, instruction for use of injection devices and proper storage of insulin. Patients should be informed that frequent, patient-performed blood glucose measurements are needed to achieve effective glycemic control to avoid both hyperglycemia and hypoglycemia. Patients must be instructed on handling of special situations such as intercurrent conditions (illness, stress, or emotional disturbances), an inadequate or skipped insulin dose, inadvertent administration of an increased insulin dose, inadequate food intake, or skipped meals. Refer patients to the LEVEMIR "Patient Information" circular for additional information.

As with all patients who have diabetes, the ability to concentrate and/or react may be impaired as a result of hypoglycemia or hyperglycemia.

Patients with diabetes should be advised to inform their health care professional if they are pregnant or are contemplating pregnancy (see PRECAUTIONS, Pregnancy).

Laboratory Tests
As with all insulin therapy, the therapeutic response to LEVEMIR should be monitored by periodic blood glucose tests. Periodic measurement of HbA_{1c} is recommended for the monitoring of long-term glycemic control.

Drug Interactions
A number of substances affect glucose metabolism and may require insulin dose adjustment and particularly close monitoring.

The following are examples of substances that may reduce

the blood-glucose-lowering effect of insulin: corticosteroids, danazol, diuretics, sympathomimetic agents (e.g., epinephrine, albuterol, terbutaline), isoniazid, phenothiazine derivatives, somatropin, thyroid hormones, estrogens, progestogens (e.g., in oral contraceptives).

The following are examples of substances that may increase the blood-glucose-lowering effect of insulin and susceptibility to hypoglycemia: oral antidiabetic drugs, ACE inhibitors, disopyramide, fibrates, fluoxetine, MAO inhibitors, propoxyphene, salicylates, somatostatin analog (e.g., octreotide), and sulfonamide antibiotics.

Beta-blockers, clonidine, lithium salts, and alcohol may either potentiate or weaken the blood-glucose-lowering effect of insulin. Pentamidine may cause hypoglycemia, which may sometimes be followed by hyperglycemia. In addition, under the influence of sympatholytic medicinal products such as beta-blockers, clonidine, guanethidine, and reserpine, the signs of hypoglycemia may be reduced or absent.

The results of *in-vitro* and *in-vivo* protein binding studies demonstrate that there is no clinically relevant interaction between insulin detemir and fatty acids or other protein bound drugs.

Mixing of Insulins
If LEVEMIR is mixed with other insulin preparations, the profile of action of one or both individual components may change. Mixing LEVEMIR with insulin aspart, a rapid acting insulin analog, resulted in about 40% reduction in $AUC_{(0-2h)}$ and C_{max} for insulin aspart compared to separate injections when the ratio of insulin aspart to LEVEMIR was less than 50%.

LEVEMIR should NOT be mixed or diluted with any other insulin preparations.

Carcinogenicity, Mutagenicity, Impairment of Fertility
Standard 2-year carcinogenicity studies in animals have not been performed. Insulin detemir tested negative for genotoxic potential in the *in-vitro* reverse mutation study in bacteria, human peripheral blood lymphocyte chromosome aberration test, and the *in-vivo* mouse micronucleus test.

Pregnancy: Teratogenic Effects: Pregnancy Category C
In a fertility and embryonic development study, insulin detemir was administered to female rats before mating, during mating, and throughout pregnancy at doses up to 300 nmol/kg/day (3 times the recommended human dose, based on plasma Area Under the Curve (AUC) ratio). Doses of 150 and 300 nmol/kg/day produced numbers of litters with visceral anomalies. Doses up to 900 nmol/kg/day (approximately 135 times the recommended human dose based on AUC ratio) were given to rabbits during organogenesis. Drug-dose related increases in the incidence of fetuses with gall bladder abnormalities such as small, bilobed, bifurcated and missing gall bladders were observed at a dose of 900 nmol/kg/day. The rat and rabbit embryofetal development studies that included concurrent human insulin control groups indicated that insulin detemir and human insulin had similar effects regarding embryotoxicity and teratogenicity.

