EHRs: Making Your Move

Chapter FastFACTS

1. **The real value of an EHR is its ability to manage data.**
2. **Qualifying physicians can earn up to $44,000 each over five years in Medicare bonus payments if they demonstrate that they are meaningfully using an EHR system.**
3. **Waiting to buy an EHR system would spread out costs over time and help ensure that your vendor meets meaningful-use criteria.**
4. **Selecting a certified vendor will ensure that your system meets all the major product standards objectives.**
5. **Choosing an EHR system based on its ability to meet your practice's needs is critical.**

Richard J. Baron, MD, an internist at Greenhouse Internists in Philadelphia, increasingly finds he can interact effectively with his patients without ever seeing them face-to-face. During one week last fall, for example, a patient with diabetes e-mailed a high-quality photo of skin changes on his foot; Dr. Baron diagnosed athlete's foot and recommended over-the-counter treatment. Another patient sent a pdf file of a pre-operative form that Dr. Baron completed and returned by e-mail. Still another sent an e-mail to report that her sister had just been diagnosed with a rare genetic disorder and asked if she should be screened for the disease.

These remote visits go beyond simple e-mail communication. Greenhouse's Website has a secure server that integrates all patient-physician e-mails with the practice's electronic health

For the treatment of hypertension

BYSTOLIC.

Significant blood pressure reductions with a low incidence of side effects.[1-3]

Bystolic®
(nebivolol) tablets
www.BYSTOLIC.com

Important Safety Information

Patients being treated with BYSTOLIC should be advised against abrupt discontinuation of therapy. Severe exacerbation of angina and the occurrence of myocardial infarction and ventricular arrhythmias have been reported following the abrupt cessation of therapy with beta blockers. When discontinuation is planned, the dosage should be reduced gradually over a 1- to 2-week period and the patient carefully monitored.

BYSTOLIC is contraindicated in severe bradycardia, heart block greater than first degree, cardiogenic shock, decompensated cardiac failure, sick sinus syndrome (unless a permanent pacemaker is in place), severe hepatic impairment (Child-Pugh >B), and in patients who are hypersensitive to any component of this product.

BYSTOLIC should be used with caution in patients with peripheral vascular disease, thyrotoxicosis, in patients treated concomitantly with beta blockers and calcium channel blockers of the verapamil and diltiazem type (ECG and blood pressure should be monitored), severe renal impairment, and any degree of hepatic impairment or in patients undergoing major surgery. In patients who have compensated congestive heart failure, BYSTOLIC should be administered cautiously. If heart failure worsens, discontinuation of BYSTOLIC should be considered. Caution should also be used in diabetic patients as beta blockers may mask some of the manifestations of hypoglycemia, particularly tachycardia.

Use caution when BYSTOLIC is co-administered with CYP2D6 inhibitors (quinidine, propafenone, fluoxetine, paroxetine, etc). When BYSTOLIC is administered with fluoxetine, significant increases in d-nebivolol may be observed (ie, an 8-fold increase in AUC).

In general, patients with bronchospastic disease should not receive beta blockers.

BYSTOLIC should not be combined with other beta blockers.

The most common adverse events with BYSTOLIC versus placebo (approximately ≥1% and greater than placebo) were headache, fatigue, dizziness, diarrhea, nausea, insomnia, chest pain, bradycardia, dyspnea, rash, and peripheral edema.

Forest Pharmaceuticals, Inc.
Pharmaceuticals • Therapeutics • Healthcare • Ethicare • Managed Care • Specialty Sales

Please see brief summary of Prescribing Information on adjacent page.

References: 1. BYSTOLIC [package insert]. St. Louis, Mo: Forest Pharmaceuticals, Inc.; 2008. **2.** Data on file. Forest Laboratories, Inc. **3.** Saunders E, Smith WB, DeSalvo KB, Sullivan WA. The efficacy and tolerability of nebivolol in hypertensive African American patients. *J Clin Hypertens.* 2007;9:866-875.

 44-1014950 01/09

Bystolic®
(nebivolol) tablets
2.5 mg, 5 mg, 10 mg and 20 mg

Rx Only

Brief Summary: For complete details please see full Prescribing Information for BYSTOLIC.

INDICATIONS AND USAGE
BYSTOLIC is indicated for the treatment of hypertension. BYSTOLIC may be used alone or in combination with other antihypertensive agents.

CONTRAINDICATIONS
BYSTOLIC is contraindicated in patients with severe bradycardia, heart block greater than first degree, cardiogenic shock, decompensated cardiac failure, sick sinus syndrome (unless a permanent pacemaker is in place), or severe hepatic impairment (Child-Pugh >B), and in patients who are hypersensitive to any component of this product.

