

The Effect of Reform on Primary Care

Chapter FastFACTS

- 1.** By various mechanisms in the Affordable Care Act (ACA), more than 95% of Americans should have health insurance by 2014.
- 2.** Although some changes are already in place, most physicians won't see the effects of reform until other changes begin in 2014.
- 3.** The law's intent is to move away from the fee-for-service system to a more capitated, risk-sharing system based on paying for performance.
- 4.** The ACA proposes dramatically changing the way Medicare and Medicaid pay doctors and hospitals.
- 5.** The law contains a number of sections aimed at promoting preventive care and improving public health.

The most far-reaching piece of U.S. healthcare legislation since the creation of Medicare 46 years ago, the Patient Protection and Affordable Care Act of 2010 (ACA) aims to reduce the ranks of the uninsured, to slow the rising cost of healthcare, and to reform the nation's healthcare delivery system to improve quality and safety. Yet it's proven to be very controversial: Nearly every day we hear of efforts to repeal, de-fund, invalidate, or otherwise wipe out this landmark law.

Are those efforts really going to stop health reform's multi-year and multifaceted implementation process? The nearly unanimous opinion of health policy experts, Washington watchers,

The BP control and RAAS inhibition of aliskiren

The added, complementary power of amlodipine

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.



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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

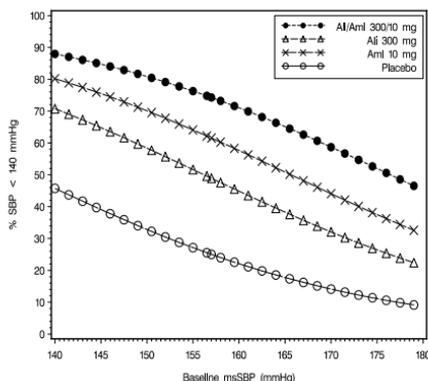


Figure 2: Probability of Achieving Diastolic Blood Pressure (DBP) <90 mmHg

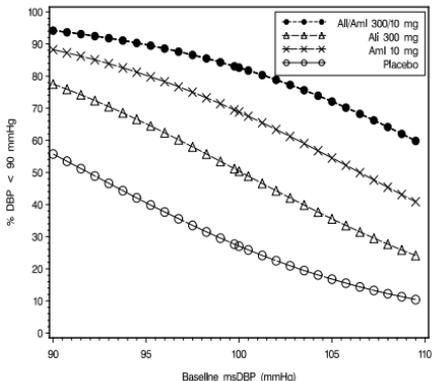


Figure 3: Probability of Achieving Systolic Blood Pressure (SBP) <130 mmHg

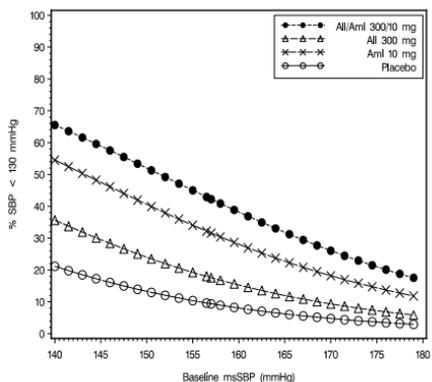
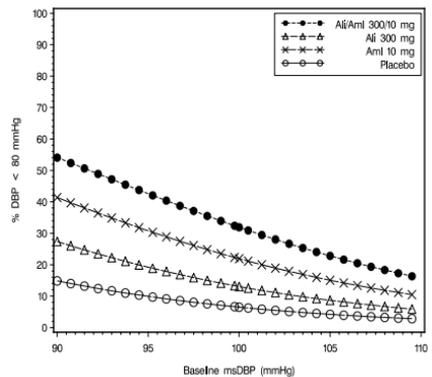


Figure 4: Probability of Achieving Diastolic Blood Pressure (DBP) <80 mmHg



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 $\leq 0.1\%$ 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 $\text{mg}/\text{kg}/\text{day}$ in rats and up to 100 $\text{mg}/\text{kg}/\text{day}$ 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 $\text{mg}/\text{kg}/\text{day}$.) 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/m² 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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healthcare consultants, and medical professional societies is that prudent physicians should prepare for change regardless of whether they occur because of this particular law. “Healthcare—lowercase—is going to change, even if the healthcare—capitalized—law gets repealed,” says Kenneth T. Hertz, a consultant with the Medical Group Management Association’s (MGMA) Health Care Consulting Group in Englewood, Colo. “There is going to be reform no matter what. Successful practices will be the ones that [ask], ‘How can I take advantage of this?’”

