A Guide to HITECH

Chapter FastFACTS

1. **Practices that can show they've fulfilled EHR "meaningful use" requirements for 90 consecutive days in 2011 will begin to receive Medicare incentive payments this May.**
2. **You can't collect EHR incentive payments under both Medicare and Medicaid simultaneously even if you qualify for both programs.**
3. **Federal criteria will grow more stringent for some in 2013 and even more so in 2015.**
4. **Physicians must begin to participate in the Medicare EHR incentive program by 2014 in order to receive any payments.**
5. **Some insurers have experimented with offering performance bonuses for EHR users, and several plan to align any EHR incentives with the federal program.**

The federal government has been investing piecemeal for years to nudge U.S. healthcare providers toward using electronic health records (EHRs) with demonstration projects, quality reporting initiatives, and incentive payments for electronic prescribing. But now the heat's really on. The American Recovery and Reinvestment Act of 2009 (ARRA), known as "the stimulus," is, in fact, stimulating provider adoption of health information technology (IT). ARRA includes a projected cash investment of up to $30 billion to pay hospitals

TEKAMLO:
A powerful combination for hypertension.

INDICATION

TEKAMLO is indicated for the treatment of hypertension, alone or with other antihypertensive agents.

Use TEKAMLO as initial therapy in patients who are likely to need multiple drugs to achieve their blood pressure goals. Base the choice of TEKAMLO as initial therapy on an assessment of potential benefits and risks. Individualize the decision to use a combination as initial therapy by weighing factors such as baseline blood pressure, the target goal, and the incremental likelihood of achieving goal with a combination compared to monotherapy.

Switch a patient whose blood pressure is not adequately controlled with aliskiren or amlodipine (or another dihydropyridine calcium channel blocker) alone to combination therapy with TEKAMLO.

TEKAMLO may be substituted for its titrated components.

Safety and efficacy of TEKAMLO in pediatric patients have not been established.

IMPORTANT SAFETY INFORMATION

WARNING: AVOID USE IN PREGNANCY

When pregnancy is detected, discontinue TEKAMLO as soon as possible. Drugs that act directly on the renin-angiotensin-aldosterone system can cause injury and even death to the developing fetus. [See *WARNINGS and Precautions (5.1)* and *Use in Special Populations (8.1)*].

Angioedema: Angioedema of the face, extremities, lips, tongue, glottis and/or larynx has been reported in patients treated with aliskiren and has necessitated hospitalization and intubation. This may occur at any time during treatment and has occurred in patients with and without a history of angioedema with ACE inhibitors (ACEI) or angiotensin receptor antagonists. Discontinue TEKAMLO immediately in patients who develop angioedema, and do not readminister.

Hypotension: Excessive hypotension was seen rarely (0.2%) in patients with uncomplicated hypertension treated with TEKAMLO in controlled trials. Volume- and/or salt-depletion should be corrected in patients prior to administration of TEKAMLO or symptomatic hypotension may occur.

Risk of MI or Angina: Rarely, initiation or change to the dose of a calcium channel blocker has resulted in the increased frequency, duration, or severity of angina or acute myocardial infarction, particularly in patients with severe obstructive coronary artery disease.

Renal Considerations: Clinical trials with TEKAMLO and aliskiren in hypertension excluded patients with severe renal dysfunction (GFR <30 mL/min). Consider periodic determinations of serum electrolytes to detect possible imbalances. No data are available on the use of TEKAMLO or aliskiren in patients with unilateral or bilateral renal artery stenosis. In studies of ACEIs in hypertensive patients with unilateral or bilateral renal artery stenosis, increases in serum creatinine or blood urea nitrogen have been reported.

Hepatic Considerations: Use caution when administering TEKAMLO to patients with severe hepatic impairment, as amlodipine is extensively metabolized by the liver and the plasma elimination half-life is 56 hours in patients with impaired hepatic function.

Patients with HF: Titrate TEKAMLO slowly in patients with heart failure.

Hyperkalemia: Increases in serum potassium >5.5 mEq/L were seen (5.5%) when aliskiren was used in combination with an ACEI in hypertensive diabetic patients. Monitor electrolytes and renal function in this population. Use caution when coadministering TEKAMLO with potassium-sparing diuretics, potassium supplements, or other potassium-containing salt substitutes.

Cyclosporine or Itraconazole: Concomitant use of TEKAMLO with cyclosporine or itraconazole is not recommended.

Furosemide: When aliskiren was coadministered with furosemide, the AUC and C_{max} of furosemide were reduced by about 30% and 50%, respectively. Patients receiving furosemide could find its effect diminished after starting aliskiren.

Common AEs: The most common adverse event in a placebo-controlled trial that occurred in at least 2% of patients treated with TEKAMLO and at a higher incidence than placebo was peripheral edema (6.2% vs 1.0%). The incidence rate of peripheral edema at high dose was 8.9%.

BP, blood pressure; RAAS, renin-angiotensin-aldosterone system.

Please see Brief Summary of Prescribing Information, including **Boxed WARNING**, on adjacent pages.

NOVARTIS

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Tekamlo™
(aliskiren and amlodipine) tablets
150/5mg • 150/10mg • 300/5mg • 300/10mg

Tekamlo (aliskiren and amlodipine) **tablets**

Initial U.S. Approval: 2010

BRIEF SUMMARY: Please see package insert for full Prescribing Information.

WARNING: AVOID USE IN PREGNANCY
When pregnancy is detected, discontinue Tekamlo as soon as possible. Drugs that act directly on the renin-angiotensin-aldosterone system can cause injury and even death to the developing fetus. *[See Warnings and Precautions (5.1) and Use in Specific Populations (8.1)]*.

1 INDICATIONS AND USAGE

Tekamlo is indicated for the treatment of hypertension, alone or with other antihypertensive agents.

Initial Therapy

Use Tekamlo as initial therapy in patients who are likely to need multiple drugs to achieve their blood pressure goals.

Base the choice of Tekamlo as initial therapy on an assessment of potential benefits and risks.

Add-On Therapy

Switch a patient whose blood pressure is not adequately controlled with aliskiren alone or amlodipine besylate (or another dihydropyridine calcium channel blocker) to combination therapy with Tekamlo.

Replacement Therapy

Tekamlo may be substituted for its titrated components.

Patients with moderate or severe hypertension are at a relatively high risk for cardiovascular events (such as strokes, heart attacks, and heart failure), kidney failure, and vision problems, so prompt treatment is clinically relevant. Individualize the decision to use a combination as initial therapy by weighing factors such as baseline blood pressure, the target goal, and the incremental likelihood of achieving goal with a combination compared to monotherapy. Individual blood pressure goals may vary based upon the patient's risk.

