Reimbursement and Other Practice Challenges

CDHC offers potential money-saving opportunities for patients and employers, and money-making opportunities for insurers. Physicians, on the other hand, face the financial risks of managing self-pay patients, processing debit cards, and establishing electronic records systems.

Fast Facts

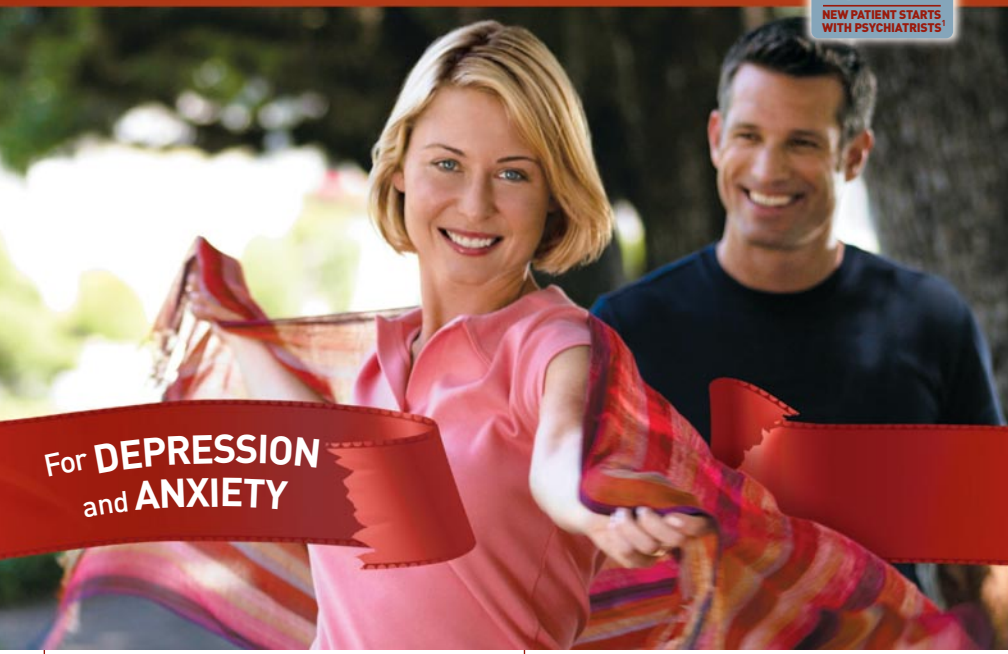
- *Most HSA plans are linked to automated bank and credit card processing companies that provide a healthcare debit card or special checks for payment of covered expenses. But swiping the card does not guarantee fast payment. Page 82.*
- *One Minnesota hospital reduced prices for MRI and CT scans by 10 to 30 percent after patients called to complain that they were finding lower prices elsewhere. Page 90.*
- *CDHC may not change the physician's responsibility to meet the legal standard of care, but it does change the judicial equation, since patients' willingness and ability to pay may factor into lawsuits. Page 93.*

Over the years, physicians have adapted to a succession of financial concepts, including fee-for-service, DRGs, HMOs, and PPOs. All of these models provided patients with at least some first-dollar coverage. Although an increasing number of CDHC plans cover some preventive services before the deductible, virtually none pay first-dollar for treatment. Consumers are responsible for paying deductibles and other out-of-pocket costs.

"Our experience is that it is not uncommon that people who

A POWERFUL SSRI
that's well tolerated

#1 PRESCRIBED SRI
NEW PATIENT STARTS WITH PSYCHIATRISTS[1]



PROVEN EFFICACY for Major Depressive Disorder and Generalized Anxiety Disorder[2]

UP TO 90% of depressed patients present with symptoms of anxiety[3]

Lexapro® escitalopram oxalate

POWER TO ENJOY LIFE™

IMPORTANT SAFETY INFORMATION - Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Antidepressants increased the risk of suicidality (suicidal thinking and behavior) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of antidepressants in children, adolescents or young adults must balance the risk to clinical need. Patients of all ages started on antidepressant therapy should be closely monitored and observed for clinical worsening, suicidality or unusual changes in behavior, especially at the beginning of therapy or at the time of dose changes. This risk may persist until significant remission occurs. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Lexapro is not approved for use in pediatric patients.

Lexapro is contraindicated in patients taking monoamine oxidase inhibitors (MAOIs), pimozide (see DRUG INTERACTIONS – Pimozide and Celexa), or in patients with hypersensitivity to escitalopram oxalate. As with other SSRIs, caution is indicated in the coadministration of tricyclic antidepressants (TCAs) with Lexapro. As with other psychotropic drugs that interfere with serotonin reuptake, patients should be cautioned regarding the risk of bleeding associated with the concomitant use of Lexapro with NSAIDs, aspirin, or other drugs that affect coagulation. The most common adverse events with Lexapro versus placebo (approximately 5% or greater and approximately 2x placebo) were nausea, insomnia, ejaculation disorder, somnolence, increased sweating, fatigue, decreased libido, and anorgasmia.

References: 1. Verispan Weekly VONA Data (Retail Only). Twenty-four–week rolling average. September 2006. **2.** LEXAPRO [package insert]. St. Louis, Mo: Forest Pharmaceuticals, Inc.; 2007. **3.** Sadock BJ, Sadock VA. *Kaplan and Sadock's Synopsis of Psychiatry: Behavioral Sciences/Clinical Psychiatry.* 9th ed. Philadelphia, Pa: Lippincott Williams & Wilkins; 2003:552.