This issue of *Doctor’s Digest* will examine what physicians, whose lives and livelihoods stand to be changed forever, should do now to prepare themselves for the dramatic changes inherent in any type of health reform, especially given all the political and logistical unknowns. There is no one-size-fits-all approach to planning for practice post-health reform. How you prepare for health reform depends on whether you are part of a large group or a small one, urban or rural, private or owned by a hospital or health system, and how far along you are in your career.

A ‘Dizzying’ Pace

Jacqueline W. Fincher, MD, a general internist in Thomson, Ga., has a vested interest in reform: She plans to continue practice for many years to come, and her daughter is a pre-med student. Her strategy is to ignore the political uproar but, at the same time, not to tune it out altogether. She is focusing on setting herself up now for the new practice environment that she expects will result from health reform—whether through the ACA or otherwise. “We are trying to be ready for whatever is coming over the next one to five years,” she says. “It is a dizzying pace.” It involves the following:

- Giving up weekends to attend user-group meetings to learn how to meaningfully use the eight-physician practice’s newly installed, state-of-the-art electronic health record (EHR) system.
- Developing checklists to make sure the doctors—four internists and four family physicians—will qualify to be paid for Medicare’s new wellness visits.
- Creating registries and tracking systems to improve quality and to network with local hospitals and nearby physician groups to meet requirements for becoming a patient-centered

medical home (PCMH).

- Exploring the possibilities of future integration and involvement in accountable care organizations (ACOs). (See “What Is an ACO?”)
- Looking constantly at workflow and efficiency, anticipating that an influx of patients from the ACA’s health insurance reforms will tax their already packed schedules.

Dr. Fincher embraces the challenges readily, not just because they are required by the government, but because she says the current system just doesn’t work. “It’s a failed system. It hasn’t been working for years, and it just continues to get worse. Unless you don’t want to be a doctor anymore, you have to start changing,” she says.

Except among the radical fringe, there is no debate about these contentions, and there hasn’t been for decades. The debate is about *how* to control costs, *how* to increase access, and *how* to improve quality. There is also no debate (and there hasn’t been for several decades) that there needs to be more consumerism in healthcare, that patients and payers should be making decisions about their healthcare. A bipartisan consensus that agrees with her says the U.S. healthcare system is bankrupting the country, reaches too few people, and is fraught with quality and safety problems. There is also broad consensus that doctors and hospitals need to be paid differently—not for doing more, but for doing the right amount better.

“There is no question that doctors are going to need to change how they practice because healthcare cost is going to exceed 20% of GDP if nothing changes, and the money we pay for healthcare is not showing up in terms of better health for Americans,” says Kevin Pho, MD, an internist at the St. Joseph Healthcare System-owned Nashua Medical Group in Nashua, N.H. Dr. Pho edits the influential and much-cited *KevinMD.com* medical and health policy blog. An estimated \$2.34 trillion was spent on healthcare in the U.S. in 2008, and the government estimates that healthcare reform will save \$124 billion over 10 years and reduce the federal deficit by half a percent of GDP over the same period. Others contend the law will save little, if anything.

“The big question is how do you transform a country with a lot of doctors practicing in small groups into something more



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integrated” in order to reduce costs, Dr. Pho says. “How doctors adjust to that is going to be a major theme going forward.”

Understanding Key Provisions

Before figuring out a strategy to best prepare you to practice in a reformed healthcare environment, you should first know which provisions in the law may affect you (see “At a Glance: How Health Reform Affects Primary Care”).

Government-directed health reform aims to address a problem that has festered for years because of too many competing interests and physician fragmentation: “We have an imbalance of supply and demand, we have high inflation, we have chronic diseases, we have an underfunded Medicare program, and we have a cottage industry where physicians are paid on a volume-only basis that everyone knows has to change,” explains John R. Thomas, president and CEO of the Irving, Tex.-based MedSynergies consulting firm. As if in direct response to these problems, the ACA is addressing three broad sets of issues relating to healthcare—access, cost, and quality:

Access: By a variety of mechanisms in the new law, more than

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What Is an ACO?