Data from the high-dose multifactorial study *[see Clinical Studies (14) in the full Prescribing Information]* provide estimates of the probability of reaching a target blood pressure with Tekamlo compared to aliskiren or amlodipine monotherapy. The figures below provide estimates of the likelihood of achieving systolic or diastolic blood pressure control with Tekamlo 300 mg/10 mg, based upon baseline systolic or diastolic blood pressure. The curve of each treatment group was estimated by logistic regression modeling. The estimated likelihood at the right tail of each curve is less reliable because of a small number of subjects with high baseline blood pressures.

Figure 1: Probability of Achieving Systolic Blood Pressure (SBP) <140 mmHg

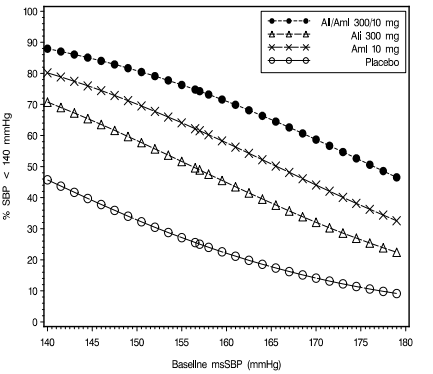


Figure 2: Probability of Achieving Diastolic Blood Pressure (DBP) <90 mmHg

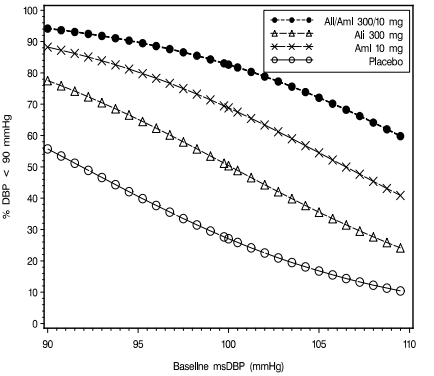


Figure 3: Probability of Achieving Systolic Blood Pressure (SBP) <130 mmHg

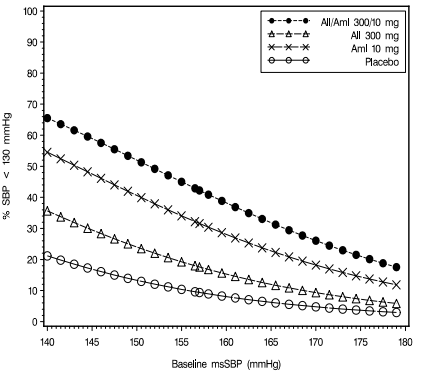
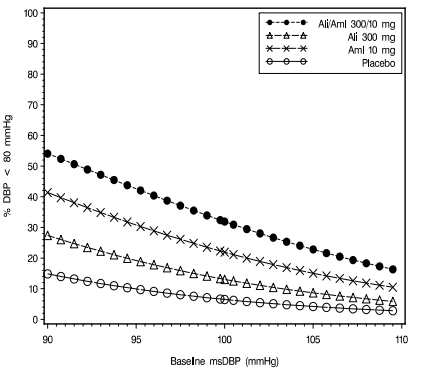


Figure 4: Probability of Achieving Diastolic Blood Pressure (DBP) <80 mmHg



The figures above provide an approximation of the likelihood of reaching a targeted blood pressure goal (e.g., SBP <140 mmHg or <130 mmHg) for the high dose groups evaluated in the study. At all levels of baseline blood pressure, the probability of achieving any given diastolic or systolic goal is greater with the combination than for either monotherapy. For example, the mean baseline SBP/DBP for patients participating in this multifactorial study was 157/100 mmHg. A patient with a baseline blood pressure of 157/100 mmHg has about a 49% likelihood of achieving a goal of <140 mmHg (systolic) and 50% likelihood of achieving <90 mmHg (diastolic) on aliskiren alone, and the likelihood of achieving these goals on amlodipine alone is

about 62% (systolic) and 69% (diastolic). The likelihood of achieving these goals on Tekamlo rises to about 74% (systolic) and 83% (diastolic). The likelihood of achieving these goals on placebo is about 25% (systolic) and 27% (diastolic) *[see Dosage and Administration (2) and Clinical Studies (14) in the full Prescribing Information]*.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Fetal/Neonatal Morbidity and Mortality

The use of drugs that act directly on the renin-angiotensin-aldosterone system during pregnancy can cause fetal and neonatal morbidity and death. No animal studies were conducted with Tekamlo; however, decreased fetal birth weight was observed in animal studies with aliskiren and intrauterine deaths were observed in animal studies with amlodipine. Tekamlo can cause fetal harm when administered to a pregnant woman. When pregnancy is detected, discontinue Tekamlo as soon as possible. If Tekamlo is used during pregnancy, or if a patient becomes pregnant while taking this drug, apprise the patient of the potential hazard to the fetus *[see Use in Specific Populations (8.1)]*.

5.2 Head and Neck Angioedema

Aliskiren

Angioedema of the face, extremities, lips, tongue, glottis and/or larynx has been reported in patients treated with aliskiren and has necessitated hospitalization and intubation. This may occur at any time during treatment and has occurred in patients with and without a history of angioedema with ACE inhibitors or angiotensin receptor antagonists. If angioedema involves the throat, tongue, glottis or larynx, or if the patient has a history of upper respiratory surgery, airway obstruction may occur and be fatal. Patients who experience these effects, even without respiratory distress, require prolonged observation, since treatment with antihistamines and corticosteroids may not be sufficient to prevent respiratory involvement. Prompt administration of subcutaneous epinephrine solution 1:1000 (0.3 to 0.5 mL) and measures to ensure a patent airway may be necessary.

Discontinue Tekamlo immediately in patients who develop angioedema and do not readminister.

5.3 Hypotension

An excessive fall in blood pressure (hypotension) was rarely seen (0.2%) in patients with uncomplicated hypertension treated with Tekamlo in controlled trials.

In patients with an activated renin-angiotensin-aldosterone system, such as volume- and/or salt-depleted patients receiving high doses of diuretics, symptomatic hypotension may occur in patients receiving renin-angiotensin-aldosterone system (RAAS) blockers. Correct these conditions prior to administration of Tekamlo, or start the treatment under close medical supervision.

If an excessive fall in blood pressure occurs with Tekamlo, place the patient in the supine position and, if necessary, give an intravenous infusion of normal saline. A transient hypotensive response is not a contraindication to further treatment, which usually can be continued without difficulty once the blood pressure has stabilized.

5.4 Risk of Myocardial Infarction or Increased Angina

Rarely, initiation or change to the dose of a calcium channel blocker has resulted in the development of documented increased frequency, duration or severity of angina or acute myocardial infarction, particularly in patients with severe obstructive coronary artery disease. The mechanism of this effect has not been elucidated.