WARNINGS
Abrupt Cessation of Therapy
Patients with coronary artery disease treated with BYSTOLIC should be advised against abrupt discontinuation of therapy. Severe exacerbation of angina and the occurrence of myocardial infarction and ventricular arrhythmias have been reported in patients with coronary artery disease following the abrupt discontinuation of therapy with β-blockers. Myocardial infarction and ventricular arrhythmias may occur with or without preceding exacerbation of the angina pectoris. Even patients without overt coronary artery disease should be cautioned against interruption or abrupt discontinuation of therapy. As with other β-blockers, when discontinuation of BYSTOLIC is planned, patients should be carefully observed and advised to minimize physical activity. BYSTOLIC should be tapered over 1 to 2 weeks when possible. If the angina worsens or acute coronary insufficiency develops, it is recommended that BYSTOLIC be promptly reinstituted, at least temporarily.

Cardiac Failure
Sympathetic stimulation is a vital component supporting circulatory function in the setting of congestive heart failure, and β-blockade may result in further depression of myocardial contractility and precipitate more severe failure. In patients who have compensated congestive heart failure, BYSTOLIC should be administered cautiously. If heart failure worsens, discontinuation of BYSTOLIC should be considered.

Angina and Acute Myocardial Infarction
BYSTOLIC was not studied in patients with angina pectoris or who had a recent MI.

Bronchospastic Diseases
In general, patients with bronchospastic diseases should not receive β-blockers.

Anesthesia and Major Surgery
If BYSTOLIC is to be continued perioperatively, patients should be closely monitored when anesthetic agents which depress myocardial function, such as ether, cyclopropane, and trichloroethylene, are used. If β-blocking therapy is withdrawn prior to major surgery, the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures.

The β-blocking effects of BYSTOLIC can be reversed by β-agonists, e.g., dobutamine or isoproterenol. However, such patients may be subject to protracted severe hypotension. Additionally, difficulty in restarting and maintaining the heartbeat has been reported with β-blockers.

Diabetes and Hypoglycemia
β-blockers may mask some of the manifestations of hypoglycemia, particularly tachycardia. Nonselective β-blockers may potentiate insulin-induced hypoglycemia and delay recovery of serum glucose levels. It is not known whether nebivolol has these effects. Patients subject to spontaneous hypoglycemia, or diabetic patients receiving insulin or oral hypoglycemic agents, should be advised about these possibilities and nebivolol should be used with caution.

Thyrotoxicosis
β-blockers may mask clinical signs of hyperthyroidism, such as tachycardia. Abrupt withdrawal of β-blockers may be followed by an exacerbation of the symptoms of hyperthyroidism or may precipitate a thyroid storm.

Peripheral Vascular Disease
β-blockers can precipitate or aggravate symptoms of arterial insufficiency in patients with peripheral vascular disease. Caution should be exercised in these patients.

Non-dihydropyridine Calcium Channel Blockers
Because of significant negative inotropic and chronotropic effects in patients treated with β-blockers and calcium channel blockers of the verapamil and diltiazem type, caution should be used in patients treated concomitantly with these agents and ECG and blood pressure should be monitored.

PRECAUTIONS
Use with CYP2D6 Inhibitors
Nebivolol exposure increases with inhibition of CYP2D6 (see **Drug Interactions**). The dose of BYSTOLIC may need to be reduced.

Impaired Renal Function
BYSTOLIC should be used with caution in patients with severe renal impairment because of decreased renal clearance. BYSTOLIC has not been studied in patients receiving dialysis.

Impaired Hepatic Function
BYSTOLIC should be used with caution in patients with moderate hepatic impairment because of decreased metabolism. Since BYSTOLIC has not been studied in patients with severe hepatic impairment, BYSTOLIC is contraindicated in this population (see **CLINICAL PHARMACOLOGY, Special Populations** and **DOSAGE AND ADMINISTRATION**).

Risk of Anaphylactic Reactions
While taking β-blockers, patients with a history of severe anaphylactic reactions to a variety of allergens may be more reactive to repeated challenge either accidental, diagnostic, or therapeutic. Such patients may be unresponsive to the usual doses of epinephrine used to treat allergic reactions.

In patients with known or suspected pheochromocytoma, an α-blocker should be initiated prior to the use of any β-blocker.

Information for Patients
Patients should be advised to take BYSTOLIC regularly and continuously, as directed. BYSTOLIC can be taken with or without food. If a dose is missed, the patient should take the next scheduled dose only (without doubling it). Patients should not interrupt or discontinue BYSTOLIC without consulting the physician.

Patients should know how they react to this medicine before they operate automobiles, use machinery, or engage in other tasks requiring alertness.

Patients should be advised to consult a physician if any difficulty in breathing occurs, or if they develop signs or symptoms of worsening congestive heart failure such as weight gain or increasing shortness of breath, or excessive bradycardia.

Patients subject to spontaneous hypoglycemia, or diabetic patients receiving insulin or oral hypoglycemic agents, should be cautioned that β-blockers may mask some of the manifestations of hypoglycemia, particularly tachycardia. Nebivolol should be used with caution in these patients.