An Accountable Care Organization (ACO) is an organization of healthcare providers—including hospitals, doctors, and health plans, integrated financially or clinically or both—that agrees to be accountable for the quality, cost, and overall care of patients. Although still largely in the experimental stages, ACOs are considered one of the most promising innovations of health reform, capable of transforming the delivery of care. Some say you can think of an ACO as an HMO 2.0.

The concept of an ACO was originally described by Dartmouth health policy expert Elliott Fisher, MD, in a 2007 *Health Affairs* article; since then, others have expanded on the idea. Most experts believe that all ACOs do not have to look the same or be organized similarly, but will depend on local market needs and capabilities. They agree, however, that all ACOs will probably share three essential characteristics: They will provide and manage care across settings. They will have to be big enough to measure and affect performance. And they will have to be able to plan budgets and assess the need for resources.

What is known so far is that ACOs have to promote evidence-based medicine, coordinate care across both inpatient and outpatient realms, and report data that allow for the evaluation of quality and cost of care. An ACO can be made up of providers who are financially integrated (i.e., owned by one entity, like Kaiser Permanente, Geisinger, Mayo, or Group Health), or they can be clinically integrated “virtual” organizations made up of private

95% of Americans should have health insurance by 2014. The most politically contentious means to that goal is the individual mandate. Other less controversial ways of increasing access are financial assistance for employers (but no employer mandate), state health insurance-purchasing exchanges (but no “public option”), expansion of public programs like Medicaid, and revised rules affecting how insurance companies do business.

In 2009, the uninsured population in the U.S. had reached 50.7 million, according to the Census Bureau. Meanwhile, the percentage of Americans getting their health insurance through their employment dropped to the lowest level (55.8%) since the government started tracking it nearly 25 years ago while the percentage of people covered by government health programs—i.e., Medicare and Medicaid—increased to the highest level ever (30.6%), with more people in Medicaid than in Medicare.

physicians linked through IPAs, PHOs, and local hospitals all sharing clinical decision support, quality reporting systems, pay-for performance programs, registries, patient outreach programs, and/or any other standardized system of coordinated care or quality improvement.

Many providers interested in setting themselves up as ACOs are treading lightly, if at all, these days because of concerns that they could run afoul of antitrust and anti-kickback rules as well as bans on self-referral. The 429-page proposed regulation defining ACOs and the Medicare Shared Savings Program of the ACA was released by Centers for Medicare & Medicaid Services (CMS) on March 31. Comments are being accepted on its provisions until June 6, and a final rule will be issued later this year.

The ACA includes demonstration projects to test and evaluate new care delivery and payment models for Medicare, including medical homes, bundled payments, and ACOs. Under the ACA, starting in 2012, a Medicare ACO that furnishes efficient, high-quality care to Medicare patients will share in Medicare's savings. Also under the ACA, a Medicare ACO can pool and redistribute payments from Medicare Parts A and B in a variety of innovative ways; but it will share in savings only if it can lower expenditures for the beneficiaries assigned to it below the expenditures for the same beneficiaries over the previous three years before entering a three-year ACO pilot program.

Some provisions regarding access have already taken effect. These include prohibitions against insurance plans' denying coverage for children with preexisting conditions and against insurance providers' setting lifetime limits on payouts. People who are uninsured because of preexisting conditions can now get insurance through a temporary high-risk pool. Small businesses can receive a tax credit to help toward the cost of buying health insurance for their lower-wage employees. Health plans also have to cover dependent children of policyholders until they reach age 26.

Thomas G. Zimmerman, DO, has already seen this change in action: A young woman patient in his largely Medicaid- and charity-care primary care clinic at South Nassau Communities Hospital in Oceanside, N.Y., who hadn't been able to find care anywhere else, has now been able to go back onto her parent's

At a Glance: How Health Reform Affects Primary Care

- ✓ Temporary 10% incentive payments for primary care physicians
- ✓ Increased geographic payment for physicians in rural and low-cost payment areas
- ✓ Expanded Medicare quality-reporting measures and incentives, then penalties for not participating in PQRS
- ✓ Increased Medicaid payments to primary care physicians
- ✓ Streamlined insurance claim-processing requirements
- ✓ Demonstration grants for alternative medical-malpractice initiatives, but no significant malpractice reform
- ✓ Expanded preventive care to be paid for by Medicare and Medicaid
- ✓ Elimination of the Medicare Part D prescription drug “donut hole”
- ✓ New Patient-Centered Outcomes Research Institute to compare clinical effectiveness of medical treatments
- ✓ Small-business tax credits
- ✓ Expanded reporting on physician performance
- ✓ New Independent Payment Advisory Board to propose reductions in Medicare costs
- ✓ New CMS Center for Innovation to promote medical home and other care-coordination models of care delivery
- ✓ New bundled-payment, shared-savings program (for pilot-testing ACOs), interprofessional health teams, and gain-sharing demonstrations
- ✓ Incentives to expand primary care workforce