5.5 Impaired Renal Function

Tekamlo

Clinical trials with Tekamlo in hypertension excluded patients with severe renal impairment.

Aliskiren

Clinical trials of aliskiren in hypertension excluded patients with severe renal dysfunction (creatinine 1.7 mg/dL for women and 2.0 mg/dL for men and/or estimated GFR <30 mL/min), a history of dialysis, nephrotic syndrome, or renovascular hypertension. Consider periodic determinations of serum electrolytes to detect possible electrolyte imbalances.

5.6 Patients with Hepatic Impairment

Amlodipine besylate

Amlodipine is extensively metabolized by the liver and the plasma elimination half-life is 56 hours in patients with impaired hepatic function, therefore, caution should be exercised when administering Tekamlo to patients with severe hepatic impairment.

5.7 Patients with Congestive Heart Failure

Amlodipine besylate

Amlodipine (5-10 mg per day) has been studied in a placebo-controlled trial of 1153 patients with NYHA Class III or IV heart failure on stable doses of ACE inhibitor, digoxin, and diuretics. Follow-up was at least 6 months, with a mean of about 14 months. There was no overall adverse effect on survival or cardiac morbidity (as defined by life-threatening arrhythmia, acute myocardial infarction, or hospitalization for worsened heart failure). Amlodipine has been compared to placebo in four 8-12 week studies of patients with NYHA Class II/III heart failure, involving a total of 697 patients. In these studies, there was no evidence of worsened heart failure based on measures of exercise tolerance, NYHA classification, symptoms, or left ventricular ejection fraction.

5.8 Renal Artery Stenosis

No data are available on the use of Tekamlo or aliskiren in patients with unilateral or bilateral renal artery stenosis or stenosis of the artery to a solitary kidney. However, in studies of ACE inhibitors in hypertensive patients with unilateral or bilateral renal artery stenosis, increases in serum creatinine or blood urea nitrogen have been reported.

5.9 Cyclosporine or Itraconazole

Aliskiren

When aliskiren was given with cyclosporine or itraconazole, the blood concentrations of aliskiren were significantly increased. Concomitant use of Tekamlo with cyclosporine or itraconazole is not recommended *[see Drug Interactions (7)]*.

6 ADVERSE REACTIONS

6.1 Clinical Studies Experience

The following serious adverse reactions are discussed in greater detail in other sections of the label:

- Risk of fetal/neonatal morbidity and mortality *[see Warnings and Precautions (5.1)]*
- Head and neck angioedema *[see Warnings and Precautions (5.2)]*
- Hypotension *[see Warnings and Precautions (5.3)]*

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 clinical trials of another drug and may not reflect the rates observed in practice.

Tekamlo

Tekamlo has been evaluated for safety in more than 2800 patients, including 372 patients for 1 year or longer.

In a placebo-controlled study, there were 51% males, 62% Caucasians, 20% Blacks, 18% Hispanics, and 17% who were over 65 years of age. In this study, the overall incidence of adverse events on therapy with Tekamlo was similar to the individual components. Discontinuation of therapy due to a clinical adverse event in this study occurred in 1.7% of patients treated with Tekamlo (2.2% in the highest dose group) versus 1.5% of patients given placebo.

Peripheral edema is a known, dose-dependent adverse effect of amlodipine. The incidence of peripheral edema for Tekamlo in short-term double-blind placebo-controlled studies was lower than or equal to that of the corresponding amlodipine doses.

The adverse event in a placebo-controlled trial that occurred in at least 2% of patients treated with Tekamlo and at a higher incidence than placebo was peripheral edema (6.2% versus 1.0%). The incidence rate of peripheral edema at high dose was 8.9%.

In a long-term safety trial, the safety profile of adverse events was similar to that seen in the short-term controlled trials.

Aliskiren

Aliskiren has been evaluated for safety in 6460 patients, including 1740 treated for longer than 6 months, and 1250 for longer than 1 year. In placebo-controlled clinical trials, discontinuation of therapy because of a clinical adverse event, including uncontrolled hypertension, occurred in 2.2% of patients treated with aliskiren, versus 3.5% of patients given placebo.

Two cases of angioedema with respiratory symptoms were reported with aliskiren use in the clinical studies. Two other cases of periorbital edema without respiratory symptoms were reported as possible angioedema and resulted in discontinuation. The rate of these angioedema cases in the completed studies was 0.06%.

In addition, 26 other cases of edema involving the face, hands, or whole body were reported with aliskiren use, including 4 leading to discontinuation.

In the placebo-controlled studies, however, the incidence of edema involving the face, hands, or whole body was 0.4% with aliskiren compared with 0.5% with placebo. In a long-term active-controlled study with aliskiren and HCTZ arms, the incidence of edema involving the face, hands, or whole body was 0.4% in both treatment arms.

Aliskiren produces dose-related gastrointestinal (GI) adverse reactions. Diarrhea was reported by 2.3% of patients at 300 mg, compared to 1.2% in placebo patients. In women and the elderly (age ≥65) increases in diarrhea rates were evident starting at a dose of 150 mg daily, with rates for these subgroups at 150 mg similar to those seen at 300 mg for men or younger patients (all rates about 2%). Other GI symptoms included abdominal pain, dyspepsia, and gastroesophageal reflux, although increased rates for abdominal pain and dyspepsia were distinguished from placebo only at 600 mg daily. Diarrhea and other GI symptoms were typically mild and rarely led to discontinuation.

Aliskiren was associated with a slight increase in cough in the placebo-controlled studies (1.1% for any aliskiren use versus 0.6% for placebo). In active-controlled trials with ACE inhibitor (ramipril, lisinopril) arms, the rates of cough for the aliskiren arms were about one-third to one-half the rates in the ACE inhibitor arms.

Other adverse reactions with increased rates for aliskiren compared to placebo included rash (1% versus 0.3%), elevated uric acid (0.4% versus 0.1%), gout (0.2% versus 0.1%), and renal stones (0.2% versus 0%).

Single episodes of tonic-clonic seizures with loss of consciousness were reported in two patients treated with aliskiren in the clinical trials. One patient had predisposing causes for seizures and had a negative electroencephalogram (EEG) and cerebral imaging following the seizures; for the other patient, EEG and imaging results were not reported. Aliskiren was discontinued and there was no rechallenge in either case.

No clinically meaningful changes in vital signs or in ECG (including QTc interval) were observed in patients treated with aliskiren.