Drug Interactions
BYSTOLIC should be used with care when myocardial depressants or inhibitors of AV conduction, such as certain calcium antagonists (particularly of the phenylalkylamine [verapamil] and benzothiazepine [diltiazem] classes), or antiarrhythmic agents, such as disopyramide, are used concurrently. Both digitalis glycosides and β-blockers slow atrioventricular conduction and decrease heart rate. Concomitant use can increase the risk of bradycardia.

BYSTOLIC should not be combined with other β-blockers. Patients receiving catecholamine-depleting drugs, such as reserpine or guanethidine, should be closely monitored, because the added β-blocking action of BYSTOLIC may produce excessive reduction of sympathetic activity. In patients who are receiving BYSTOLIC and clonidine, BYSTOLIC should be discontinued for several days before the gradual tapering of clonidine.

CYP2D6 Inhibitors: Use caution when BYSTOLIC is co-administered with CYP2D6 inhibitors (quinidine, propafenone, fluoxetine, paroxetine, etc.) (see **CLINICAL PHARMACOLOGY, Drug Interactions**).

Carcinogenesis, Mutagenesis, Impairment of Fertility
In a two-year study of nebivolol in mice, a statistically significant increase in the incidence of testicular Leydig cell hyperplasia and adenomas was observed at 40 mg/kg/day (5 times the maximally recommended human dose of 40 mg on a mg/m^2 basis). Similar findings were not reported in mice administered doses equal to approximately 0.3 or 1.2 times the maximum recommended human dose. No evidence of a tumorigenic effect was observed in a 24-month study in Wistar rats receiving doses of nebivolol 2.5, 10 and 40 mg/kg/day (equivalent to 0.6, 2.4, and 10 times the maximally recommended human dose). Co-administration of dihydrotestosterone reduced blood LH levels and prevented the Leydig cell hyperplasia, consistent with an indirect LH-mediated effect of nebivolol in mice and not thought to be clinically relevant in man.

A randomized, double-blind, placebo- and active-controlled, parallel-group study in healthy male volunteers was conducted to determine the effects of nebivolol on adrenal function, luteinizing hormone, and testosterone levels. This study demonstrated that 6 weeks of daily dosing with 10 mg of nebivolol had no significant effect on ACTH-stimulated mean serum cortisol $AUC_{0\text{-}120\ min}$, serum LH, or serum total testosterone.

Effects on spermatogenesis were seen in male rats and mice at ≥40 mg/kg/day (10 and 5 times the MRHD, respectively). For rats the effects on spermatogenesis were not reversed and may have worsened during a four-week recovery period. The effects of nebivolol on sperm in mice, however, were partially reversible.

Mutagenesis: Nebivolol was not genotoxic when tested in a battery of assays (Ames, *in vitro* mouse lymphoma $TK^{+/-}$, *in vitro* human peripheral lymphocyte chromosome aberration, *in vivo* Drosophila melanogaster sex-linked recessive lethal, and *in vivo* mouse bone marrow micronucleus tests).

Pregnancy: Teratogenic Effects. Pregnancy Category C:
Decreased pup body weights occurred at 1.25 and 2.5 mg/kg in rats, when exposed during the perinatal period (late gestation, parturition and lactation). At 5 mg/kg and higher doses (1.2 times the MRHD), prolonged gestation, dystocia and reduced maternal care were produced with corresponding increases in late fetal deaths and stillbirths and decreased birth weight, live litter size and pup survival. Insufficient numbers of pups survived at 5 mg/kg to evaluate the offspring for reproductive performance.

In studies in which pregnant rats were given nebivolol during organogenesis, reduced fetal body weights were observed at maternally toxic doses of 20 and 40 mg/kg/day (5 and 10 times the MRHD), and small reversible delays in sternal and thoracic ossification associated with the reduced fetal body weights and a small increase in resorption occurred at 40 mg/kg/day (10 times the MRHD). No adverse effects on embryo-fetal viability, sex, weight or morphology were observed in studies in which nebivolol was given to pregnant rabbits at doses as high as 20 mg/kg/day (10 times the MRHD).

Labor and Delivery

Nebivolol caused prolonged gestation and dystocia at doses ≥5 mg/kg in rats (1.2 times the MRHD). These effects were associated with increased fetal deaths and stillborn pups, and decreased birth weight, live litter size and pup survival rate, events that occurred only when nebivolol was given during the perinatal period (late gestation, parturition and lactation).

No studies of nebivolol were conducted in pregnant women. BYSTOLIC should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

Studies in rats have shown that nebivolol or its metabolites cross the placental barrier and are excreted in breast milk. It is not known whether this drug is excreted in human milk.

Because of the potential for β-blockers to produce serious adverse reactions in nursing infants, especially bradycardia, BYSTOLIC is not recommended during nursing.