Nursing mothers
It is unknown whether LEVEMIR is excreted in significant amounts in human milk. For this reason, caution should be exercised when LEVEMIR is administered to a nursing mother. Patients with diabetes who are lactating may require adjustments in insulin dose, meal plan, or both.

Pediatric use
In a controlled clinical study, HbA_{1c} concentrations and rates of hypoglycemia were similar among patients treated with LEVEMIR and patients treated with NPH human insulin.

Geriatric use
Of the total number of subjects in intermediate and long-term clinical studies of LEVEMIR, 85 (type 1 studies) and 363 (type 2 studies) were 65 years and older. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. In elderly patients with diabetes, the initial dosing, dose increments, and maintenance dosage should be conservative to avoid hypoglycemic reactions. Hypoglycemia may be difficult to recognize in the elderly.

ADVERSE REACTIONS
Adverse events commonly associated with human insulin therapy include the following:

Body as Whole: allergic reactions (see PRECAUTIONS, Allergy).

Skin and Appendages: lipodystrophy, pruritus, rash. Mild injection site reactions occurred more frequently with LEVEMIR than with NPH human insulin and usually resolved in a few days to a few weeks (see PRECAUTIONS, Allergy).

Other:

Hypoglycemia: (see WARNINGS and PRECAUTIONS).

In trials of up to 6 months duration in patients with type 1 and type 2 diabetes, the incidence of severe hypoglycemia with LEVEMIR was comparable to the incidence with NPH, and, as expected, greater overall in patients with type 1 diabetes (Table 4).

Weight gain:
In trials of up to 6 months duration in patients with type 1 and type 2 diabetes, LEVEMIR was associated with somewhat less weight gain than NPH (Table 4). Whether these observed differences represent true differences in the effects of LEVEMIR and NPH insulin is not known, since these trials were not blinded and the protocols (e.g., diet and exercise instructions and monitoring) were not specifically directed at exploring hypotheses related to weight effects of the treatments compared. The clinical significance of the observed differences has not been established.

Table 4: Safety Information on Clinical Studies

			Weight (kg)		Hypoglycemia (events/subject/month)	
	Treatment	# of subjects	Baseline	End of treatment	Major*	Minor**
Type 1						
Study A	LEVEMIR	N=276	75.0	75.1	0.045	2.184
	NPH	N=133	75.7	76.4	0.035	3.063
Study C	LEVEMIR	N=492	76.5	76.3	0.029	2.397
	NPH	N=257	76.1	76.5	0.027	2.564
Study D	LEVEMIR	N=232	N/A	N/A	0.076	2.677
Pediatric	NPH	N=115	N/A	N/A	0.083	3.203
Type 2						
Study E	LEVEMIR	N=237	82.7	83.7	0.001	0.306
	NPH	N=239	82.4	85.2	0.006	0.595
Study F	LEVEMIR	N=195	81.8	82.3	0.003	0.193
	NPH	N=200	79.6	80.9	0.006	0.235

* Major = requires assistance of another individual because of neurologic impairment

** Minor = plasma glucose <56 mg/dl, subject able to deal with the episode him/herself

OVERDOSAGE
Hypoglycemia may occur as a result of an excess of insulin relative to food intake, energy expenditure, or both. Mild episodes of hypoglycemia usually can be treated with oral glucose. Adjustments in drug dosage, meal patterns, or exercise may be needed. More severe episodes with coma, seizure, or neurologic impairment may be treated with intramuscular/subcutaneous glucagon or concentrated intravenous glucose. After apparent clinical recovery from hypoglycemia, continued observation and additional carbohydrate intake may be necessary to avoid reoccurrence of hypoglycemia.

More detailed information is available on request.

Rx only

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to set all the pieces in place, Dr. Bagley says. Once the 2005 legislation created the mechanism, details had to be worked out about how PSOs would operate and what would be required of them. The AHRQ's "final rule" for PSOs was not published until November 21, 2008, and became effective only on January 19, 2009. (See the Federal Register legislation at *http://www.pso.ahrq.gov/regulations/2008-27475_pi-1.pdf*).

It also took time for individual organizations to set up their PSOs and to apply for AHRQ certification. Today there are 66 PSOs. The AHRQ updates the list weekly and posts it at *http://www.pso.ahrq.gov/listing/psoforms.htm*.