Please see brief summary of prescribing information for LEXAPRO on following page.

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Brief Summary: For complete details, please see full prescribing information for Lexapro.

Suicidality and Antidepressant Drugs Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of Lexapro or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Lexapro is not approved for use in pediatric patients. (See WARNINGS: Clinical Worsening and Suicide Risk, PRECAUTIONS: Information for Patients, and PRECAUTIONS: Pediatric Use)

CONTRAINDICATIONS Concomitant use in patients taking monoamine oxidase inhibitors (MAOIs) is contraindicated (see **WARNINGS**). Concomitant use in patients taking pimozide is contraindicated (see **Drug Interactions – Pimozide and Celexa**). Lexapro is contraindicated in patients with a hypersensitivity to escitalopram or citalopram or any of the inactive ingredients in Lexapro. **WARNINGS WARNINGS-Clinical Worsening and Suicide Risk Clinical Worsening and Suicide Risk** Patients with major depressive disorder (MDD), both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. Suicide is a known risk of depression and certain other psychiatric disorders, and these disorders themselves are the strongest predictors of suicide. There has been a long-standing concern, however, that antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients during the early phases of treatment. Pooled analyses of short-term placebo-controlled trials of antidepressant drugs (SSRIs and others) showed that these drugs increase the risk of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults (ages 18-24) with major depressive disorder (MDD) and other psychiatric disorders. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction with antidepressants compared to placebo in adults aged 65 and older. The pooled analyses of placebo-controlled trials in children and adolescents with MDD, obsessive compulsive disorder (OCD), or other psychiatric disorders included a total of 24 short-term trials of 9 antidepressant drugs in over 4400 patients. The pooled analyses of placebo-controlled trials in adults with MDD or other psychiatric disorders included a total of 295 short-term trials (median duration of 2 months) of 11 antidepressant drugs in over 77,000 patients. There was considerable variation in risk of suicidality among drugs, but a tendency toward an increase in the younger patients for almost all drugs studied. There were differences in absolute risk of suicidality across the different indications, with the highest incidence in MDD. The risk differences (drug vs. placebo), however, were relatively stable within age strata and across indications. These risk differences (drug-placebo difference in the number of cases of suicidality per 1000 patients treated) are provided in **Table 1. TABLE 1: Age Range and Drug-Placebo Difference in Number of Cases of Suicidality per 1000 Patients Treated:** Increases Compared to Placebo; <18 (14 additional cases); 18-24 (5 additional cases); Decreases Compared to Placebo; 25-64 (1 fewer case); ≥65 (6 fewer cases). No suicides occurred in any of the pediatric trials. There were suicides in the adult trials, but the number was not sufficient to reach any conclusion about drug effect on suicide. It is unknown whether the suicidality risk extends to longer-term use, i.e., beyond several months. However, there is substantial evidence from placebo-controlled maintenance trials in adults with depression that the use of antidepressants can delay the recurrence of depression. **All patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases.** The following symptoms, anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, and mania, have been reported in adult and pediatric patients being treated with antidepressants for major depressive disorder as well as for other indications, both psychiatric and nonpsychiatric. Although a causal link between the emergence of such symptoms and either the worsening of depression and/or the emergence of suicidal impulses has not been established, there is concern that such symptoms may represent precursors to emerging suicidality. Consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients whose depression is persistently worse, or who are experiencing emergent suicidality or symptoms that might be precursors to worsening depression or suicidality, especially if these symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms. If the decision has been made to discontinue treatment, medication should be tapered, as rapidly as is feasible, but with recognition that abrupt discontinuation can be associated with certain symptoms (see PRECAUTIONS and DOSAGE AND ADMINISTRATION—Discontinuation of Treatment with Lexapro, for a description of the risks of discontinuation of Lexapro). **Families and caregivers of patients being treated with antidepressants for major depressive disorder or other indications, both psychiatric and nonpsychiatric, should be alerted about the need to monitor patients for the emergence of agitation, irritability, unusual changes in behavior, and the other symptoms described above, as well as the emergence of suicidality, and to report such symptoms immediately to health care providers. Such monitoring should include daily observation by families and caregivers.** Prescriptions for Lexapro should be written for the smallest quantity of tablets consistent with good patient management, in order to reduce the risk of overdose. **Screening Patients for Bipolar Disorder:** A major depressive episode may be the initial presentation of bipolar disorder. It is generally believed (though not established in controlled trials) that treating such an episode with an antidepressant alone may increase the likelihood of precipitation of a mixed/manic episode in patients at risk for bipolar disorder. Whether any of the symptoms described above represent such a conversion is unknown. However, prior to initiating treatment with an antidepressant, patients with depressive symptoms should be adequately screened to determine if they are at risk for bipolar disorder; such screening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder, and depression. It should be noted that Lexapro is not approved for use in treating bipolar depression. **Potential for Interaction with Monoamine Oxidase Inhibitors In patients receiving serotonin reuptake inhibitor drugs in combination with a monoamine oxidase inhibitor (MAOI), there have been reports of serious, sometimes fatal, reactions including hyperthermia, rigidity, myoclonus, autonomic instability with possible rapid fluctuations of vital signs, and mental status changes that include extreme agitation progressing to delirium and coma. These reactions have also been reported in patients who have recently discontinued SSRI treatment and have been started on an MAOI. Some cases presented with features resembling neuroleptic malignant syndrome. Furthermore, limited animal data on the effects of combined use of SSRIs and MAOIs suggest that these drugs may act synergistically to elevate blood pressure and evoke behavioral excitation. Therefore, it is recommended that Lexapro should not be used in combination with an MAOI, or within 14 days of discontinuing treatment with an MAOI. Similarly, at least 14 days should be allowed after stopping Lexapro before starting an MAOI. Serotonin syndrome has been reported in two patients who were concomitantly receiving linezolid, an antibiotic which is a reversible non-selective MAOI.** ***Serotonin Syndrome:*** The development of a potentially life-threatening serotonin syndrome may occur with SNRIs and SSRIs, including Lexapro treatment, particularly with concomitant use of serotonergic drugs (including triptans) and with drugs which impair metabolism of serotonin (including MAOIs). Serotonin syndrome symptoms may include mental status changes (e.g., agitation, hallucinations, coma), autonomic instability (e.g., tachycardia, labile blood pressure, hyperthermia), neuromuscular aberrations (e.g., hyperreflexia, incoordination) and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea). The concomitant use of Lexapro with MAOIs intended to treat depression is contraindicated (see **CONTRAINDICATIONS** and **WARNINGS - Potential for Interaction with Monoamine Oxidase Inhibitors.