Amlodipine besylate

Amlodipine (Norvasc®) has been evaluated for safety in more than 11,000 patients in U.S. and foreign clinical trials. Other adverse events that have been reported <1% but >0.1% of patients in controlled clinical trials or under conditions of open trials or marketing experience where a causal relationship is uncertain were:

Cardiovascular: arrhythmia (including ventricular tachycardia and atrial fibrillation), bradycardia, chest pain, peripheral ischemia, syncope, postural hypotension, vasculitis

Central and Peripheral Nervous System: neuropathy peripheral, paresthesia, tremor, vertigo

Gastrointestinal: anorexia, constipation, dyspepsia,** dysphagia, diarrhea, flatulence, pancreatitis, vomiting, gingival hyperplasia

General: allergic reaction, asthenia,** back pain, hot flushes, malaise, pain, rigors, weight gain, weight decrease

Musculoskeletal System: arthralgia, arthrosis, muscle cramps,** myalgia

Psychiatric: sexual dysfunction (male** and female), insomnia, nervousness, depression, abnormal dreams, anxiety, depersonalization

Respiratory System: dyspnea, epistaxis

Skin and Appendages: angioedema, erythema multiforme, pruritus,** rash,** rash erythematous, rash maculopapular

**These events occurred in less than 1% in placebo-controlled trials, but the incidence of these side effects was between 1% and 2% in all multiple dose studies.

Special Senses: abnormal vision, conjunctivitis, diplopia, eye pain, tinnitus

Urinary System: micturition frequency, micturition disorder, nocturia

Autonomic Nervous System: dry mouth, sweating increased

Metabolic and Nutritional: hyperglycemia, thirst

Hemopoietic: leukopenia, purpura, thrombocytopenia

Other events reported with amlodipine at a frequency of ≤0.1% of patients include: cardiac failure, pulse irregularity, extrasystoles, skin discoloration, urticaria, skin dryness, alopecia, dermatitis, muscle weakness, twitching, ataxia, hypertonia, migraine, cold and clammy skin, apathy, agitation, amnesia, gastritis, increased appetite, loose stools, rhinitis, dysuria, polyuria, parosmia, taste perversion, abnormal visual accommodation, and xerophthalmia. Other reactions occurred sporadically and cannot be distinguished from medications or concurrent disease states such as myocardial infarction and angina.

6.2 Clinical Laboratory Test Abnormalities

RBC Count, Hemoglobin and Hematocrit: Small mean changes from baseline were seen in RBC count, hemoglobin and hematocrit in patients treated with both Tekamlo and aliskiren monotherapy. This effect is also seen with other agents acting on the renin-angiotensin system. In aliskiren monotherapy trials these decreases led to slight increases in rates of anemia compared to placebo (0.1% for any aliskiren use, 0.3% for aliskiren 600 mg daily, vs. 0% for placebo). No patients discontinued due to anemia.

Blood Urea Nitrogen (BUN)/Creatinine: Elevations in BUN (>40 mg/dL) and creatinine (>2.0 mg/dL) in patients treated with Tekamlo were <1.0%.

Serum Potassium: Increases in serum potassium >5.5 mEq/L were infrequent in patients with essential hypertension treated with both Tekamlo and aliskiren monotherapy (0.9% compared to 0.6% with placebo). However, when aliskiren was used in combination with an angiotensin-converting enzyme inhibitor (ACEI) in a diabetic population, increases in serum potassium were more frequent (5.5%). Monitor electrolytes and renal function in this population.

6.3 Post-marketing Experience

The following adverse reactions have been identified during postapproval use of either aliskiren or amlodipine. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to estimate their frequency or establish a causal relationship to drug exposure:

Hypersensitivity: angioedema requiring airway management and hospitalization

Aliskiren: peripheral edema, blood creatinine increased

Amlodipine: The following postmarketing event has been reported infrequently where a causal relationship is uncertain: gynecomastia. In postmarketing experience, jaundice and hepatic enzyme elevations (mostly consistent with cholestasis or hepatitis), in some cases severe enough to require hospitalization, have been reported in association with use of amlodipine.

7 DRUG INTERACTIONS

No drug interaction studies have been conducted with Tekamlo and other drugs, although studies with the individual aliskiren and amlodipine besylate components are described below.

Aliskiren

Effects of Other Drugs on Aliskiren

Based on *in vitro* studies, aliskiren is metabolized by CYP 3A4.

Irbesartan: Coadministration of irbesartan reduced aliskiren C_{max} up to 50% after multiple dosing.

P-glycoprotein Effects: Pgp (MDR1/Mdr1a/1b) was found to be the major efflux system involved in absorption and disposition of aliskiren in preclinical studies. The potential for drug interactions at the Pgp site will likely depend on the degree of inhibition of this transporter.

Atorvastatin: Coadministration of atorvastatin resulted in about a 50% increase in aliskiren C_{max} and AUC after multiple dosing.

Ketoconazole: Coadministration of 200 mg twice-daily ketoconazole with aliskiren resulted in an approximate 80% increase in plasma levels of aliskiren. A 400-mg once-daily dose was not studied but would be expected to increase aliskiren blood levels further.

Verapamil: Coadministration of a single oral dose of 300 mg aliskiren with 240 mg verapamil increased AUC and C_{max} of aliskiren by ~2-fold. However, no dosage adjustment is necessary.

Itraconazole: Coadministration of 100 mg itraconazole with 150 mg aliskiren resulted in approximately 5.8-fold increase in C_{max} and 6.5-fold increase in AUC of aliskiren. Concomitant use of aliskiren with itraconazole is not recommended.

Cyclosporine: Coadministration of 200 mg and 600 mg cyclosporine with 75 mg aliskiren resulted in an approximately 2.5-fold increase in C_{max} and 5-fold increase in AUC of aliskiren. Concomitant use of aliskiren with cyclosporine is not recommended.

Drugs with no clinically significant effects: Coadministration of lovastatin, atenolol, warfarin, furosemide, digoxin, celecoxib, hydrochlorothiazide, ramipril, amlodipine besylate, metformin and amlodipine did not result in clinically significant increases in aliskiren exposure.

Effects of Aliskiren on Other Drugs

Aliskiren does not inhibit the CYP450 isoenzymes (CYP1A2, 2C8, 2C9, 2C19, 2D6, 2E1, and CYP 3A) or induce CYP 3A4.

Furosemide: When aliskiren was coadministered with furosemide, the AUC and C_{max} of furosemide were reduced by about 30% and 50%, respectively. Patients receiving furosemide could find its effect diminished after starting aliskiren.

Drugs with no clinically significant effects: Coadministration of aliskiren did not significantly affect the pharmacokinetics of lovastatin, digoxin, valsartan, amlodipine, metformin, celecoxib, atenolol, atorvastatin, ramipril or hydrochlorothiazide.

Warfarin: The effects of aliskiren on warfarin pharmacokinetics have not been evaluated.

