Understanding New Incentives

Chapter FastFACTS

1. **The stimulus package offers Medicare incentives for qualifying practices with electronic health records—up to $44,000 over five years.**
2. **Adopting e-prescribing can result in a 2% bonus in Medicare payments in 2009 and 2010.**
3. **There will be a penalty for not participating in e-prescribing as of 2012.**
4. **The stimulus package made some important changes to HIPAA that affect your practice.**
5. **Making changes to Medicare and the way physicians are paid is key to healthcare reform.**

If the recession has a silver lining, it may be that magnifying the problems with today's healthcare system has provided an impetus for change. The stimulus package is one opportunity—aside from full-fledged reform attempts still being discussed—to address some of the problems.

President Obama signed the American Recovery and Reinvestment Act (ARRA) into law on February 17, 2009 (*www.recovery.gov*). The ARRA provides $787 billion in new spending and $30 billion for health information technology (HIT). Some healthcare providers, including community health centers, are already feeling the impact of these dollars (see "The Stimulus Plan in Action: One Example," p. 28). This chapter will discuss the potential impact ARRA and health reform may have on your practice.

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.

novo nordisk®

Please see brief summary of Prescribing Information on adjacent page.

 135155-R1 November 2008

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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Manufactured by Novo Nordisk A/S, 2880 Bagsvaerd, Denmark

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The Stimulus Plan in Action: One Example

The stimulus package is already finding a way to make a difference in primary care. Here's an example of how it works.

In Illinois, the Lake County Health Department received three federal stimulus grants this year through ARRA for its community health centers.

The first stimulus grant, awarded in March, provides $1.3 million over two years and will be used to provide primary care services at a community health center scheduled to open in the spring of 2010. The new health center will offer medical, dental, and mental health services and alleviate long lines at the other health center in the community. The grand funding enabled the health department to hire new staff, including a family practice physician, psychiatrists, a dentist, dental assistants, and clinical support staff. The new community health center is projected to serve 2,885 patients in the first year of operation. Other health department programs, including behavioral health and community health, will also be housed in the new 85,000-square-foot building.

The second grant of $647,998, awarded in March, was used to respond to an increased demand for primary care services due to the recession. The funding was used to hire 11 full-time staff members to respond to calls, accommodate more patients, and extend operating hours at one community health center. The new staff members include a physician, a mid-level provider, two clinical support staff persons, four intake clerks, one medical records staff person, one laboratory support person, and one biller. The two-year grant is specifically geared to increase access to healthcare for the "new" poor and for those who would not have accessed services because they were employed and had health insurance. Charges for services are based on patient income.

A third grant of $1,715,440, awarded in July, is being used to expand another health center, including adding exam rooms and one dental operator, the Women, Infants, and Children program, behavioral health, and nutrition counseling to continue serving the increasing need. Funds were also used to purchase a new telephone system to support a call center for the community health center system.

"We are very thankful for these federal stimulus grants," said Irwene T. Pierce, MSN, executive director of the Lake County Health Department/Community Health Center. "Increasing access to healthcare is a major priority for us, especially during this downturn in the economy. These grants are helping us serve more underserved residents of Lake County with high-quality services."

The Effect on Medicare and Medicaid

A majority of the Medicare incentives in the stimulus package for medical practices are for electronic health records (EHRs). Here's how they work. Physicians who use EHRs that meet ARRA requirements in 2011 or 2012 can receive up to 75% of allowable charges, with a maximum of $44,000 over five years. Physicians who practice in "health professional shortage areas" can receive a 10% additional payment.

In order to qualify for Medicare incentives, your medical practice must be a "meaningful" EHR user, meaning that your physicians use electronic prescribing (e-prescribing), report clinical quality measures, and demonstrate information exchange. As of press time it had not yet been determined whether practices report in 2010 for their first payment in 2011, or report in 2011 for their first payment in 2012 (see *http://www5.mgma.com/ecom/Default.aspx?tabid=188&action=ECDProductDetails&args=4716*).