"The whole idea of the patient safety organization legislation," Dr. Bagley explains, "was [to create] a way to collect and systematically analyze errors." Having a central collection point for error data makes it possible to recognize patterns that might otherwise be overlooked. For example, if 50 separate individual physicians report the same error, but each reports only a single instance of that error, the problem causing that error might not be noticed. But in the new system, "even if it occurs infrequently, it begins to add up," he says.

PSOs can aggregate errors, see if there are any systematic causes, then recommend system solutions, Dr. Bagley says. That's more valuable than punishing one individual who made an error, he says.

Being able to report errors without risk offers some protection for physicians. Although there is no guarantee that physicians will not be sued for causing harm to a patient, the patient safety database cannot be used to discover errors, Dr. Bagley explains. In other words, Dr. Jones may be sued by Mrs. Smith if he gave Mrs. Smith the wrong vaccine; but Mrs. Smith's attorney cannot use the database "for discovery," to find out whether Dr. Jones has given other patients polio vaccine when they were supposed to get a tetanus shot. Dr. Jones's practice may have reported a dozen or more similar errors, but the database information would not be available to Mrs. Smith's attorney.

By having errors reported this way, PSOs can aggregate the

errors, see if there are any systematic causes, then recommend system solutions, Dr. Bagley says. That's more valuable than punishing one individual who made an error, he says. It's similar, he adds, to how the aviation industry improved its quality when the Federal Aviation Administration instituted a voluntary aviation safety reporting program. That happened in 1975 and was then broadened in 1976 by including the National Aeronautics and Space Administration, which designed and administrates the Aviation Safety Reporting System (ASRS). "They had a long history of pilots reporting near-misses or errors that didn't cause any trouble," he says, "but were clearly putting the system, the plane, and the people in jeopardy. Only by analyzing or collating the hundreds of reports can you learn what you need to learn to make the system more reliable. (For more on the ASRS see *http://asrs.arc.nasa.gov/overview/immunity.html#20*.)

So far, many programs are focusing on hospitals and large organizations rather than on private practices and small facilities. It's all so new that "there haven't been a lot of products [developed that are] very useable in the small practice," Dr. Bagley explains. The organizational structures designed for large settings are not as useful for small practices. For example, Dr. Bagley notes, in a small organization, one person may be both the "quality officer" and the "safety officer."

No doubt there will be more small practice applications someday; but until then, small practices can get a head start by looking at programs designed for large facilities and adapting components applicable to their own needs.

Or they can look into patient safety programs that reach out to physician offices. For example, the NPSF's Stand Up For Patient Safety is an organizational membership program that delivers "tools, information, and resources designed to support the implementation and ongoing management of patient safety initiatives in settings ranging from large healthcare systems to small community hospitals, from physician offices to ambulatory care centers," Ms. Pinakiewicz explains. Stand Up for Patient Safety, launched in 2002, has grown to include more

than 400 healthcare organizations. For more information, see *http://www.npsf.org/hp/su/*.

Reporting and Regulation

At this point, the Patient Safety Act and PSO reporting requirements are aimed mainly at hospitals and inpatient facilities and vary state by state, Ms. Pinakiewicz says. Regulations for the ambulatory care setting are still ahead and will face greater challenges because of their size, number of contacts, and smaller infrastructures, she says.

"I can't tell you at this particular point where any given state is [in addressing] the ambulatory sector, but it is a direction in which everybody needs to move," she says. "It's all part of the process of being open and transparent."

Many physicians are already informally engaged in performance measurement and quality reporting by using the data they report in health plan claims to track their practice's performance, quality, and errors. It's not a matter of being compliant or noncompliant with reporting requirements because "there really is no requirement" for many private practice physicians who aren't participating in a PSO, Dr. Letourneau says. These doctors are simply submitting their normal claims, then gathering their performance data from those claims for their own use.