coverage. “That’s great,” he says, noting that few doctors outside clinics like his will treat patients who lack private insurance or Medicare. “We have long waiting lists here, and if we have to send patients to the county hospital for specialties here who don’t accept Medicaid or charity—like orthopedics—patients might have to wait for several months; [and] we never get a report back.”

Still, most physicians won’t see the effects of reform until the more dramatic changes begin in 2014. That’s when the individual mandate starts; it’s also the deadline for states to have created health insurance exchanges to help people without employer-pro-

vided insurance to buy policies, which will be made more affordable by government tax credits for low- and middle-income Americans. Businesses with 50 or more workers will be assessed a penalty if they don't provide insurance and their workers have to resort to the new exchanges to get coverage.

Cost: To slow the rate of growth in how much the nation spends on healthcare, the ACA proposes dramatically changing the way Medicare and Medicaid pay doctors and hospitals. The law calls for several years of pilots, demonstrations, and experiments to develop diverse models. The intent is to move away from the fee-for-service system to a more bundled, or capitated, risk-sharing system based on paying for performance. To that end, the law encourages hospitals and doctors to come together to create ACOs.

In addition, since 10% of patients account for nearly two-thirds of total healthcare costs, the law recognizes that the only way to reduce costs over the long term is by coordinating care to prevent avoidable complications for patients with chronic illness. Cost controls in the bill, therefore, intersect with quality control initiatives, such as medical homes and team-based care.

The law also addresses costs by the following means:

- delineating certain direct cuts from some Medicare payments, such as those made to private health insurance plans in Medicare (i.e., Medicare Advantage plans);
- making it easier to go after practitioners and suppliers who cheat Medicare and Medicaid and to recoup money lost to fraud and abuse;
- imposing payment penalties on hospitals with high risk-adjusted readmission rates; and
- creating incentives for hospitals to reduce their rates of hospital-acquired infections and other avoidable conditions. Hospi-

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tals that continue to have rates within the top 25% will face reductions in their Medicare and Medicaid payments.

According to Mark W. Browne, MD, a med-peds physician and consultant specializing in healthcare quality with Pershing Yoakley & Associates in Knoxville, Tenn., and faculty member for the American College of Physician Executives (ACPE), many cost-control clauses in the health reform law are complex because they are meant in many instances to accomplish several goals at once. “Penalties are going to be relative, meaning that in a healthcare reform world, not only do you have to do well, but you have to do better than everybody else,” he says. “You might do the right thing; but if most people do the right thing better, you might not get paid at all.”

The Obama administration has said that one of the most important cost-control mechanisms in the law is the establishment of the Independent Payment Advisory Board (IPAB), an independent panel of medical experts. Starting in 2014, that panel will propose policies for reducing costs if Medicare’s per capita costs exceed a certain threshold. The secretary of the U.S. Department of Health & Human Services (HHS) must institute these policies unless Congress enacts alternative policies leading to equivalent savings. This is one of the most controversial clauses in the law and is considered at greatest risk of being repealed by Congress.

To finance the reforms, the government will tax the most expensive employer-sponsored plans. Beginning in 2013, high-salaried workers will pay more in Medicare payroll taxes; and there will be a new Medicare payroll tax on unearned income such as stock dividends and capital gains. As high-income earners, many physicians will face this added tax burden.

Quality: The law contains a number of sections aimed at promoting preventive care, improving public health, and providing patients with information on health decisions and disease prevention. It will pay doctors to report—and in later years, penalize doctors who don’t—on the quality of the care they provide. (This will be done through an expanded Medicare’s Patient Quality Reporting System [PQRS].)

The ACA also includes some small fixes in the Medicare system, such as filling the prescription drug “donut hole” by 2020,

and bigger ones, like paying for an annual wellness visit that doesn't include co-pays or deductibles for seniors. It also creates a new Medicare and Medicaid Center on Innovation to jumpstart trials of innovative payment-and-delivery-system reforms, including medical home models. There are grant programs to support "interprofessional" teams and collaborative care.