**) If concomitant treatment of Lexapro with a 5-hydroxytryptamine receptor agonist (triptan) is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose increases (see **PRECAUTIONS - Drug Interactions**).The concomitant use of Lexapro with serotonin precursors (such as tryptophan) is not recommended (see **PRECAUTIONS - Drug Interactions**). **PRECAUTIONS General** Discontinuation of Treatment with Lexapro During marketing of Lexapro and other SSRIs and SNRIs (serotonin and norepinephrine reuptake inhibitors), there have been spontaneous reports of adverse events occurring upon discontinuation of these drugs, particularly when abrupt, including the following: dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g., paresthesias such as electric shock sensations), anxiety, confusion, headache, lethargy, emotional lability, insomnia, and hypomania. While these events are generally self-limiting, there have been reports of serious discontinuation symptoms. Patients should be monitored for these symptoms when discontinuing treatment with Lexapro. A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose but at a more gradual rate (see **DOSAGE AND ADMINISTRATION**). Abnormal Bleeding Published case reports have documented the occurrence of bleeding episodes in patients treated with psychotropic drugs that interfere with serotonin reuptake. Subsequent epidemiological studies, both of the case-control and cohort design, have demonstrated an association between use of psychotropic drugs that interfere with serotonin reuptake and the occurrence of upper gastrointestinal bleeding. In two studies, concurrent use of a nonsteroidal anti-inflammatory drug (NSAID) or aspirin potentiated the risk of bleeding (see **Drug Interactions**). Although these studies focused on upper gastrointestinal bleeding, there is reason to believe that bleeding at other sites may be similarly potentiated. Patients should be cautioned regarding the risk of bleeding associated with the concomitant use of Lexapro with NSAIDs, aspirin, or other drugs that affect coagulation. Hyponatremia Cases of hyponatremia and SIADH (syndrome of inappropriate antidiuretic hormone secretion) have been reported in association with Lexapro treatment. All patients with these events have recovered with discontinuation of escitalopram and/or medical intervention. Hyponatremia and SIADH have also been reported in association with other marketed drugs effective in the treatment of major depressive disorder. Activation of Mania/Hypomania In placebo-controlled trials of Lexapro in major depressive disorder, activation of mania/hypomania was reported in one (0.1%) of 715 patients treated with Lexapro and in none of the 592 patients treated with placebo. One additional case of hypomania has been reported in association with Lexapro treatment. Activation of mania/hypomania has also been reported in a small proportion of patients with major affective disorders treated with racemic citalopram and other marketed drugs effective in the treatment of major depressive disorder. As with all drugs effective in the treatment of major depressive disorder, Lexapro should be used cautiously in patients with a history of mania. Seizures Although anticonvulsant effects of racemic citalopram have been observed in animal studies, Lexapro has not been systematically evaluated in patients with a seizure disorder. These patients were excluded from clinical studies during the product's premarketing testing. In clinical trials of Lexapro, cases of convulsion have been reported in association with Lexapro treatment. Like other drugs effective in the treatment of major depressive disorder, Lexapro should be introduced with care in patients with a history of seizure disorder. Interference with Cognitive and Motor Performance In a study in normal volunteers, Lexapro 10 mg/day did not produce impairment of intellectual function or psychomotor performance. Because any psychoactive drug may impair judgment, thinking, or motor skills, however, patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that Lexapro therapy does not affect their ability to engage in such activities. Use in Patients with Concomitant Illness Clinical experience with Lexapro in patients with certain concomitant systemic illnesses is limited. Caution is advisable in using Lexapro in patients with diseases or conditions that produce altered metabolism or hemodynamic responses. Lexapro has not been systematically evaluated in patients with a recent history of myocardial infarction or unstable heart disease. Patients with these diagnoses were generally excluded from clinical studies during the product's premarketing testing. In subjects with hepatic impairment, clearance of racemic citalopram was decreased and plasma concentrations were increased. The recommended dose of Lexapro in hepatically impaired patients is 10 mg/day (see **DOSAGE AND ADMINISTRATION**). Because escitalopram is extensively metabolized, excretion of unchanged drug in urine is a minor route of elimination. Until adequate numbers of patients with severe renal impairment have been evaluated during chronic treatment with Lexapro, however, it should be used with caution in such patients (see **DOSAGE AND ADMINISTRATION**). **Information for Patients** Physicians are advised to discuss the following issues with patients for whom they prescribe Lexapro. Patients should be cautioned about the risk of serotonin syndrome with the concomitant use of Lexapro and triptans, tramadol or other serotonergic agents. In a study in normal volunteers, Lexapro 10 mg/day did not impair psychomotor performance. The effect of Lexapro on psychomotor coordination, judgment, or thinking has not been systematically examined in controlled studies. Because psychoactive drugs may impair judgment, thinking, or motor skills, patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that Lexapro therapy does not affect their ability to engage in such activities. Patients should be told that, although Lexapro has not been shown in experiments with normal subjects to increase the mental and motor skill impairments caused by alcohol, the concomitant use of Lexapro and alcohol in depressed patients is not advised. Patients should be made aware that escitalopram is the active isomer of Celexa (citalopram hydrobromide) and that the two medications should not be taken concomitantly. Patients should be advised to inform their physician if they are taking, or plan to take, any prescription or over-the-counter drugs, as there is a potential for interactions. Patients should be cautioned about the concomitant use of Lexapro and NSAIDs, aspirin, or other drugs that affect coagulation since the combined use of psychotropic drugs that interfere with serotonin reuptake and these agents has been associated with an increased risk of bleeding. Patients should be advised to notify their physician if they become pregnant or intend to become pregnant during therapy. Patients should be advised to notify their physician if they are breastfeeding an infant. While patients may notice improvement with Lexapro therapy in 1 to 4 weeks, they should be advised to continue therapy as directed. Prescribers or other health professionals should inform patients, their families, and their caregivers about the benefits and risks associated with treatment with Lexapro and should counsel them in its appropriate use. A patient Medication Guide about "Antidepressant Medicines, Depression and other Serious Mental Illness, and Suicidal Thoughts or Actions" is available for Lexapro. The prescriber or health professional should instruct patients, their families, and their caregivers to read the Medication Guide and should assist them in understanding its contents. Patients should be given the opportunity to discuss the contents of the Medication Guide and to obtain answers