Geriatric Use

Of the 2800 patients in the U.S.-sponsored placebo-controlled clinical hypertension studies, 478 patients were 65 years of age or older. No overall differences in efficacy or in the incidence of adverse events were observed between older and younger patients.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established. Pediatric studies in ages newborn to 18 years old have not been conducted because of incomplete characterization of developmental toxicity and possible adverse effects on long-term fertility (see **Carcinogenesis, Mutagenesis, and Impairment of Fertility**).

ADVERSE REACTIONS

The data described below reflect worldwide clinical trial exposure to BYSTOLIC in 6545 patients, including 5038 patients treated for hypertension and the remaining 1507 subjects treated for other cardiovascular diseases. Doses ranged from 0.5 mg to 40 mg. Patients received BYSTOLIC for up to 24 months, with over 1900 patients treated for at least 6 months, and approximately 1300 patients for more than one year. In placebo-controlled clinical trials comparing BYSTOLIC with placebo, discontinuation of therapy due to adverse events was reported in 2.8% of patients treated with nebivolol and 2.2% of patients given placebo. The most common adverse events that led to discontinuation of BYSTOLIC were headache (0.4%), nausea (0.2%) and bradycardia (0.2%).

Adverse Reactions in Controlled Trials

Table 1 lists treatment-emergent signs and symptoms that were reported in three 12-week, placebo-controlled monotherapy trials involving 1597 hypertensive patients treated with either 5 mg, 10 mg or 20-40 mg of BYSTOLIC and 205 patients given placebo and for which the rate of occurrence was at least 1% of patients treated with nebivolol and greater than the rate for those treated with placebo in at least one dose group.

Table 1. Treatment-Emergent Adverse Events with an Incidence (over 6 weeks) ≥1% in BYSTOLIC-Treated Patients and at a Higher Frequency than Placebo-Treated Patients

	Placebo (n = 205) (%)	Nebivolol 5 mg (n = 459) (%)	Nebivolol 10 mg (n = 461) (%)	Nebivolol 20-40 mg (n = 677) (%)
Headache	6	9	6	7
Fatigue	1	2	2	5
Dizziness	2	2	3	4
Diarrhea	2	2	2	3
Nausea	0	1	3	2
Insomnia	0	1	1	1
Chest pain	0	0	1	1
Bradycardia	0	0	0	1
Dyspnea	0	0	1	1
Rash	0	0	1	1
Peripheral edema	0	1	1	1

Other Adverse Events Observed During Worldwide Clinical Trials

Listed below are other reported adverse events with an incidence of at least 1% in the more than 5300 patients treated with BYSTOLIC in controlled or open-label trials, whether or not attributed to treatment, except for those already appearing in **Table 1**, terms too general to be informative, minor symptoms, or events unlikely to be attributable to drug because they are common in the population. These adverse events were in most cases observed at a similar frequency in placebo-treated patients in the controlled studies.

Body as a Whole: asthenia.

Gastrointestinal System Disorders: abdominal pain

Metabolic and Nutritional Disorders: hypercholesterolemia and hyperuricemia

Nervous System Disorders: paraesthesia

Laboratory

In controlled monotherapy trials, BYSTOLIC was associated with an increase in BUN, uric acid, triglycerides and a decrease in HDL cholesterol and platelet count.

Events Identified from Spontaneous Reports of BYSTOLIC Received Worldwide

The following adverse events have been identified from spontaneous reports of BYSTOLIC received worldwide and have not been listed elsewhere. These adverse events have been chosen for inclusion due to a combination of seriousness, frequency of reporting or potential causal connection to BYSTOLIC. Events common in the population have generally been omitted. Because these events were reported voluntarily from a population of uncertain size, it is not possible to estimate their frequency or establish a causal relationship to BYSTOLIC exposure: abnormal hepatic function (including increased AST, ALT and bilirubin), acute pulmonary edema, acute renal failure, atrioventricular block (both second- and third-degree), bronchospasm, erectile dysfunction, hypersensitivity (including urticaria, allergic vasculitis and rare reports of angioedema), myocardial infarction, pruritus, psoriasis, Raynaud's phenomenon, peripheral ischemia/claudication, somnolence, syncope, thrombocytopenia, various rashes and skin disorders, vertigo, and vomiting.

OVERDOSAGE

In clinical trials and worldwide postmarketing experience there were reports of BYSTOLIC overdose. The most common signs and symptoms associated with BYSTOLIC overdosage are bradycardia and hypotension. Other important adverse events reported with BYSTOLIC overdose include cardiac failure, dizziness, hypoglycemia, fatigue and vomiting. Other adverse events associated with β-blocker overdose include bronchospasm and heart block.

The largest known ingestion of BYSTOLIC worldwide involved a patient who ingested up to 500 mg of BYSTOLIC along with several 100 mg tablets of acetylsalicylic acid in a suicide attempt. The patient experienced hyperhidrosis, pallor, depressed level of consciousness, hypokinesia, hypotension, sinus bradycardia, hypoglycemia, hypokalemia, respiratory failure and vomiting. The patient recovered.

Due to extensive drug binding to plasma proteins, hemodialysis is not expected to enhance nebivolol clearance.