Amlodipine besylate

In clinical trials, amlodipine has been safely administered with thiazide diuretics, beta-blockers, angiotensin-converting enzyme inhibitors, long-acting nitrates, sublingual nitroglycerin, digoxin, warfarin, non-steroidal anti-inflammatory drugs, antibiotics, and oral hypoglycemic drugs.

Cimetidine: Co-administration of amlodipine with cimetidine did not alter the pharmacokinetics of amlodipine.

Grapefruit juice: Co-administration of 240 mL of grapefruit juice with a single oral dose of amlodipine 10 mg in 20 healthy volunteers had no significant effect on the pharmacokinetics of amlodipine.

Maalox® (antacid): Co-administration of the antacid Maalox with a single dose of amlodipine had no significant effect on the pharmacokinetics of amlodipine.

Sildenafil: A single 100 mg dose of sildenafil in subjects with essential hypertension had no effect on the pharmacokinetic parameters of amlodipine. When amlodipine and sildenafil were used in combination, each agent independently exerted its own blood pressure lowering effect.

Atorvastatin: Co-administration of multiple 10 mg doses of amlodipine with 80 mg of atorvastatin resulted in no significant change in the steady-state pharmacokinetic parameters of atorvastatin.

Digoxin: Co-administration of amlodipine with digoxin did not change serum digoxin levels or digoxin renal clearance in normal volunteers.

Ethanol (alcohol): Single and multiple 10 mg doses of amlodipine had no significant effect on the pharmacokinetics of ethanol.

Warfarin: Co-administration of amlodipine with warfarin did not change the warfarin prothrombin response time.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category D *[See Warnings and Precautions Section]*

The use of drugs that act directly on the renin-angiotensin-aldosterone system during the second and third trimesters of pregnancy can cause fetal and neonatal morbidity and death. In addition, first trimester use of ACE inhibitors has been associated with birth defects in retrospective data. No animal studies were conducted with Tekamlo; however, decreased fetal birth weight was observed in animal studies with aliskiren and intrauterine deaths were observed in animal studies with amlodipine. Tekamlo can cause fetal harm when administered to a pregnant woman. When pregnancy is detected, discontinue Tekamlo as soon as possible. If Tekamlo is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.

Human Data and Clinical Considerations

Maternal hypertension is associated with increased risks for preterm delivery, intrauterine growth restriction, placental abruption, preeclampsia, and perinatal mortality. Appropriate management of maternal hypertension during pregnancy is important to optimize outcomes for both mother and fetus. Renin inhibitors (like aliskiren), angiotensin II receptor antagonists and angiotensin converting enzyme (ACE) inhibitors exert similar effects on the renin-angiotensin-aldosterone system. Based on several dozen published cases, ACE inhibitor use during the second and third trimesters of pregnancy is associated with fetal and neonatal injury, including hypotension, neonatal skull hypoplasia, anuria, reversible or irreversible renal failure, and death. Decreased fetal renal function may result in oligohydramnios and associated with fetal limb contractures, craniofacial deformation, and hypoplastic lung development. Prematurity, intrauterine growth retardation, and patent ductus arteriosus have been reported in women using these drugs, but it is not clear whether these occurrences were due to drug exposure. Limited data are conflicting about whether first trimester use of ACE inhibitors is associated with an increased risk of birth defects, but the drugs' mechanism of action raises a theoretical concern.

When pregnancy occurs in a patient using Tekamlo, the physician should discontinue Tekamlo treatment as soon as possible. Inform the patient about potential risks to the fetus based on the time of gestational exposure to Tekamlo (first trimester only or later). If exposure occurs beyond the first trimester, perform an ultrasound examination.

In rare cases when another antihypertensive agent cannot be used to treat the pregnant patient, serial ultrasound examinations should be used to assess the intraamniotic environment. Routine fetal testing with non-stress tests, biophysical profiles, and/or contraction stress tests may be appropriate based on gestational age and standards of care in the community. If oligohydramnios occurs in these situations,

individualized decisions about continuing or discontinuing Tekamlo treatment and about pregnancy management should be made by the patient and her physicians. Patients and physicians should be aware that oligohydramnios may not appear until after the fetus has sustained irreversible injury.

Infants exposed to Tekamlo *in-utero* should be closely observed for hypotension, oliguria, and hyperkalemia. If oliguria occurs, these infants may require blood pressure and renal perfusion support. Exchange transfusion or dialysis may be required to reverse hypotension and/or support decreased renal function.

Animal Data

No reproductive toxicity studies have been conducted with the combination of aliskiren and amlodipine besylate. However, these studies have been conducted for aliskiren and amlodipine besylate alone.

Aliskiren

In developmental toxicity studies, pregnant rats and rabbits received oral aliskiren hemifumarate during organogenesis at doses up to 20 and 7 times the maximum recommended human dose (MRHD) based on body surface area (mg/m^2), respectively, in rats and rabbits. (Actual animal doses were up to 600 mg/kg/day in rats and up to 100 mg/kg/day in rabbits.) No teratogenicity was observed; however, fetal birth weight was decreased in rabbits at doses 3.2 times the MRHD based on body surface area (mg/m^2). Aliskiren was present in placentas, amniotic fluid and fetuses of pregnant rabbits.

Amlodipine

In developmental toxicity studies, pregnant rats and rabbits received oral amlodipine maleate during organogenesis at doses approximately 10 and 20 times the maximum recommended human dose (MRHD) based on body surface area (mg/m^2), respectively, in rats and rabbits. (Actual animal doses were up to 10 mg/kg/day.) No evidence of teratogenicity or other embryofetal toxicity was observed. However, litter size was decreased approximately 50% and the number of intrauterine deaths was increased approximately 5-fold for rats receiving amlodipine maleate at doses approximately 10 times the MRHD based on body surface area (mg/m^2) for 14 days before mating and throughout mating and gestation. Amlodipine maleate has been shown to prolong both the gestation period and the duration of labor in rats at this dose.

8.3 Nursing Mothers

It is not known whether aliskiren or amlodipine is excreted in human milk. Both aliskiren and amlodipine are secreted in the milk of lactating rats. Because of the potential for serious adverse reactions in human milk-fed infants from Tekamlo, a decision should be made whether to discontinue nursing or discontinue Tekamlo, taking into account the importance of the drug to the mother.

8.4 Pediatric Use

Safety and effectiveness of Tekamlo in pediatric patients have not been established.

8.5 Geriatric Use

Tekamlo

In the short-term controlled clinical trials of Tekamlo, 17% of patients treated with Tekamlo were ≥65 years. No overall differences in safety or effectiveness were observed between these subjects and younger subjects. 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.