to any questions they may have. Patients should be advised of the following issues and asked to alert their prescriber if these occur while taking Lexapro. **Clinical Worsening and Suicide Risk:** Patients, their families, and their caregivers should be encouraged to be alert to the emergence of anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, mania, other unusual changes in behavior, worsening of depression, and suicidal ideation, especially early during anti-depressant treatment and when the dose is adjusted up or down. Families and caregivers of patients should be advised to look for the emergence of such symptoms on a day-to-day basis, since changes may be abrupt. Such symptoms should be reported to the patient's prescriber or health professional, especially if they are severe, abrupt in onset, or were not part of the patient's presenting symptoms. Symptoms such as these may be associated with an increased risk for suicidal thinking and behavior and indicate a need for very close monitoring and possibly changes in the medication. **Laboratory Tests** There are no specific laboratory tests recommended. **Concomitant Administration with Racemic Citalopram** Citalopram - Since escitalopram is the active isomer of racemic citalopram (Celexa), the two agents should not be coadministered. **Drug Interactions Serotonergic Drugs:** Based on the mechanism of action of SNRIs and SSRIs including Lexapro, and the potential for serotonin syndrome, caution is advised when Lexapro is coadministered with other drugs that may affect the serotonergic neurotransmitter systems, such as triptans, linezolid (an antibiotic which is a reversible non-selective MAOI), lithium, tramadol, or St. John's Wort (see **WARNINGS-Serotonin Syndrome**). The concomitant use of Lexapro with other SSRIs, SNRIs or tryptophan is not recommended (see **PRECAUTIONS - Drug Interactions**). **Triptans:** There have been rare postmarketing reports of serotonin syndrome with use of an SSRI and a triptan. If concomitant treatment of Lexapro with a triptan is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose increases (see **WARNINGS - Serotonin Syndrome**). CNS Drugs - Given the primary CNS effects of escitalopram, caution should be used when it is taken in combination with other centrally acting drugs. Alcohol - Although Lexapro did not potentiate the cognitive and motor effects of alcohol in a clinical trial, as with other psychotropic medications, the use of alcohol by patients taking Lexapro is not recommended. Monoamine Oxidase Inhibitors (MAOIs) - See **CONTRAINDICATIONS** and **WARNINGS**. **Drugs That Interfere With Hemostasis (NSAIDs, Aspirin, Warfarin, etc.)** Serotonin release by platelets plays an important role in hemostasis. Epidemiological studies of the case-control and cohort design that have demonstrated an association between use of psychotropic drugs that interfere with serotonin reuptake and the occurrence of upper gastrointestinal bleeding have also shown that concurrent use of an NSAID or aspirin potentiated the risk of bleeding. Thus, patients should be cautioned about the use of such drugs concurrently with Lexapro. Cimetidine - In subjects who had received 21 days of 40 mg/day racemic citalopram, combined administration of 400 mg/day cimetidine for 8 days resulted in an increase in citalopram AUC and C_{max} of 43% and 39%, respectively. The clinical significance of these findings is unknown. Digoxin - In subjects who had received 21 days of 40 mg/day racemic citalopram, combined administration of citalopram and digoxin (single dose of 1 mg) did not significantly affect the pharmacokinetics of either citalopram or digoxin. Lithium - Coadministration of racemic citalopram (40 mg/day for 10 days) and lithium (30 mmol/day for 5 days) had no significant effect on the pharmacokinetics of citalopram or lithium. Nevertheless, plasma lithium levels should be monitored with appropriate adjustment to the lithium dose in accordance with standard clinical practice. Because lithium may enhance the serotonergic effects of escitalopram, caution should be exercised when Lexapro and lithium are coadministered. Pimozide and Celexa - In a controlled study, a single dose of pimozide 2 mg co-administered with racemic citalopram 40 mg given once daily for 11 days was associated with a mean increase in QTc values of approximately 10 msec compared to pimozide given alone. Racemic citalopram did not alter the mean AUC or C_{max} of pimozide. The mechanism of this pharmacodynamic interaction is not known. Sumatriptan - There have been rare postmarketing reports describing patients with weakness, hyperreflexia, and incoordination following the use of an SSRI and sumatriptan. If concomitant treatment with sumatriptan and an SSRI (e.g., fluoxetine, fluvoxamine, paroxetine, sertraline, citalopram, escitalopram) is clinically warranted, appropriate observation of the patient is advised. Theophylline - Combined administration of racemic citalopram (40 mg/day for 21 days) and the CYP1A2 substrate theophylline (single dose of 300 mg) did not affect the pharmacokinetics of theophylline. The effect of theophylline on the pharmacokinetics of citalopram was not evaluated. Warfarin - Administration of 40 mg/day racemic citalopram for 21 days did not affect the pharmacokinetics of warfarin, a CYP3A4 substrate. Prothrombin time was increased by 5%, the clinical significance of which is unknown. Carbamazepine - Combined administration of racemic citalopram (40 mg/day for 14 days) and carbamazepine (titrated to 400 mg/day for 35 days) did not significantly affect the pharmacokinetics of carbamazepine, a CYP3A4 substrate. Although trough citalopram plasma levels were unaffected, given the enzyme-inducing properties of carbamazepine, the possibility that carbamazepine might increase the clearance of escitalopram should be considered if the two drugs are coadministered. Triazolam - Combined administration of racemic citalopram (titrated to 40 mg/day for 28 days) and the CYP3A4 substrate