If overdose occurs, BYSTOLIC should be stopped and general supportive and specific symptomatic treatment should be provided. Based on expected pharmacologic actions and recommendations for other β-blockers, the following general measures should be considered when clinically warranted:

Bradycardia: Administer IV atropine. If the response is inadequate, isoproterenol or another agent with positive chronotropic properties may be given cautiously. Under some circumstances, transthoracic or transvenous pacemaker placement may be necessary.

Hypotension: Administer IV fluids and vasopressors. Intravenous glucagon may be useful.

Heart Block (second or third degree): Patients should be carefully monitored and treated with isoproterenol infusion. Under some circumstances, transthoracic or transvenous pacemaker placement may be necessary.

Congestive Heart Failure: Initiate therapy with digitalis glycoside and diuretics. In certain cases, consideration should be given to the use of inotropic and vasodilating agents.

Bronchospasm: Administer bronchodilator therapy such as a short-acting inhaled β_2-agonist and/or aminophylline.

Hypoglycemia: Administer IV glucose. Repeated doses of IV glucose or possibly glucagon may be required.

In the event of intoxication where there are symptoms of shock, treatment must be continued for a sufficiently long period consistent with the 12-19 hour effective half-life of BYSTOLIC. Supportive measures should continue until clinical stability is achieved.

Call the National Poison Control Center (800-222-1222) for the most current information on β-blocker overdose treatment.

Forest Pharmaceuticals, Inc.
Subsidiary of Forest Laboratories, Inc.
St. Louis, MO 63045, USA
Licensed from Mylan Laboratories, Inc.
Under license from Janssen
Pharmaceutica N.V., Beerse, Belgium

Rev. 8/08

record (EHR) system. (While the terms "electronic health record" and "electronic medical record" are often used interchangeably, EHR is now the more widely accepted term used by government and other agencies to refer to computerized records.) That means that whenever Dr. Baron or another of the practice's four physicians sends or receives an e-mail, it's automatically copied to the patient's EHR. Documents such as test results and images are easily attached to e-mails, and physicians sign prescriptions electronically. As a result, the office staff rarely mails out paperwork; and patients don't have to visit the office to pick up forms.

Greenhouse is part of a growing minority of small practices that are realizing the promise of EHRs and other technologies. While Dr. Baron and his colleagues say they would never return to the days of paper files, they acknowledge that the transition hasn't been easy. Systems run smoothly at the practice these days, but the staff has had five years to adjust to the EHR. Now, with small- to medium-size offices under increasing pressure to incorporate technology into their practices, Dr. Baron is happy that he got on board early.

"People look at the expense [of buying an EHR system]—and it is high, but the really huge expense is implementing it," Dr. Baron says. "But none of us wanted to go back [to paper] after we first implemented EHRs, and that's 20 times truer today."

Other practices are thinking about getting on board, inspired by recent government incentives and regulations that could jump-start wide-scale adoption of EHRs and trigger a long-overdue technological revolution in medicine. Even if you're among those waiting for the details to shake out, it's time to understand EHRs' potential and the options for your practice. While some practices, like Greenhouse, may feel ready to look at how the many facets of technology can work for their practice, others may feel most comfortable starting slowly, perhaps by initiating electronic prescribing (e-prescribing) or creating a more patient-friendly Website.

No matter your comfort level, it's inevitable that your practice will undergo some sort of technological change or, at the very least, plan for one. In this issue of *Doctor's Digest* we'll ease that process by showing you what those options are: Chapters 1

and 2 are devoted to EHRs, probably your greatest concern, and the various ways these changes can improve patient care and affect the long-term success of your practice.

A New World of Information

At first, EHRs may seem like little more than a way to computerize your paper files. But that's only the starting point; adopting EHRs will open a new world of information management, exchange, and access that can lead to an efficient, patient-centered practice.

To get an idea of that value, here are two past winners of the Healthcare Information and Management Systems Society's (HIMSS) Davies Awards of Excellence, given to providers that successfully use technology to improve patient care:

Valdez Family Clinic in San Antonio, Tex., a solo-physician practice, won a Davies award in 2007. As a result of implementing the EHR, the practice went virtually paperless. Billing increased $21.93 per patient visit, and the clinic saved $31,000 a year by moving billing in-house. The anticipated increase in net revenue for the first year was $187,118.

Riverpoint Pediatrics in Chicago, a solo-physician practice with three nurses and five other staff members, won a Davies primary care award in 2004. After adopting EHRs, the practice decreased the average wait time by 36 minutes (40%); reduced time to refill prescriptions from between 24 and 48 hours to 15 minutes; boosted immunization rates from 50% to 95%; and reduced physician response time to phone inquiries from 24 hours to 15 minutes. Over four years, Riverpoint increased collection rates from 52% to 88%, grew its patient base by 100%, and boosted both revenue and profit by about 90%.