Aliskiren

Impact of aging on aliskiren pharmacokinetics has been assessed, when compared to young adults (18-40 years), aliskiren mean AUC and C_{max} in elderly subjects (>65 years) are increased by 57% and 28%, respectively. However, differences in efficacy and safety between the elderly and younger populations were minor, indicating that differences in exposure due to age do not significantly alter the clinical effect of the drug. Therefore, no starting dose adjustment in geriatric population is required.

Amlodipine

Other reported clinical experience has not identified differences in responses between the elderly and younger patients. However, elderly patients have decreased clearance of amlodipine with a resulting increase of AUC of approximately 40-60%. In general dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.

10 OVERDOSAGE

Aliskiren

Limited data are available related to overdosage in humans. The most likely manifestation of overdosage would be hypotension. If symptomatic hypotension should occur, provide supportive treatment.

Amlodipine besylate

Single oral doses of amlodipine maleate equivalent to 40 mg amlodipine/kg and 100 mg amlodipine/kg in mice and rats, respectively, caused deaths. Single oral amlodipine maleate doses equivalent to 4 or more

mg amlodipine/kg or higher in dogs (11 or more times the maximum recommended human dose on a mg/m^2 basis) caused a marked peripheral vasodilation and hypotension.

Overdosage might be expected to cause excessive peripheral vasodilation with marked hypotension and possibly a reflex tachycardia. In humans, experience with intentional overdosage of amlodipine is limited. Reports of intentional overdosage include a patient who ingested 250 mg and was asymptomatic and was not hospitalized; another (120 mg) was hospitalized, underwent gastric lavage and remained normotensive; the third (105 mg) was hospitalized and had hypotension (90/50 mmHg) which normalized following plasma expansion. A case of accidental drug overdose has been documented in a 19-month-old male who ingested 30 mg amlodipine (about 2 mg/kg). During the emergency room presentation, vital signs were stable with no evidence of hypotension, but a heart rate of 180 bpm. Ipecac was administered 3.5 hours after ingestion and on subsequent observation (overnight) no sequelae were noted.

If massive overdose should occur, active cardiac and respiratory monitoring should be instituted. Frequent blood pressure measurements are essential. Should hypotension occur, cardiovascular support including elevation of the extremities and the judicious administration of fluids should be initiated. If hypotension remains unresponsive to these conservative measures, administration of vasopressors (such as phenylephrine) should be considered with attention to circulating volume and urine output. Intravenous calcium gluconate may help to reverse the effects of calcium entry blockade. As amlodipine is highly protein bound, hemodialysis is not likely to be of benefit.

16 STORAGE

Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) in original container.

Protect from heat and moisture.

Dispense in tight container (USP).

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and physicians to install EHRs or to compensate those who already have done so. Add in billions more in consulting and infrastructure support, and you have this country's largest single investment in EHRs.

Eligible providers may receive up to $44,000 from Medicare or $63,750 from Medicaid, paid out over several years, if they install a "certified" EHR system and achieve "meaningful use" according to a set of federal criteria that will grow more stringent in 2013 as one progresses along and even more so in 2015. The timing depends on when they start using an EHR and whether they meet federal standards for meaningful use. These payments and the requirements are detailed in the ARRA section known as the Health Information Technology for Economic and Clinical Health (HITECH) Act. The government expects to get back $11 billion of its cash outlay over the next eight years in better care, less waste, and reduced Medicare payments to providers who don't adopt EHRs. Those physicians who aren't computerized by 2015 will see their Medicare payments reduced by 1%; the penalties could creep up to 5% by 2019 if 75% of physicians haven't adopted EHRs by then. (There are no Medicaid penalties in the current plans.) The Congressional Budget Office projects that HITECH will prompt 90% of physicians to adopt EHRs by 2019, compared with 65% if there were no HITECH incentives or penalties.

Since the Centers for Medicare & Medicaid Services (CMS) expects to start paying Medicare incentives this May to practices that have fulfilled EHR meaningful use requirements for 90 consecutive days in 2011, you should start today to determine if you are eligible for payments, how much you stand to gain, how to get the payments, and how to coordinate with other government incentive programs (see "Other Incentive Programs"). This issue of *Doctor's Digest* will guide you in that effort, then show you how to find an EHR that meets government requirements, how

to use it in a way that will qualify you to receive maximum HITECH incentive payments, and where to find help with system selection and implementation.

Are You Eligible?

The first step is to determine whether you qualify for HITECH payments. CMS has set the following eligibility criteria for participating in the HITECH program under either Medicare or Medicaid:

Medicare: Doctor of medicine or osteopathy, doctor of dental surgery or dental medicine, doctor of podiatry, doctor of optometry, or chiropractor. Eligible providers may not be hospital based. (A provider is considered hospital based if 90% or more of his or her services are performed in a hospital inpatient or emergency room setting.) The payments go to a provider rather than his or her practice—but they can be reassigned to one and only one other entity: Each eligible provider can receive only one incentive payment per year regardless of the number of practices or locations he or she serves.

Medicaid: Physician, nurse practitioner, certified nurse-midwife, dentist, or physician assistant (PA) who furnishes services in a federally qualified health center or rural health clinic that is led by a PA. To qualify for an EHR incentive payment, a Medicaid-eligible provider must not be hospital based (see definition above) and must meet one of the following criteria:

- Have a minimum 30% Medicaid patient volume*
- Have a minimum 20% Medicaid patient volume and be a pediatrician*
- Practice predominantly in a federally qualified health center or rural health center and have a minimum 30% patient volume attributable to needy individuals

If you're eligible to participate under both Medicare and Medicaid, you'll be required to choose one or the other—you can't collect under both programs simultaneously. You need to select which program you want to participate in when you register (see

*Children's Health Insurance Program (CHIP) patients do not count towards the Medicaid patient volume criteria.

"How to Register for HITECH Incentive Payments"). You can change your mind as often as you want, until you receive your first payment; after that, you can switch only once before 2015. To compare the programs, see "Comparing Medicare and Medicaid Incentives."