Medicaid EHR incentives are stricter. Physicians, dentists, certified nurse midwives, nurse practitioners, and physician assistants can receive the same benefit, but they must be non-hospital-based professionals in practices with Medicaid patient volume of at least 30%. Non-hospital-based pediatricians with Medicaid patient volume of at least 20% are eligible as well as rural health clinics and federally qualified health centers in which 30% of their patient volume consists of those who receive Medicaid, SCHIP, reduced charges (by a provider on a sliding scale), or uncompensated medical care. States can make payments to Medicaid providers totaling no more than 85% of net average allowable costs for certified EHR technology.

The job of defining what criteria make a technology "certified" has been given to the secretary of Health & Human Services (HHS). Depending on what eventually falls into that category, physicians may find that their previously certified EHR

technology does not qualify for this incentive. In addition, certification issues that may affect you have not been finalized for the incentive program.

E-prescribing and PQRI Incentives

There are other potential boosts for Medicare payments under the recovery act through legislation called the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008. To be eligible your practice will have to electronically submit a certain number (yet to be determined) of prescriptions under Part D during the reporting period or report the applicable e-prescribing quality measure in at least half of the cases in which the measure is reportable by the eligible professional during the reporting year. Practices that accept stimulus incentives in 2011 are not eligible for these e-prescribing initiatives.

Eligible practitioners who adopt e-prescribing will receive a 2% bonus from Medicare in 2009 and 2010. In 2011 and 2012, the bonus will drop to 1%; in 2013, it will drop to .5%.

A bonus will be paid if the estimated allowed Medicare Part B charges from the e-prescribing measure codes are at least 10% of the total Medicare Part B allowed charges on at least half of all applicable cases. However, all covered professional services furnished between January 1, 2009, and December 31, 2009, must be submitted no later than February 28, 2010. In addition, a group practice reporting option targeting high-cost patients and those with chronic conditions is to be developed by 2010.

Be aware that there's a penalty for not participating: Those who do not e-prescribe receive a 1% penalty in 2012, 1.5% in 2013, and 2% in 2014 and beyond.

If you have both Medicare and Medicaid patients and are e-prescribing, you can get paid only once. The HHS secretary is required to ensure that the Medicare and Medicaid incentive payments to healthcare providers are coordinated to prevent duplicate funding.

"The Centers for Medicare & Medicaid Services (CMS) and other governmental agencies have been directed before to implement programs, and they always comply—eventually," Mr. La Penna says. "The regulations must be defined and the processes readied in order to implement; and the physician prac-

tice can probably determine the implications of these bills, but actual timing is yet TBD [to be determined]."

Changes in Technology

The Certification Commission for Health Information Technology (CCHIT) will most likely be chosen to certify that an EHR is qualified under ARRA. Again, you will need to wait until 2011 to apply for incentive payments; but you can earn incentives now from CMS for using e-prescribing, and earn bonuses under the Medicare Physician Quality Reporting Initiative (PQRI). See "It's Not Too Late for PQRI Participation," below.

It's not certain whether the stimulus package will require the federal government to produce a "free" EHR. "As far as I know, there is no laboratory or test site or designated vendor that is developing 'soon-to-be-free' software for an EMR rollout," Mr. La Penna says. However, he notes that consumers are working with Google and Microsoft to allow for free storage of EMR-related data. "These are the initiatives to watch. They are con-

It's Not Too Late for PQRI Participation

The PQRI is Medicare's effort to link physicians' payments to quality. If you haven't already tapped into the program in which you can earn a 2% bonus, based on total allowed charges, you still can. Just select the quality measures applicable to your patient panels and submit the designated quality data codes on claims for services paid under the Medicare physician fee schedule between January 1 and December 31, 2009. There are 153 quality measures and seven measures groups in the 2009 PQRI program. For a complete list, check *www.cms.hhs.gov/pqri.*

PQRI program reporting is claims based. CPT Category II codes (or temporary G-codes where CPT II codes are not available) are used for reporting quality measure data. To be eligible for the bonus payment, you must report on a minimum of three quality measures for at least 80% of the cases in which the measure was reportable. If it is determined that reporting occurred less than 80% of the time for any one of the selected measures, you would be ineligible for the bonus.