Dr. Letourneau adds that, in Maine, "We've actually taken a somewhat different tack, which is to ask practices to voluntarily submit clinical data [as well as claims data], which only they can generate." That means those physicians don't merely send in data reporting that the practice saw a patient with diabetes and submitted a claim for it. Instead, they'll add more detail, such as this: "I am tracking diabetic patients through my clinical information system, which is an EMR or a disease registry. Now I can tell you that I have 100 patients with diabetes; and of those X% who were seen in the past year, X% were tested in accordance with evidence-based guidelines such as hemoglobin A1C testing, or had a foot or eye exam.

"That's a whole different level of data from what you can get out of claims data," Dr. Letourneau says. Often providers in her state feel that this type of report more accurately reflects their performance.

How You Can Recognize a PSO

How can you tell whether a patient safety organization (PSO) has passed the Agency for Healthcare Research and Quality's (AHRQ) rules? PSOs that have been accepted by the Secretary of Health and Human Services are listed in AHRQ's directories and have met the requirements of Section 3.104(a) of the Patient Safety Rule. Only these PSOs are authorized to use the "Listed PSO" logo shown here.

Although practices in general clearly need to exert more effort in this system, Dr. Letourneau has found that many in Maine are willing to do so. In fact, about half of the primary care practices in the state voluntarily participate in that clinical reporting. Although participants may be eligible for some modest pay-for-performance rewards from payers and employers, she believes the real motivation is a desire to see how they are doing and to use that data for improvement.

Participating physicians may use EMRs, which make it easier to capture this type of data. Although they will have to create reports, which can be cumbersome, eventually the reports become part of the workflow, she says. Given the current incentives to adopt electronic records, more practices may be able to do this type of performance measurement and public reporting.

For now, those without EMRs are using paper records and chronic disease registries, which can take time: After the patient's visit, somebody has to capture the three, four, five, or six data points about the patient visit so that they can be used in a report.

Once medicine has its own confidential error-reporting system like the one the aviation industry has set up, Ms. Pinakiewicz thinks physicians will feel comfortable reporting instances of

errors or suboptimal performance that could have led to an error. That will make it easier to create repositories of data and to look for trends across the system, then bring them to light, she says. "Everybody needs to know [if there's a negative finding] and you need to focus on changing it," just as the aviation industry did, she says.

Physicians can now go to the Stand Up program for ambulatory settings and see if they want to apply its features to their own practice. (For more information, see *http://npsf.org/hp/su/Ambulatory.php*.) Those who join NPSF get a five-book resource guide that talks about the competencies of patient safety work, ways to set up a safety culture in your practice, and what the issues are with leadership and accountability. This information can dramatically change how practices work, shifting them from focusing on improved productivity and maximal use of time to new goals that are quality- and patient-oriented.

The discussion of national healthcare reform shows increasing emphasis on understanding the need to hold healthcare providers—both hospitals and physicians—accountable for outcomes of care, Dr. Letourneau says. That means physicians will likely see a higher level of regulation, particularly concerning Medicare funding and accountability for outcome. There's also likely to be greater expectations of upfront contracting or payment expectations, she says.

Because it's still early in the process, Dr. Letourneau is using the terms "patient safety" and "quality" somewhat interchangeably. In the inpatient world, "patient safety" is commonly used and encompasses such issues as avoidable errors, healthcare-acquired infections, and medication safety, she says. "In the ambulatory world, the focus has been more on improving quality," she says.

For a snapshot of what's in place and sources for more information, see "Where to Find the Latest Reporting Requirements," opposite.

Quality Reporting

In addition to all the obvious benefits of improving quality and reporting results, quality improvements can generate financial rewards. For example, physicians and other healthcare pro-