triazolam (single dose of 0.25 mg) did not significantly affect the pharmacokinetics of either citalopram or triazolam. Ketoconazole - Combined administration of racemic citalopram (40 mg) and ketoconazole (200 mg), a potent CYP3A4 inhibitor, decreased the C_{max} and AUC of ketoconazole by 21% and 10%, respectively, and did not significantly affect the pharmacokinetics of citalopram. Ritonavir - Combined administration of a single dose of ritonavir (600 mg), both a CYP3A4 substrate and a potent inhibitor of CYP3A4, and escitalopram (20 mg) did not affect the pharmacokinetics of either ritonavir or escitalopram. CYP3A4 and -2C19 Inhibitors - *In vitro* studies indicated that CYP3A4 and -2C19 are the primary enzymes involved in the metabolism of escitalopram. However, coadministration of escitalopram (20 mg) and ritonavir (600 mg), a potent inhibitor of CYP3A4, did not significantly affect the pharmacokinetics of escitalopram. Because escitalopram is metabolized by multiple enzyme systems, inhibition of a single enzyme may not appreciably decrease escitalopram clearance. Drugs Metabolized by Cytochrome P4502D6 - *In vitro* studies did not reveal an inhibitory effect of escitalopram on CYP2D6. In addition, steady state levels of racemic citalopram were not significantly different in poor metabolizers and extensive CYP2D6 metabolizers after multiple-dose administration of citalopram, suggesting that coadministration, with escitalopram, of a drug that inhibits CYP2D6, is unlikely to have clinically significant effects on escitalopram metabolism. However, there are limited *in vivo* data suggesting a modest CYP2D6 inhibitory effect for escitalopram, i.e., coadministration of escitalopram (20 mg/day for 21 days) with the tricyclic antidepressant desipramine (single dose of 50 mg), a substrate for CYP2D6, resulted in a 40% increase in C_{max} and a 100% increase in AUC of desipramine. The clinical significance of this finding is unknown. Nevertheless, caution is indicated in the coadministration of escitalopram and drugs metabolized by CYP2D6. Metoprolol - Administration of 20 mg/day Lexapro for 21 days in healthy volunteers resulted in a 50% increase in C_{max} and 82% increase in AUC of the beta-adrenergic blocker metoprolol (given in a single dose of 100 mg). Increased metoprolol plasma levels have been associated with decreased cardioselectivity. Coadministration of Lexapro and metoprolol had no clinically significant effects on blood pressure or heart rate. Electroconvulsive Therapy (ECT) - There are no clinical studies of the combined use of ECT and escitalopram. **Carcinogenesis, Mutagenesis, Impairment of Fertility** Carcinogenesis Racemic citalopram was administered in the diet to NMRI/BOM strain mice and COBS WI strain rats for 18 and 24 months, respectively. There was no evidence for carcinogenicity of racemic citalopram in mice receiving up to 240 mg/kg/day. There was an increased incidence of small intestine carcinoma in rats receiving 8 or 24 mg/kg/day racemic citalopram. A no-effect dose for this finding was not established. The relevance of these findings to humans is unknown. Mutagenesis Racemic citalopram was mutagenic in the *in vitro* bacterial reverse mutation assay (Ames test) in 2 of 5 bacterial strains (Salmonella TA98 and TA1537) in the absence of metabolic activation. It was clastogenic in the *in vitro* Chinese hamster lung cell assay for chromosomal aberrations in the presence and absence of metabolic activation. Racemic citalopram was not mutagenic in the *in vitro* mammalian forward gene mutation assay (HPRT) in mouse lymphoma cells or in a coupled *in vitro*/*in vivo* unscheduled DNA synthesis (UDS) assay in rat liver. It was not clastogenic in the *in vitro* chromosomal aberration assay in human lymphocytes or in two *in vivo* mouse micronucleus assays. Impairment of Fertility When racemic citalopram was administered orally to 16 male and 24 female rats prior to and throughout mating and gestation at doses of 32, 48, and 72 mg/kg/day, mating was decreased at all doses, and fertility was decreased at doses ≥ 32 mg/kg/day. Gestation duration was increased at 48 mg/kg/day. **Pregnancy** Pregnancy Category C In a rat embryo/fetal development study, oral administration of escitalopram (56, 112, or 150 mg/kg/day) to pregnant animals during the period of organogenesis resulted in decreased fetal body weight and associated delays in ossification at the two higher doses (approximately ≥ 56 times the maximum recommended human dose [MRHD] of 20 mg/day on a body surface area [mg/m^2] basis). Maternal toxicity (clinical signs and decreased body weight gain and food consumption), mild at 56 mg/kg/day, was present at all dose levels. The developmental no-effect dose of 56 mg/kg/day is approximately 28 times the MRHD on a mg/m^2 basis. No teratogenicity was observed at any of the doses tested (as high as 75 times the MRHD on a mg/m^2 basis). When female rats were treated with escitalopram (6, 12, 24, or 48 mg/kg/day) during pregnancy and through weaning, slightly increased offspring mortality and growth retardation were noted at 48 mg/kg/day which is approximately 24 times the MRHD on a mg/m^2 basis. Slight maternal toxicity (clinical signs and decreased body weight gain and food consumption) was seen at this dose. Slightly increased offspring mortality was seen at 24 mg/kg/day. The no-effect dose was 12 mg/kg/day which is approximately 6 times the MRHD on a mg/m^2 basis. In animal reproduction studies, racemic citalopram has been shown to have adverse effects on embryo/fetal and postnatal development, including teratogenic effects, when administered at doses greater than human therapeutic doses. In two rat embryo/fetal development studies, oral administration of racemic citalopram (32, 56, or 112 mg/kg/day) to pregnant animals during the period of organogenesis resulted in decreased embryo/fetal growth and survival and an increased incidence of fetal abnormalities (including cardiovascular and skeletal defects) at the high