Review the quality measures to see which are applicable to your practice. Review your total Medicare claims submitted between January 1 and December 31, 2009, and multiply by 2% in order to accurately estimate your potential bonus.

sumer driven; and they will be free, just as commercial TV is free, with ads. No one really knows the future of where this might take medical information," he explains.

In general, though, EMR systems are becoming more user friendly and customizable so that they can be more easily implemented, notes Bill Bristow, partner, DoctorsManagement, Knoxville Tenn. "For most practices, it has not been a question of 'if' they were going to implement a system but rather when and which system they would install," he says.

The stimulus package stipulates that the HIT national coordinator will support developing and updating a publicly available EHR unless the HHS secretary determines that the marketplace is already meeting providers' needs.

"ARRA sets out a lot of money for practices to adopt health information practices and initiation projects. The industry is still in its infancy," explains Robert M. Tennant, senior policy adviser, MGMA, Washington, D.C. He says the Office of the National Coordinator for Health Information Technology (ONCHIT) will coordinate grants and loans to healthcare providers.

ARRA's concept is that physicians will exchange clinical data in order to create a health information exchange (HIE), according to Mr. Tennant. An HIE is a way to share health information electronically within a hospital system, region, or community to expedite access to clinical data and retrieval in order to provide better patient care. But theory differs from practice. Every HIE appears to be driven on a different model. "Very few HIEs are actively sharing clinical data, and very few have a stable clinical model. . . .It would be better to develop HIEs in a standardized way to facilitate the data exchange," he adds. (See "Health Information Data Currently Exchanged," opposite.)

The key to helping a particular practice succeed with the program may be at the state level. While ARRA will reimburse HIT providers for using technology, state grants will provide physicians with cash up front, which will help them acquire technology needed to implement HIT and HIEs. Technical assistance will be offered to healthcare providers through entities termed "Regional Extension Centers." For updates on this issue see the ONCHIT Website, *http://www.hhs.gov/recovery/reports/plans/onc_hit.pdf*.

Health Information Data Currently Exchanged

	2008	2009	Change (+/-)
Laboratory	26	49	+23
Medication data (including outpatient prescriptions)	n/a	48	n/a
Outpatient laboratory results	25	45	+20
Outpatient episodes	23	43	+20
Radiology results	23	39	+16
Emergency department episodes	27	36	+9
Inpatient diagnoses and procedures	27	35	+8
Care summaries	n/a	34	n/a
Inpatient discharge summaries	n/a	32	n/a
Pathology	18	32	+14
Dictation/transcription	20	31	+11
Cardiology	15	27	+12
Claims: pharmacy, medical, and/or hospital	n/a	27	n/a
Enrollment/eligibility	17	25	+8
Pulmonary	13	23	+10

Source: Reprinted with permission from eHealth Initiative. The full report of "Migrating toward meaningful use: the state of health information exchange" based on the results of the eHealth Initiative's 2009 sixth annual survey of health information exchange is available at http://www. ehealthinitiative.org/sites/default/files/file/2009%20Survey%20Report% 20FINAL .pdf.

"This will be different from state to state," Mr. La Penna says. "Some doctors will be impacted immediately with others seeing less impact or none at all for a long time as their particular state works out the details within their own infrastructure."

The stimulus money, while increasing EHR's appeal, may not be the key reason experts say the technology is ready for general use. According to a survey by IVANS, Inc., a healthcare connectivity provider, one-half of providers surveyed said that they plan to implement an EHR, not to save money or get stimulus money, but because they believe it will improve medicine.

Changes to HIPAA

The president's economic stimulus package also made numerous changes to the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those changes affect electronic and paper records that contain patient-identifiable health information (PHI). Details will be determined later through the federal regulatory process.

According to the MGMA, these changes require medical practices to do the following:

- Stop using identifiable patient data for some healthcare operations.
- Use de-identified patient data or disclose only the minimum data possible to conduct administrative transactions.
- Provide patients with a copy of their EHR record on a CD, Website, or other electronic medium.
- Notify each patient whose PHI has been disclosed due to a breach by letter within 60 days; and if more than 500 patients are involved, notify local media and HHS.
- Account for certain protected health information disclosures if the covered entity uses EHR (practices using EHR are required to track all treatment, payment, and healthcare operation disclosures).
- Follow patient direction to restrict disclosures to health plans if the patient has paid his/her premium in full.
- Apply HIPAA requirements and penalties to business associates and others, and apply certain provisions to vendors of personal health records and HIEs.