"The problem most doctors think they're trying to solve when they adopt EHRs is the generation of a progress note," Dr. Baron says. "People believe that the progress note is the primary care product because that's how the Medicare payment system

works—it's based on how many organ systems you asked about or how many body parts you touched." But generating notes uses only the word-processing capacity of the EHR when the real value of the system is its ability to manage data, he says.

Building the Foundation

Despite the potential of EHRs, primary care offices have been slow to embrace the technology. According to preliminary estimates of the 2009 National Ambulatory Medical Care Survey conducted by the National Center for Health Statistics, almost 44% of office-based physicians reported using full or partial EHRs, up from 41.5% in 2008 and 34% in 2007. However, only 6.3% said they had fully functional EHRs while 20.5% had basic systems, defined as including demographics, problem lists, clinical notes, prescription orders, and lab and imaging results but excluding more advanced features such as medical history and follow-up, electronic prescribing, and warnings and alerts.

One explanation is that even if you embrace the idea of technology for your practice in theory, you may still worry about the financial and time commitments necessary to successfully implement an EHR system. Until recently those concerns had merit: Little help has been available in overcoming those obstacles. But the passage of the American Recovery and Reinvestment Act (ARRA) of 2009 has changed the playing field by allowing physicians to qualify for significant financial incentives to purchase EHRs.

How the Federal Incentives Work

ARRA offers long-awaited financial help for small practices—if they comply with certain standards and timelines. The legislation, which dedicates more than $19 billion to health information technology (HIT), allows qualifying physicians to earn up to $44,000 per physician over five years in Medicare bonus payments if they demonstrate that they are meaningfully using an EHR system. But the bonuses disappear in 2016. Moreover, starting in 2015, physicians who don't have EHRs will face a 1% cut in Medicare reimbursements, rising to 2% in 2016 and 3% in 2017 and thereafter (see "The Move to EHRs: The Stimulus Package's Incentives," p. 16).

In general, physicians can receive the maximum incentive payment of $18,000 only in payment years 2011 or 2012. However, the Centers for Medicare and Medicaid Services (CMS) gives providers a break in their first year of using a new system. During that year only, physicians are eligible for payments if they report on "meaningful use" of an EHR for a continuous 90-day period anytime during that year; after that, the required reporting period expands to a full year. After 2012, maximum payments in the first, second, third, fourth, and fifth years are $15,000, $12,000, $8,000, $4,000, and $2,000, respectively. Financial incentives are 10% more for physicians who practice in areas with a shortage of providers.

Although these financial incentives are tempting to primary care practices looking for a little help in getting started, pay particular attention to the "meaningful use" criteria for EHRs to make sure you qualify for payments. Generally, meaningful use falls into three broad categories: the ability to e-prescribe, report on quality, and share data electronically.

Should You Buy Now or Wait?

The government is moving forward with its HIT plan by recently issuing two rules: In late December, CMS and the Office of the National Coordinator for Health Information Technology (ONC) released a proposed rule on meaningful use and an interim final rule for initial standards governing EHRs. The

The Move to EHRs: the Stimulus Package's Incentives

Maximum total amount of EHR incentives available to Medicare providers until 2016

Calendar Year (CY)	First CY in which the eligible provider receives an incentive payment				
	2011	2012	2013	2014	2015
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**

Source: U.S. Dept. of Health and Human Services.
http://www.cms.hhs.gov/apps/media/press/factsheet.asp?Counter=3563

rules will be finalized this year following a public comment period. Together, the two regulations have the potential to change the health IT landscape, say some experts, by creating a new class of EHRs.

"The surprise news is that the way the government defines EHR technology is likely to redefine EHRs very significantly and to simplify features and functions," says David C. Kibbe, MD, MBA, an expert on health HIT and a senior advisor to the American Academy of Family Physicians (AAFP). That may be bad news for vendors that were certified under the old criteria but good news for small practices looking for simpler, less-expensive ways to adopt technology.

So should you buy an EHR now—to prepare to qualify for the stimulus payments in 2011—or wait until the current regulations assume their final form?

In the short-term, the new government financial incentives and

regulations surrounding meaningful use of EHRs send mixed signals to doctors, experts acknowledge. On one hand, doctors who have not yet converted from paper need to be planning for EHRs in order to take advantage of the stimulus money; on the other hand, moving too quickly to qualify for incentives or avoid penalties might have disastrous consequences for a small practice.

"The average private-practice physician is going to be overwhelmed with the operations and support of EHRs for the next five years," says Edward J. Zych, JD, associate chief legal officer for the Geisinger Healthcare System in Danville, Pa., where he has helped lead implementation of the company's EHR system. "If you have an internal medicine physician in a rural environment who has not a large margin of income above cost, for that person to invest between $10,000 and $50,000 in a medical record system because that's the only way Medicare will pay them could be life-threatening to the practice."

The offer of financial incentives is likely to bring vendors "out of the woodwork," Mr. Zych adds, as physicians who have never before used computerized records start to explore their options. One danger is that "anyone interested in trying to get stimulus money will be jumping at anything that appears to be meaningful use-certified, regardless of how it fits with their practice," says Mr. Zych.