Where to Find the Latest Reporting Requirements

- **The Center for Medicare & Medicaid Services** is a main source of information on reporting requirements and incentives.
  Start here:
  http://www.cms.hhs.gov/, the home page. Then go to the Physician Quality Reporting Initiative (PQRI) at *http://www.cms.hhs.gov/pqri/.*
- The **American College of Physicians** Website offers presentations, information, and reporting resources for Medicare's 2009 PQRI pay-for-reporting program. Go to the practice management center's section for information on the physician quality reporting initiative. Physicians can check the list of qualified registries such as the American Board of Family Medicine, Inc., the American Osteopathic Association, Lehigh Valley Physician Group Patient Registry, and others to see if they're already members of a reporting organization.
  Start here:
  http://www.acponline.org/running_practice/practice_management/payment_coding/pqri.htm.
- The **Agency for Healthcare Research and Quality** is the hub for patient safety organizations (PSOs). The site includes a listing of all PSOs, information about the PSO listing process, a network of patient safety databases, legislation, regulations, PSO contacts, and related information.
  Start here:
  The PSO home page: *http://www.pso.ahrq.gov/.*
- The **National Patient Safety Foundation** (NPSF) offers a selection of resources and tools to help physician offices and healthcare systems of various sizes with implementation and management of patient safety initiatives. Its Stand Up for Patient Safety section focuses on the needs of ambulatory care providers.
  Start here:
  The NPSF home page is at *http://www.npsf.org.*

fessionals in a given practice may be eligible to participate in the Physician Quality Reporting Initiative (PQRI) from the Center for Medicare and Medicaid Services (CMS). Since the CMS implemented the PQRI in 2007, physicians who satisfactorily report data on quality measures for covered services provided to Medicare beneficiaries have been eligible for incentive payments. The incentive bonus, which started in 2007 at 1.5% of

total charges for professional services covered by the physician fee schedule provided during the calendar year, increased to 2.0% in 2009. Incentive payments have been authorized through 2010. For information on using "patient identifiers," which is required for PQRI reporting, see "Keeping Track of Unique Patient Care Incidents," opposite.

Those eligible to participate are the following:

Medicare physicians

- Doctor of Medicine
- Doctor of Osteopathy
- Doctor of Podiatric Medicine
- Doctor of Optometry
- Doctor of Oral Surgery
- Doctor of Dental Medicine
- Doctor of Chiropractic

Practitioners

- Physician Assistant
- Nurse Practitioner
- Clinical Nurse Specialist
- Certified Registered Nurse Anesthetist (and Anesthesiologist Assistant)
- Certified Nurse Midwife
- Clinical Social Worker
- Clinical Psychologist
- Registered Dietician
- Nutrition Professional
- Audiologist (as of 1/1/2009)

Therapists

- Physical Therapist
- Occupational Therapist
- Qualified Speech-Language Therapist (as of 7/1/2009)

A total of 153 quality measures were selected for the 2009 PQRI. Details about the measures, including codes and reporting instructions for claims or registry-based reporting and information about the 31 quality measures that require two or more quality data codes, are available for download from the CMS Website. (See *http://www.cms.hhs.gov/PQRI/15_MeasuresCodes.asp#TopOfPage*.)

The 2009 PQRI data collection worksheets are available from

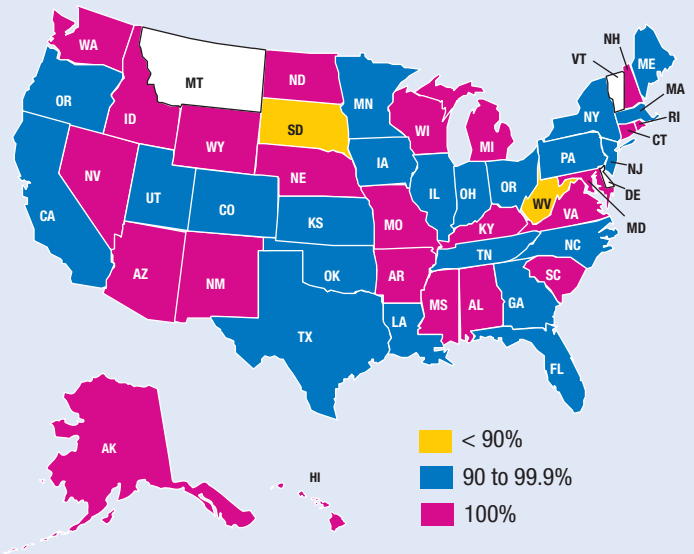
Keeping Track of Unique Patient Care Incidents

A "patient identifier" is a number used to track unique patient care incidents when reporting healthcare data to quality improvement (QI) and similar healthcare databases. It is a way of identifying how many unique incidents of X were treated with X during X period of time. In a retail store, the identifier would be the equivalent of a barcode or radio-frequency identification (RFID) tag located in or on the merchandise that tells the company and the store where that specific item is at all times (although this patient identifier does not transmit information as RFID tags do).