In order to keep up with all types of changes from the incentive plan as well as HIPAA and others, physicians or staff members should ask patients for their insurance information when scheduling appointments, check patient insurance cards and information at every visit, and question patients about employer status and any changes in status.

Protecting Electronic Health Data

The ARRA requires physician offices and other HIPAA-covered entities to notify all affected individuals when there's a breach of information that is not secured through technology or methodology as specified by HHS. This guidance relates to

HIPAA because it provides the means by which physicians, clinics, and hospitals can determine whether a breach has occurred, and which notification obligations under MIPPA and its regulations apply.

Last July, HHS secretary Kathleen Sebelius gave authority to the Office of Civil Rights (OCR), which administers and enforces HIPAA, to do the same for the Security Standards for the Protection of Electronic Protected Health Information. The theory is that having one agency within HHS enforcing both rules will eliminate duplication and increase the efficiency of investigations and resolutions of failures to comply.

According to HHS, transitioning authority for the administration and enforcement of the security rule won't interrupt the management or processing of any complaints filed prior to the transition. Consumers may continue to submit HIPAA security complaints using the administrative simplification enforcement tool (ASET), found at *https:htct.hhs.gov/aset*. New security complaints may also be sent to the OCR (*http://www.hhs.gov/ocr/privacy/hipaa/complaints/*). CMS retains its enforcement authority for complaints about transactions and code sets or how unique identifiers are filed or processed.

"This means that a practice, independent of any stimulus or grant program, will have to comply with a set of regulations that will be enforced by independent agencies. The need for security is being tightened, and some of these regulations support consumer standards that have been undefined," Mr. La Penna explains. "If there is an existing EMR or EHR [system], the implication is to see if the vendor is qualified under these new guidelines and standards to comply and assist the practice in its own compliance."

Beyond Stimulus: Healthcare Reform

As the details of the stimulus package as well as other efforts to change the current system (see "Other Changes Already Underway," p.37) play out, experts say it may be up to large-

scale healthcare reform to make a real difference. That reform, they say, can not only address some of the effects of the recession on patients and the healthcare system, but also prepare physicians for post-recession practice.

"The few cents being spent on primary care [in the stimulus package] are not going to be enough to turn primary care around," Mr. La Penna says. "One thing that is positive is that the money being put into the stimulus plan will save on healthcare costs by covering the uninsured and underinsured. This may have an indirect positive impact for physicians. Medicare will be used as a tool to shift payments from specialty to primary care, while Medicaid will be augmented by a new healthcare program format."

The best hip replacement surgery is reimbursed at the same rate as the worst job for the same procedure, Mr. Bristow notes. "Consequently, under the present system, the only way to

Other Changes Already Underway

In a move separate from the stimulus plan but likely to have a positive effect on primary care physicians seeking a foothold during this recession, the Centers for Medicare and Medicaid Services last summer announced a reimbursement redistribution from specialists to primary care physicians. The redistribution amounts to a nearly 8% increase for primary care physicians and a double-digit decrease for some specialties.

The playing field could level further. CMS would like to adjust the practice expense relative value units (PE RVUs), which provide reimbursement for the equipment, office supplies, and building space used for physician services. CMS thinks it has overpaid physicians who own imaging equipment by underestimating how often physicians use the equipment. The current reimbursement formula assumes a 50% utilization rate (25 hours out of a 50-hour work week). Cardiology, radiology, nuclear medicine, and radiation oncology specialists will be hardest hit by this change in the Medicare fee schedule.

Medicare is also conducting demonstration projects, such as the patient-centered medical home, that could create incentives for work that has not been rewarded in the past, such as care coordination, according to J. James Rohack, MD, president of AMA. Last summer the AMA passed policy to support the patient-centered medical home model as a way to provide care to patients, without restricting access to specialty care.

increase revenue or income is to 'do more' and not necessarily to 'do better.' How quality is to be measured becomes the unknown and subjective and, in my experience, becomes the loophole for the unscrupulous," he states.