In light of the proposed government regulations, it probably makes sense for physicians to take a "wait-and-see" attitude, says AAFP's Dr. Kibbe. "If you don't have an EHR now and you're contemplating purchasing it in the next two years and want to be assured it will meet the meaningful-use criteria, then you should probably hold off until it's really clear who the certified vendors and products will be," he advises. Because the meaningful-use rule could change substantially before it

becomes final, "getting information now and following it could be dangerous," he adds. He advises physicians to learn about the stimulus program and product certification guidelines but to hold off on purchases until later this year.

Waiting could also mean spreading out the costs: The new requirements for EHRs create standardization across products, allowing physicians to assemble compatible systems piecemeal from a variety of vendors instead of making a single major investment in one comprehensive system from one vendor. "That is a significant change in the lay of the land," says Dr. Kibbe, who is principal of The Kibbe Group LLC.

Getting Down to Details

The CMS's proposed rule outlines how physicians must use EHRs in order to qualify for financial incentives. It states that physicians must use certified EHR technology "in a manner that improves quality, safety, and efficiency of healthcare delivery, reduces healthcare disparities, engages patients and families, improves care coordination, improves population and public health, and ensures adequate privacy and security protections for personal health information." The proposed CMS requirements set the minimum standard for acceptable EHR use: Individual states will be allowed to request additional measures but cannot request fewer or less rigorous standards. The rule calls for a phase-in period for providers, starting with "reasonable criteria" in line with current technology and progressing to stricter standards as technology evolves and physicians become more adept at using the systems.

The initial period of EHR use, or Stage 1, focuses on capturing health information electronically in order to track key clinical conditions and coordinate patient care, according to the proposed rule published in the Jan. 13, 2010, Federal Register. Physicians are also expected to implement clinical decision support tools for disease and medication management and report on clinical quality measures. For specific Stage 1 criteria, see "What Does 'Meaningful Use' Mean?," opposite.

Stage 2 focuses on achieving more extensive use of HIT at the point-of-care and information exchange, such as use of computerized provider-order entry and electronic transmission of test

What Does 'Meaningful Use' Mean?

Here are some of the 25 criteria for meeting Stage 1 of meaningful use, listed by the proposed objectives set by CMS. The complete text of the proposed rule is online at *http://www.regulations.gov/search/Regs/home.html#documentDetail? R=0900006480a74a4b*.

- Use CPOE for at least 80% of all orders.
- Maintain an up-to-date problem list of current and active diagnoses based on ICD-9-CM or SNOMED CT®, with at least 80% of all unique patients having at least one entry or an indication of none recorded.
- Generate and transmit at least 75% of all permissible prescriptions electronically.
- Maintain an active medication list, with at least 80% of all unique patients having at least one entry.
- Generate at least one report listing patients by specific conditions to use for quality improvement, reduction of disparities, research, and outreach.
- Implement five clinical decision support rules relevant to specialty or high clinical priority, including for diagnostic test ordering, along with the ability to track compliance with those rules.
- Submit claims electronically to public and private payers for at least 80% of all claims filed electronically.
- Provide at least 805 patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, and allergies) upon request within 48 hours.
- Provide clinical summaries to at least 80% of all patients for each office visit.
- Protect electronic health information by conducting a security risk analysis, and implement security updates as necessary.

results. Stage 3 stresses using decision support to manage key conditions, patient access to self-management tools, access to comprehensive patient data, and improvement of population health.

Other details of the proposed meaningful-use rule include the following:

- Participating providers must designate either the Medicare or Medicaid program, not both. Changes will be allowed only

once during payment years 2012 through 2014.

- Payments under Medicare will be disbursed through Medicare Administrative Contractors (MAC) or carriers to the Tax Identification Number provided by qualifying providers.
- Providers can reassign their incentive payment to one employer or entity if they meet certain conditions.
- Medicare Advantage (MA) organizations can also qualify for EHR incentives through their affiliated providers. To qualify, MA-affiliated providers must provide at least 20 hours of patient care services per week, on average. For a subcontracted provider, at least 80% of professional services must be furnished to enrollees of the MA organization.

The ONC interim final rule addresses information exchange between different systems and providers. The rule begins to define a common language for information exchange, says the Department of Health and Human Services (HHS), including standard formats for clinical summaries and prescriptions; standard terms for clinical problems, procedures, lab tests, medications, and allergies; and standards for secure online transmission of information.

"The whole point is using information in a different way for better healthcare," says P. Jon White, MD, IT director for the Agency for Healthcare Research and Quality (AHRQ) and a family physician. "Meaningful use says that the government doesn't just want to incent doctors to use EHRs but wants them to deliver better care. These tools will help give physicians the information they need to find out what's going well, what's not, and what they can do to improve."