dose. This dose was also associated with maternal toxicity (clinical signs, decreased body weight gain). The developmental no-effect dose was 56 mg/kg/day. In a rabbit study, no adverse effects on embryo/fetal development were observed at doses of racemic citalopram of up to 16 mg/kg/day. Thus, teratogenic effects of racemic citalopram were observed at a maternally toxic dose in the rat and were not observed in the rabbit. When female rats were treated with racemic citalopram (4.8, 12.8, or 32 mg/kg/day) from late gestation through weaning, increased offspring mortality during the first 4 days after birth and persistent offspring growth retardation were observed at the highest dose. The no-effect dose was 12.8 mg/kg/day. Similar effects on offspring mortality and growth were seen when dams were treated throughout gestation and early lactation at doses ≥ 24 mg/kg/day. A no-effect dose was not determined in that study. There are no adequate and well-controlled studies in pregnant women; therefore, escitalopram should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Pregnancy-Nonteratogenic Effects** Neonates exposed to Lexapro and other SSRIs or SNRIs, late in the third trimester, have developed complications requiring prolonged hospitalization, respiratory support, and tube feeding. Such complications can arise immediately upon delivery. Reported clinical findings have included respiratory distress, cyanosis, apnea, seizures, temperature instability, feeding difficulty, vomiting, hypoglycemia, hypotonia, hypertonia, hyperreflexia, tremor, jitteriness, irritability, and constant crying. These features are consistent with either a direct toxic effect of SSRIs and SNRIs or, possibly, a drug discontinuation syndrome. It should be noted that, in some cases, the clinical picture is consistent with serotonin syndrome (see **WARNINGS**). Infants exposed to SSRIs in late pregnancy may have an increased risk for persistent pulmonary hypertension of the newborn (PPHN). PPHN occurs in 1–2 per 1000 live births in the general population and is associated with substantial neonatal morbidity and mortality. In a retrospective, case-control study of 377 women whose infants were born with PPHN and 836 women whose infants were born healthy, the risk for developing PPHN was approximately six-fold higher for infants exposed to SSRIs after the 20th week of gestation compared to infants who had not been exposed to antidepressants during pregnancy. There is currently no corroborative evidence regarding the risk for PPHN following exposure to SSRIs in pregnancy; this is the first study that has investigated the potential risk. The study did not include enough cases with exposure to individual SSRIs to determine if all SSRIs posed similar levels of PPHN risk. When treating a pregnant woman with Lexapro during the third trimester, the physician should carefully consider both the potential risks and benefits of treatment (see **DOSAGE AND ADMINISTRATION**). Physicians should note that in a prospective longitudinal study of 201 women with a history of major depression who were euthymic at the beginning of pregnancy, women who discontinued antidepressant medication during pregnancy were more likely to experience a relapse of major depression than women who continued antidepressant medication. **Labor and Delivery** The effect of Lexapro on labor and delivery in humans is unknown. **Nursing Mothers** Racemic citalopram, like many other drugs, is excreted in human breast milk. There have been two reports of infants experiencing excessive somnolence, decreased feeding, and weight loss in association with breastfeeding from a citalopram-treated mother; in one case, the infant was reported to recover completely upon discontinuation of citalopram by its mother and, in the second case, no follow-up information was available. The decision whether to continue or discontinue either nursing or Lexapro therapy should take into account the risks of citalopram exposure for the infant and the benefits of Lexapro treatment for the mother. **Pediatric Use** Safety and effectiveness in the pediatric population have not been established (see **BOX WARNING** and **WARNINGS—Clinical Worsening and Suicide Risk**). One placebo-controlled trial in 264 pediatric patients with MDD has been conducted with Lexapro, and the data were not sufficient to support a claim for use in pediatric patients. Anyone considering the use of Lexapro in a child or adolescent must balance the potential risks with the clinical need. **Geriatric Use** Approximately 6% of the 1144 patients receiving escitalopram in controlled trials of Lexapro in major depressive disorder and GAD were 60 years of age or older; elderly patients in these trials received daily doses of Lexapro between 10 and 20 mg. The number of elderly patients in these trials was insufficient to adequately assess for possible differential efficacy and safety measures on the basis of age. Nevertheless, greater sensitivity of some elderly individuals to effects of Lexapro cannot be ruled out. In two pharmacokinetic studies, escitalopram half-life was increased by approximately 50% in elderly subjects as compared to young subjects and C_{max} was unchanged (see **CLINICAL PHARMACOLOGY**). 10 mg/day is the recommended dose for elderly patients (see **DOSAGE AND ADMINISTRATION**). Of 4422 patients in clinical studies of racemic citalopram, 1357 were 60 and over, 1034 were 65 and over, and 457 were 75 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but again, greater sensitivity of some elderly individuals cannot be ruled out. **ADVERSE REACTIONS** Adverse event information for Lexapro was collected from 715 patients with major depressive disorder who were exposed to escitalopram and from 592 patients who were exposed to placebo in double-blind, placebo-controlled trials. An additional 284 patients with major depressive disorder were newly exposed to escitalopram in open-label trials. The adverse event information for Lexapro in patients with