In healthcare, this unique number is necessary to track incidences of care in reporting databases. The Joint Commission requires patient identifiers on hospital reports; but they're used in many other quality-based databases, too. For more information on patient identifiers, go to *http://manual.jointcommission.org.*

Two Patient Identifiers: 2007 State Rates*

The percentage of hospitals that met the Joint Commission's National Patient Safety Goal of improving the accuracy of patient identification by using at least two identifiers when providing care, treatment, or services.



*1,466 hospitals underwent onsite surveys during 2007. Delaware, Montana, and Vermont did not have enough surveys in 2007 to make state comparisons useful.

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the American Medical Association (AMA). (Click the link at the bottom of the PQRI Website). The worksheets walk the physician (or a staff person designated to manage PQRI for the practice) through the process by helping him or her to identify patients for whom PQRI measures and codes apply, to capture clinical information that will be translated into the claims process, and to integrate the measures into the practice. The dual goal is to track reporting and improve quality.

PQRI also discusses the 131 individual quality measures that are now eligible for claims-based reporting, including acute bronchitis, pain assessment, asthma, various cancers, chest pain, chronic kidney disease, chronic obstructive pulmonary disease, diabetes mellitus, eye care, heart failure, medication management, and osteoarthritis.

The AMA's physician resources site also provides information on the six measures groups that are eligible for 2009 PQRI claims-based reporting:

- back pain
- chronic kidney disease
- diabetes mellitus
- perioperative care
- preventive care and screening
- rheumatoid arthritis

Each topic includes the group description and a PDF data collection sheet. It also specifies required criteria, such as the patient's age and gender, and a sample of reporting methods and codes that might be used for patients in that group, such as #39: osteoporosis screening or therapy for women 65 and older; #114: tobacco use inquiry; and #115: advising smokers to quit. The companion data collection sheet lets users check reporting requirements, eligibility, and individual measures; reporting instructions are included at the end of the form.

The AMA also provides the Physician Consortium for Performance Improvement (PCPI), whose goal is to enhance quality of care and patient safety by developing evidence-based clinical performance measures and measurement resources for physicians. PCPI consists of more than 100 medical specialty societies and state medical societies, including AHRQ and CMS, as well as individual members. (Applications for membership

are available on the Website at *http://www.ama-assn.org/ama/pub/physician-resources/clinical-practice-improvement/clinical-quality/physician-consortium-performance-improvement.shtml*.)

Another helpful resource for physicians is QualityNet (*www.qualitynet.org*), a site established by the CMS "to provide healthcare quality improvement news, resources and data reporting tools, and applications used by healthcare providers and others." The help desk is open from 7 a.m. to 7 p.m. Monday through Friday by phone and fax (both toll-free) or e-mail. The site includes a directory listing quality improvement organizations by state. QualityNet is the only CMS-approved site for secure communications and healthcare quality data exchange among quality improvement organizations, hospitals, physician offices, nursing homes, end-stage renal disease networks and facilities, and data vendors. Private practice doctors who want to access their PQRI feedback reports can use this site (click the "Physician Offices" tab) to register for authorized access to the CMS computer services account. The goals of this physician-focused quality initiative are listed in "The CMS Connection to Physician Quality Care," below.

To help physicians master the complexities of PQRI, ACP has devoted a section of its Practice Management Center Website to the 2009 PQRI program. (See *http://www.acponline.org/ running_practice/practice_management/payment_coding/pqri.htm*.)

The CMS Connection to Physician Quality Care

Building on its ongoing strategies and programs in other healthcare settings, the Centers for Medicare & Medicaid Services (CMS) established the Physician Focused Quality Initiative in order to

1. **Assess** the quality of care for key illnesses and clinical conditions that affect many people with Medicare
2. **Support** clinicians in providing appropriate treatment of the conditions identified
3. **Prevent** health problems that are avoidable
4. **Investigate** the concept of payment for performance

For more information go to *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1187820137434*.