Meeting Certification Criteria

Physicians can ensure that the system they purchase has the approved capabilities if they select a vendor certified by HHS-approved certifying bodies. Currently, the Certification Commission for Health Information Technology (CCHIT) is the only official certification agency; but more are expected to be announced this year, in line with the government's recently proposed product standards. Certifying bodies rate products on usability and ensure that vendors meet all the major objectives of meaningful use.

Besides direct payments to physicians, the ARRA included $2 billion to promote the use of health HIT through the HHS Office of the National Coordinator. Two grant programs have been launched under the Health Information Technology for Economic and Clinical Health (HITECH) Act to support implementation and meaningful use of EHRs:

The Health Information Technology Extension Program ($643 million over four years) provides grants to qualifying nonprofit organizations to help physicians adopt EHRs. The grants are expected to support at least 70 centers across the country, including at least 100,000 primary care providers, in selecting and implementing certified EHR products; redesigning office workflows; and complying with privacy and security requirements. Primary care physicians in small practices (fewer than 10 physicians) will be the main beneficiaries of the grant program, HHS says. Physicians can contact centers established in their areas to receive on-site technical assistance and support. The HHS is expected to award 20 grants in the first quarter of 2010 and another 25 in the third quarter, with the remaining grants awarded by the end of the year, at which time all centers are expected to be operating at full capacity.

A national HIT Research Center ($50 million) will be a repository for best practices and will help the regional centers collaborate with each other and key stakeholders.

ARRA's financial incentives will convince many physicians to finally make the EHR plunge, leading to a long-sought-after critical mass of EHR users, according to a recent study based on data from Bridges to Excellence's Physicians Office Link Project and published in the May 2009 issue of the *American Journal of Managed Care (http://www.ajmc.com/media/pdf/AJMC_09May_deBrantes305to310.pdf)* .

Bridging the Funding Gap

How can a small practice afford to implement a system now but wait years for the stimulus payments to kick in? The answer is a bill—approved in the House late last year and awaiting approval by the Senate—that would provide guaranteed loans to physicians for purchasing EHRs and other technology. If approved, the program would provide much-needed bridge

financing for physicians who purchase EHRs but may wait years to receive stimulus dollars.

"This could be the missing piece in terms of cash flow," said Alan L. Silver, MD, MPH, medical officer at IPRO, a New York-based nonprofit healthcare consulting company. Even if physicians qualify for federal stimulus dollars, he points out, they won't receive the money right away; and it will be paid over a

"At the end of the day, I want to be thinking about whether the EHR will help me function in practice. Will it be a long-term solution? If I have one shot at an incentive, what do I want to spend it on? Each practice has to answer what's right for them."

Michael S. Barr, MD, MBA, FACP
Vice President
Practice Advocacy and Improvement
Division of Governmental Affairs & Public Policy
American College of Physicians, Philadelphia

period of four years. That delay creates a crunch for small practices that typically have little in cash reserves.

The Small Business Health IT Financing ACT (HR 3014) would authorize the loans through the Small Business Administration (SBA), which would guarantee up to 90% of the amount of a loan used for EHRs or other technology involved in the delivery of care. The House also passed the Small Business Early Stage Investment Act, a grant program designed for small businesses working in healthcare IT. At press time, the loan bill had been referred to the Senate Committee on Small Business and Entrepreneurship.

In addition, some private companies also are offering to help finance physicians' initial purchase of EHRs. For example, McKesson Corp., a healthcare services and HIT company, recently announced two financing options for physicians who purchase its Practice Partner, Lytec MD, or Medisoft Clinical EHR systems. Physicians who license any of these systems through McKesson or a McKesson EHR-certified reseller are eligible for either a no-interest loan for 12 months with a 25%

down payment, or cash rebates of $1,000 for the first provider and $500 for each additional provider in a practice. In addition, Allscripts says it's offering a special financing package with monthly pricing that includes software, support, and maintenance. For more information, go to the vendors' Websites.

Choosing Your System

Federal incentives and support are significant considerations; but ultimately you should select an EHR system based on your specific practice needs, advises Michael S. Barr, MD, MBA, FACP, vice president, practice advocacy and improvement, Division of Governmental Affairs & Public Policy, at the American College of Physicians (ACP):

"At the end of the day, I want to be thinking about whether the EHR will help me function in practice. Will it be a long-term solution? If I have one shot at an incentive, what do I want to spend it on? Each practice has to answer what's right for them," Dr. Barr says. "The stimulus will help practices that make the investment; but beyond that, what HIT is able to do is to redesign your practice."

Other experts agree that financial incentives, while welcome, are not reasons in themselves to move forward. Instead, realize that EHRs are a necessary next step if you want to stay in practice over the next decade and that technology is a requisite cost of doing business. Just as it has changed the way we bank and shop, technology is gradually transforming the way physicians practice medicine.

"It's really changed what we're able to do for patients, and it's made us better doctors," says Dr. Baron of his EHR system. "Now we look back and wonder at the information vacuum in which we made decisions before EHRs."