Calculating Your HITECH Payment

Here's how the calculation works for the Medicare HITECH program: Each physician in a practice can collect an amount equal to 75% of allowable Medicare charges, up to the maximum for each calendar year (see "Medicare HITECH Maximum Incentive Payment Schedule"). To be eligible to receive the full $18,000

How to Register for HITECH Incentive Payments

Registration to receive HITECH payments opened on Jan. 3. To register, go to *http://www.cms.gov/EHRIncentivePrograms/20_RegistrationandAttestation.asp.* You will need the following:

- National Provider Identifier (NPI)
- National Plan and Provider Enumeration System (NPPES) User ID and Password (obtainable through the CMS Website if you don't already have one)
- Payee Tax Identification Number if you are reassigning your benefits to your practice
- Payee National Provider Identifier (NPI) if you wish to reassign your benefits

Medicare HITECH Incentive Payment Schedule

Calendar Year	First calendar year for which the eligible provider receives an incentive payment				
	2011	**2012**	**2013**	**2014**	**2015 on**
2011	$18,000	—	—	—	—
2012	12,000	$18,000	—	—	—
2013	8,000	12,000	$15,000	—	—
2014	4,000	8,000	12,000	$12,000	—
2015	2,000	4,000	8,000	8,000	$0
2016	—	2,000	4,000	4,000	0
TOTAL	$44,000	$44,000	$39,000	$24,000	$0

incentive payment for 2011, you need at least $24,000 in allowable Medicare charges and proof of meaningful use of EHRs for at least 90 consecutive days in 2011. (A physician with $20,000 in allowable Medicare charges would receive a maximum payment of $15,000.) Physicians who participate through Medicare and practice in a federally designated Health Professional Shortage Area can get a 10% higher payment, for a maximum of $48,400. Medicaid HITECH programs are governed by states; check with your state for specifics on how your incentives will be calculated (see "Medicaid HITECH Maximum Incentive Payment Schedule").

While Medicare HITECH payments can begin as early as this May, physicians need to start participating in the program by 2014 in order to get any incentive payments at all. To get the highest payment possible, you need to start by 2012. For details on both programs see "Comparing Medicare and Medicaid Incentives." For information about coordinating payments and taxes see "Accounting for HITECH Payments."

You must keep using the EHR in accordance with federal requirements to continue getting the payments, which stretch over a maximum of five years for Medicare and six for Medicaid. The requirements for meaningful use are relatively easy initially (see Chapter 3), but the bar will be raised for the second

Medicaid HITECH Incentive Payment Schedule

The schedule for Medicaid payments varies by state, and at press time most states were still drafting their plans; but the initial payment is higher than that for Medicare, the requirements for qualifying are more relaxed, and the program stretches over six years rather than five. At this writing, the states ready to take registration for Medicaid payments were Alaska, Iowa, Kentucky, Louisiana, Michigan, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, and Texas. California, Missouri, and North Dakota were planning to open registration in February, with the rest of the states following by the end of the summer.

To earn the first year's Medicaid HITECH payment, providers have to show only that they're adopting EHRs and have enough Medicaid patients to qualify; they don't have to demonstrate meaningful use of the EHR until year two. Physicians have until 2015 to start their qualification period, and incentives will stop after 2021.

Here's the maximum payment schedule:

Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Total
$21,250	$8,500	$8,500	$8,500	$8,500	$8,500	$63,750

stage of the program, now scheduled to begin in 2013, and again for the third stage, which is expected to begin in 2015. At this writing, professional and trade associations were weighing in on the criteria for Stage 2, with proposed rules expected later this year. Penalties for not using an EHR, or for using it inadequately, are scheduled to begin in 2016.

The Money Is There

While last November's elections were widely regarded as a referendum on both healthcare reform and the Obama administration's efforts to stimulate the economy, experts say it's unlikely

Comparing Medicare and Medicaid Incentives

	Medicare EHR Incentive Program	Medicaid EHR Incentive Program
When can I start participating?	As soon as the federal program launches	Once your state offers the program (check with your state for expected launch date)
What are the maximum incentives?	Up to $44,000 in incentives, and up to $48,400 if practicing in a Health Provider Shortage Area	Up to $63,750 in incentives
What kind of EHR use is required?	Demonstrate meaningful use of certified EHR technology every year to qualify for payment	Can qualify for payment by adopting, implementing, upgrading, or demonstrating meaningful use of certified EHR technology in first participation year. Required to demonstrate meaningful use in each subsequent year to qualify for payment
When do I have to begin participating?	Must participate by the second year to receive the maximum incentive payment	Must participate by 2016 to receive the maximum incentive payment

the new Congress will do anything to dislodge HITECH or cut its funding. Efforts to reap the quality benefits and potential cost savings from IT have had consistent bipartisan support, and the Office of the National Coordinator for Health Information Technology (ONCHIT), the federal body charged with spreading the health IT gospel, was created by the second Bush administration.

"HITECH was a recognition that costs are out of control and care is not of high enough quality," says Michael Zaroukian, MD, PhD, FACP, professor of medicine and chief medical information officer at Michigan State University, and a member of the

American College of Physicians (ACP) medical informatics subcommittee as well as a practicing internist. "It was designed both to be an economic stimulus and to begin the process of measuring and improving quality and bending the cost curve. We are comfortable that the payments will be there if you can demonstrate meaningful use. The only question is whether you can get to that point."

The first HITECH payments—$2.86 million to a Kentucky hospital and $21,250 each to two Oklahoma physicians, all under the Medicaid program—were issued within a few days of the program's official kick-off date in January.

Time to Take The Plunge

Even if you have some sort of clinical computing capability in your office—almost half of U.S. physicians do, according to a recent study from the National Center for Health Statistics—that equipment may not meet the level required to receive HITECH incentives. Only 10% of U.S. physician office systems met the survey's criteria for a "full" EHR, and even many of those probably can't meet all of the initial meaningful use requirements. However, those requirements are causing vendors to tweak or in some cases completely overhaul their products, and it's getting easier by the day to find EHRs that can qualify their users to receive HITECH payments (see Chapter 2). Unless you're planning to retire soon, or join a practice that already has (or is planning for) a federally qualified EHR, or sell your practice to a hospital that will extend its EHR to your office, it's time to think hard about adopting an EHR. Even if you can't make the government incentive numbers work for you—e.g., you don't do enough business with either Medicare or Medicaid to reap a significant payment—consider taking the EHR plunge. Here's why:

•Private insurers follow Medicare. When the federal government, especially the Medicare program, decides to use its economic clout to encourage or discourage any aspect of medical practice, private insurers are never far behind. National health IT coordinator David Blumenthal, MD, and two colleagues published an article in the September 2010 issue of *Health Affairs* that pushes hard for private payers to follow the government's

Other Incentive Programs

While the EHR incentive payment is the biggest one available for most Medicare and Medicaid providers, two others remain in place: the Physician Quality Reporting Initiative (PQRI) and the e-prescribing program, or eRx for short. About 85,000 physicians participated in PQRI in 2008, the most recent year for which statistics are available, and they collected about $92 million. The eRx program was authorized under the 2008 Medicare Improvement for Patients and Providers Act.

PQRI: In 2011, PQRI pays 1% of allowable Medicare charges to physicians who report certain quality measures to CMS; the payment drops to 0.5% in 2012 and stays there until 2015, when CMS begins imposing a penalty of 1.5% of Medicare charges for not participating. (There's no comparable penalty for physicians who participate in the program through Medicaid.)

eRx: The eRx incentive is 1% of allowable charges for 2011 and 2012, dropping to 0.5% in 2013. Beginning in 2012, Medicare will also impose a 1% penalty for not using e-prescribing. The penalty increases to 1.5% in 2013 and 2% in 2014. Medicaid imposes no penalty.