“Nobody wants to call this capitation or managed care because that got a bad name a decade ago, but [what health reform is calling for] is basically risk-for-care, which is shifting from employers and insurers onto providers. It is getting dressed up in different clothes, but it’s the same.”

Jonathan M. Niloff, MD, MBA
 Founder and Chief Medical Officer
 MedVentive Inc.
 Boston

Workforce Reform

Since access, cost, and quality are all affected by real and projected healthcare workforce shortages, the law also contains a number of provisions that will affect medical and nursing education, training programs, and career choices. The mismatch between supply and demand in the workforce, particularly as the population ages and the nation's problem with chronic diseases grows, is partly to blame for the steep curve occurring in healthcare cost inflation.

Here's how the ACA addresses this issue:

- It expands loan repayment programs and the National Health Service Corps.
- It sets up a national workforce commission to recommend ways of meeting the demand for healthcare workers and for eliminating barriers to primary care careers.
- Starting this year, it allows unused residency slots to be redistributed to hospitals who agree to use the new slots for primary care and general surgery.
- In 2013-2014, the law will increase Medicaid payments for many primary care services to equal those of Medicare in an

effort to encourage more doctors to treat Medicaid patients.

- Starting this year and continuing through 2015, it gives existing primary care physicians a 10% bonus for designated primary care services they provide in outpatient and nursing home settings so long as at least 60% of their Medicare work is for primary care.

“I have the sense that the Affordable Care Act has turned on a light bulb in the area of preventive care,” says Charles Cutler, MD, a general internist in Norristown, Pa., and chair of the American College of Physicians’ (ACP) Board of Governors. “I think health reform acted as a stimulus, a really potent reminder that [prevention] is important in the delivery of healthcare.”

Political Uncertainty

The ACA is now the law of the land; many of its provisions are being implemented; and many payers, providers, and patients are proceeding with the assumption that these provisions will continue. But some physicians are hesitating to begin or continue changes they may have made a year ago when the law was newly inked, given the 2010 election results, the court battles, and the budget debate.

“A doctor needs the wisdom of Solomon to know what the right thing to do is at this point,” Dr. Cutler says. Should a small practice invest in expensive information technology? Should it be talking to its local hospital? Should it merge with others? Should it change the way it operates? Is it time to start thinking about retirement or time to hire younger doctors or mid-level practitioners? Or should it maintain the status quo assuming that little will change in the short term?

Dr. Cutler says his practice is answering some of these questions by participating in Medicare’s quality reporting program, a step he figures will help them provide better patient care regardless of future reform measures. He is, however, holding off on investing in a full-scale EHR system, which places him within the 14% of physicians surveyed by the Centers for Disease Control (CDC) last year who reported that they were not planning to apply for the government’s current financial incentives to go electronic. (The EHR incentives are in the HITECH portion of the American Recovery and Reinvestment Act

[ARRA], generally known as the stimulus bill, and not the ACA; but most consider them an integral part of health reform.)

Although many are taking a wait-and-see approach, Jonathan M. Niloff, MD, MBA, founder and chief medical officer of Med-Ventive Inc., in Boston, an early ACO that developed out of the CareGroup Healthcare System and Beth Israel Deaconess Medical Center, recommends that practices go all out to prepare. “Nobody wants to call this capitation or managed care because that got a bad name a decade ago, but [what health reform is calling for] is basically risk-for-care, which is shifting from employers and insurers onto providers. It is getting dressed up in different clothes, but it’s the same,” Dr. Niloff says.

In reality, he says, a small practice doing this alone “is going to be killed. ... They need to get enough of them together [to form] a big enough pool of patients to have some actuarial risk stability, and they need a sufficiently organized structure that they are working together. And if their risk includes hospital risk, they need to get themselves aligned with their partner hospitals,” he says.

While only time will tell which strategies for coping with health reform were the right ones, nearly everyone agrees that the political debate over Health Reform—uppercase—is unlikely to change health reform—lowercase—in a significant way. Cecil B. Wilson, MD, president of AMA and an internist in Winter Park, Fla., suggests that doctors should not wait to see how it all ends up to begin examining their practice. “If we don’t make a change, what’s bad now [for physicians] will only continue to get worse. We have made the case that healthcare is not a Democratic or a Republican issue. It’s an issue for all of us, and it should not be caught up in partisan politics.”