At press time, healthcare legislation plans were taking shape in Congress. Because of the fluid nature of the healthcare reform process, please check the Library of Congress site at *http://thomas.loc.gov* and the Kaiser Family Foundation's health reform page at *http://healthreform.kff.org/*. These bills address issues such as requiring most or all individuals to have "acceptable health coverage" or else pay a penalty; mandating that healthcare insurance can't be canceled or denied for a prior illness; expanding Medicaid; creating healthcare insurance standards; increasing Medicare payments to physicians; and establishing state-based purchasing pools.

The American Medical Association (AMA) is throwing its political weight behind the reform effort, saying that certain ideas being considered would improve the private market for patients and strengthen Medicare. "Improvements to the health system will benefit the American people—whether they have private insurance or are in Medicare," says J. James Rohack, MD, president of AMA.

Dr. Rohack specifically notes that the AMA supports phasing out the "doughnut hole" gap in Medicare prescription drug coverage—a correction that the AMA has supported since 2007. The AMA also supports repealing Medicare's physician payment system, which he says projects steep payment cuts that put seniors' access to care at risk.

Medicare Reform Leading the Way?

Many say reforming Medicare and shoring up the physician payment system is key to any reform effort. "When payments

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don't cover the cost of providing 21st century medical care, it is difficult for physicians to continue to care for all Medicare patients and make quality improvements to their practice," Dr. Rohack says.

In fact, 82% of 11,950 physicians surveyed by The Physicians' Foundation between May and July 2008 said their practices would be "unsustainable" if proposed cuts to Medicare reimbursements were made; 12% of these physicians have already closed their practices to Medicare patients. Thirty-six percent said that Medicare reimbursement is less than their cost of providing care to patients.

A letter from ACP to the Obama administration stated that "Without funding to stabilize primary care practices, many will go under and have to close" due to slower collections, the credit crunch, uncompensated care, and investment losses.

ACP has recommended that Congress fund a 10% bonus for all Medicare services performed by primary care physicians, for 18 months. A letter from ACP to the Obama administration in 2008 stated that "Without funding to stabilize primary care practices, many will go under and have to close" due to slower collections, the credit crunch, uncompensated care, and investment losses (*http://www.acponline.org/advocacy/where_we_stand/workforce/stimulus.pdf*).

The overhaul of the Medicare physician pay system is expected to cost $311 billion from 2010 to 2019, according to the White House Office of Management and Budget, *www.whitehouse.gov/omb/budget/fy2010/assets/summary.pdf*. The president would like for these measures to be exceptions to his proposal that lawmakers be required to pay fully for all new entitlement and tax-cut spending. Exempting physician-payment measures from the requirements could make it easier for lawmakers to pass a complete overhaul of the payment system. The House could, in its fiscal 2010 budget, exempt up to $38 billion worth of a physician pay boost from Democratic pay-as-you-go rules, but there is no such break in the Senate.

Such an overhaul could be the key to transforming the health-

care system, says the Commonwealth Fund, a private foundation whose goal is to promote a high-performing healthcare system that achieves better access, improved quality, and greater efficiency, in its 2008 Annual Report (see *http://www.commonwealthfund.org/Content/Annual-Reports/2008-Annual-Report.aspx*).

"Medicare could lead the way by instituting a system for the rapid testing, adoption, and spread of innovative payment methods. These should include rewarding high-performing healthcare organizations for results, not for the quantity of services delivered," according to The Commonwealth Fund. Its annual report lists the most promising changes to provider payment:

1. Providing financial rewards for top-performing providers
2. Paying a global fee for acute hospital episodes, including 30-day follow-up care
3. Recognizing physician practices or health systems that serve as patient-centered medical homes

According to the report, each of these payment methods "provides an incentive for healthcare providers to improve quality of care, coordinate care across care settings and over time, and prevent avoidable hospitalization and complications." In summary, the report states, "On issues of cost, quality, and coverage, a transformed Medicare payment system is the key to a transformed health system."