All eligible providers can participate in PQRI and the HITECH EHR incentive program at the same time. Because the HITECH meaningful use standards include using e-prescribing, Medicare participants can't collect both an EHR payment and an eRx payment. However, Medicaid providers who fulfill all the requirements for each program can collect all three incentives.

lead in rewarding the adoption of EHRs. Their recommendations go beyond incentive payments and penalties. They include redesigning benefits (for example, lower co-payments to steer patients to providers who are "meaningful users"), awarding "star" ratings to EHR-using providers, and requiring clinicians to be meaningful users to participate in payer contracts or qualify for hospital admitting privileges. "The more closely all of these different sectors work together to spur the meaningful use of health IT, the more likely we will be to realize the potential of improved quality and efficiency in a transformed U.S. healthcare system," the authors say.

If the insurance industry follows suit as usual, physicians can look forward to similar near-term incentives and long-term penalties. "Physicians will have to think about the reality of

being de-selected" if they don't use an EHR, says Dr. Zaroukian.

The industry group America's Health Insurance Plans (AHIP) issued a statement last summer strongly supporting the objectives of HITECH. Some insurers have already experimented with offering performance bonuses for EHR users; and several, including Aetna, United Healthcare, WellPoint, and Highmark Blue Cross/Blue Shield, have said they'll align any EHR incentives with the federal program.

■ **Board certification and state licensure will require EHR proficiency.** Shortly after the meaningful use regulations were finalized last summer, the heads of the American Board of Medical Specialties (ABMS) and the Federation of State Medical Boards (FSMB) both gave press briefings describing how their member organizations plan to incorporate federal EHR goals into certification and licensure. "By aligning ABMS Maintenance of Certification with the meaningful use objectives of HHS, we can enhance the knowledge, skill, and use of health IT by physicians to improve performance and patient outcomes," said ABMS president and CEO Kevin Weiss, MD, MPH, and ABMS advisor Sheldon D. Horowitz, MD, in a *Health Affairs* blog post following the briefing.

Humavun Chaudhry, DO, president and CEO of the FSMB, noted that maintenance of licensure (MOL) may depend on adopting EHRs since in many cases state medical boards follow the standards set by ABMS. Other MOL requirements can be met using quality and performance data pulled from a certified EHR.

■ **Practices without an EHR may be legally vulnerable.** "If most prudent physicians in your practice area are using an EHR and you're not, you have the potential to fall below the standard of care," says David B. Troxel, MD, medical director at The Doctors Company, a Napa, Calif.-based major malpractice insurer. He says that in general, providers who fall below practice standards can be found negligent, and sticking with paper records has the potential to open a practice to lawsuits if it can be shown that the alleged error wouldn't have happened if an EHR had been used. "We're not there yet, but a number of people are thinking ahead and raising this question."

■ **Practices with EHRs may make more money.** Implementing an EHR could cost $120,000 or more per physician; and most of that is the cost of lost productivity while physicians figure out how to work with the new system, according to a study released in December by CDW Healthcare, Vernon Hills, Ill., a hardware and software reseller. However, the study also projected that once fully adopted, EHRs will increase productivity and resulting revenue by up to $150,000 per physician per year.

Moving Forward

The most important reason to get an EHR is the same one the government gives for pursuing the HITECH goal: Electronic medical records properly installed and used can help providers give more and better patient care at lower cost. While the data on their use in the United States reflect their adoption—spotty at best—countries that have achieved the full use of EHRs envisioned by HITECH (in which all physicians and hospitals share complete patient data) are also seeing the benefits. For example, physicians in Denmark, where EHR use and data sharing are all but universal, save almost an hour of administrative time daily compared with the days of paper records. They're also seeing more patients per day with no sign of burnout, according to a Commonwealth Fund study.

Many organizations, from the giant HMO Kaiser Permanente to solo physician offices, have used their EHRs to do more effective tracking and follow-up. "The more meaningful information we have from our EHR, the better job we can do looking at our population as a whole," says Kallanna Manjunath, MD, chief medical officer and a pediatrician at Whitney M. Young, Jr. Health Center in Albany, N.Y., a federally qualified community health center that is applying for HITECH incentives under Medicaid.

The American Academy of Family Physicians (AAFP) has been urging its members to adopt EHRs for years. "They should implement [EHRs] because it's the right thing to do for their patients and their practice," says Steven Waldren, MD, director of the AAFP's Center for Health Information Technology.

Ultimately, getting an EHR may not be a choice if you want to remain competitive no matter how the healthcare system evolves, Dr. Zaroukian says. "Even if reform gets derailed, the

Accounting for HITECH Payments

One peculiarity of the HITECH incentives is that they will be paid—and taxable— to individual physicians even though their practices will generally be paying for implementing EHRs. Physicians have the option of assigning the payments back to the practice, which would help defray the considerable costs. But is there anything forcing them to do so, aside from a moral imperative and a desire to reduce their taxable income?

It depends on the contract between the practice and the physician, says Robert E. Schile, a certified public accountant and principal for healthcare at the accounting firm LarsonAllen, LLP, Minneapolis. "If the physicians have a contract with the employer that requires them to assign the payment over, then they would. But absent any specific contract language, the physician doesn't have to," he says. Some executives in larger or hospital-owned practices are already arranging to require the physicians to assign their incentives back to the practice. (Mr. Schile says this can be done either by telling the CMS to pay the incentive to the practice or by receiving the payment as an individual, then writing a check to the practice, and having both transactions recorded on the physician's tax return.) Others are expecting that's what will happen, but aren't taking steps until the practice achieves meaningful EHR use and the money starts coming in.

Mr. Schile recommends talking about it now, and making sure all physicians in the practice agree about what's going to happen. If the incentive payment comes back to the practice, the practice may want to provide for physicians to receive some kind of bonus for becoming proficient EHR users. If physicians' compensation is partly or wholly based on how many patients they see, the practice might ease or waive those requirements while physicians are learning to incorporate the EHR into their practice. "Often we see that when an organization converts to electronic records, there's a dip in physician productivity," Mr. Schile says. "We see a lot of practices holding physicians harmless from productivity clauses in their contracts until they get used to the EHR."

system is still broken," he says. "Whatever the new model turns out to be, we're moving from paying for quantity to paying for quality, and anyone who decides not to move forward [on an EHR] is betting on an old model that's not going to survive. You'll have to prove the quality and value of your care; and without data, you'll have a heck of a time proving your quality is where it should be."