LEXAPRO® (escitalopram oxalate) TABLETS/ORAL SOLUTION

GAD was collected from 429 patients exposed to escitalopram and from 427 patients exposed to placebo in double-blind, placebo-controlled trials. Adverse events during exposure were obtained primarily by general inquiry and recorded by clinical investigators using terminology of their own choosing. Consequently, it is not possible to provide a meaningful estimate of the proportion of individuals experiencing adverse events without first grouping similar types of events into a smaller number of standardized event categories. In the tables and tabulations that follow, standard World Health Organization (WHO) terminology has been used to classify reported adverse events. The stated frequencies of adverse events represent the proportion of individuals who experienced, at least once, a treatment-emergent adverse event of the type listed. An event was considered treatment-emergent if it occurred for the first time or worsened while receiving therapy following baseline evaluation. **Adverse Events Associated with Discontinuation of Treatment Major Depressive Disorder** Among the 715 depressed patients who received Lexapro in placebo-controlled trials, 6% discontinued treatment due to an adverse event, as compared to 2% of 592 patients receiving placebo. In two fixed-dose studies, the rate of discontinuation for adverse events in patients receiving 10 mg/day Lexapro was not significantly different from the rate of discontinuation for adverse events in patients receiving placebo. The rate of discontinuation for adverse events in patients assigned to a fixed dose of 20 mg/day Lexapro was 10%, which was significantly different from the rate of discontinuation for adverse events in patients receiving 10 mg/day Lexapro (4%) and placebo (3%). Adverse events that were associated with the discontinuation of at least 1% of patients treated with Lexapro, and for which the rate was at least twice that of placebo, were nausea (2%) and ejaculation disorder (2% of male patients). **Generalized Anxiety Disorder** Among the 429 GAD patients who received Lexapro 10-20 mg/day in placebo-controlled trials, 8% discontinued treatment due to an adverse event, as compared to 4% of 427 patients receiving placebo. Adverse events that were associated with the discontinuation of at least 1% of patients treated with Lexapro, and for which the rate was at least twice the placebo rate, were nausea (2%), insomnia (1%), and fatigue (1%). **Incidence of Adverse Events in Placebo-Controlled Clinical Trials Major Depressive Disorder Table 2** enumerates the incidence, rounded to the nearest percent, of treatment-emergent adverse events that occurred among 715 depressed patients who received Lexapro at doses ranging from 10 to 20 mg/day in placebo-controlled trials. Events included are those occurring in 2% or more of patients treated with Lexapro and for which the incidence in patients treated with Lexapro was greater than the incidence in placebo-treated patients. The prescriber should be aware that these figures cannot be used to predict the incidence of adverse events in the course of usual medical practice where patient characteristics and other factors differ from those which prevailed in the clinical trials. Similarly, the cited frequencies cannot be compared with figures obtained from other clinical investigations involving different treatments, uses, and investigators. The cited figures, however, do provide the prescribing physician with some basis for estimating the relative contribution of drug and non-drug factors to the adverse event incidence rate in the population studied. The most commonly observed adverse events in Lexapro patients (incidence of approximately 5% or greater and approximately twice the incidence in placebo patients) were insomnia, ejaculation disorder (primarily ejaculatory delay), nausea, sweating increased, fatigue, and somnolence (see **TABLE 2**). **TABLE 2: Treatment-Emergent Adverse Events: Incidence in Placebo-Controlled Clinical Trials for Major Depressive Disorder* [Lexapro (N=715) and Placebo (N=592)]: Autonomic Nervous System Disorders:** Dry Mouth (6% and 5%); Sweating Increased (5% and 2%). **Central & Peripheral Nervous System Disorders:** Dizziness (5% and 3%). **Gastrointestinal Disorders:** Nausea (15% and 7%); Diarrhea (8% and 5%); Constipation (3% and 1%); Indigestion (3% and 1%); Abdominal Pain (2% and 1%). **General:** Influenza-like Symptoms (5% and 4%); Fatigue (5% and 2%). **Psychiatric Disorders:** Insomnia (9% and 4%); Somnolence (6% and 2%); Appetite Decreased (3% and 1 %); Libido Decreased (3% and 1%). **Respiratory System Disorders:** Rhinitis (5% and 4%); Sinusitis (3% and 2%). **Urogenital:** Ejaculation Disorder[1,2] (9% and <1%); Impotence[2] (3% and <1%); Anorgasmia[3] (2% and <1%).*Events reported by at least 2% of patients treated with Lexapro are reported, except for the following events which had an incidence on placebo ≥ Lexapro: headache, upper respiratory tract infection, back pain, pharyngitis, inflicted injury, anxiety. [1]Primarily ejaculatory delay. [2]Denominator used was for males only (N=225 Lexapro; N=188 placebo). [3]Denominator used was for females only (N=490 Lexapro; N=404 placebo). **Generalized Anxiety Disorder Table 3** enumerates the incidence, rounded to the nearest percent of treatment-emergent adverse events that occurred among 429 GAD patients who received Lexapro 10 to 20 mg/day in placebo-controlled trials. Events included are those occurring in 2% or more of patients treated with Lexapro and for which the incidence in patients treated with Lexapro was greater than the incidence in placebo-treated patients. The most commonly observed adverse events in Lexapro patients (incidence of approximately 5% or greater and approximately twice the incidence in placebo patients) were nausea, ejaculation disorder (primarily ejaculatory delay), insomnia, fatigue, decreased libido, and anorgasmia (see **TABLE 3**). **TABLE 3: Treatment-Emergent Adverse Events: Incidence in Placebo-Controlled Clinical Trials for Generalized Anxiety Disorder* [Lexapro (N=429) and Placebo (N=427)]: Autonomic Nervous System Disorders:** Dry Mouth (9% and 5%); Sweating Increased (4% and 1%). **Central & Peripheral Nervous System Disorders:** Headache (24% and 17%); Paresthesia (2% and 1%). **Gastrointestinal Disorders:** Nausea (18% and 8%); Diarrhea (8% and 6%); Constipation (5% and 4%); Indigestion (3% and 2%); Vomiting (3% and 1%); Abdominal Pain (2% and 1%); Flatulence (2% and 1%); Toothache (2% and 0%). **General:** Fatigue (8% and 2%); Influenza-like symptoms (5% and 4%). **Musculoskeletal:** Neck/Shoulder Pain (3% and 1%). **Psychiatric Disorders:** Somnolence (13% and 7%); Insomnia (12% and 6%); Libido Decreased (7% and 2%); Dreaming Abnormal (3% and 2%); Appetite Decreased (3% and 1%); Lethargy (3% and 1%); Yawning (2% and 1%). **Urogenital:** Ejaculation Disorder[1,2] (14% and 2%); Anorgasmia[3] (6% and <1%); Menstrual Disorder (2% and 1%). *Events reported by at least 2% of patients treated with Lexapro are reported, except for the following events which had an incidence on placebo ≥ Lexapro: inflicted injury, dizziness, back pain, upper respiratory tract infection, rhinitis, pharyngitis. [1]Primarily ejaculatory delay. [2]Denominator used was for males only (N=182 Lexapro; N=195 placebo). [3]Denominator used was for females only (N=247 Lexapro; N=232 placebo). **Dose Dependency of Adverse Events** The potential dose dependency of common adverse events (defined as an incidence rate of ≥5% in either the 10 mg or 20 mg Lexapro groups) was examined on the basis of the combined incidence of adverse events in two fixed-dose trials. The overall incidence rates of adverse events in 10 mg Lexapro-treated patients (66%) was similar to that of the placebo-treated patients (61%), while the incidence rate in 20 mg/day Lexapro-treated patients was greater (86%). **Table 4** shows common adverse events that occurred in the 20 mg/day Lexapro group with an incidence that was approximately twice that of the 10 mg/day Lexapro group and approximately twice that of the placebo group. **TABLE 4: Incidence of Common Adverse Events* in Patients with Major Depressive Disorder Receiving Placebo (N=311), 10 mg/day Lexapro (N=310), 20 mg/day Lexapro (N=125)]: Insomnia** (4%, 7%, 14%); **Diarrhea** (5%, 6%, 14%); **Dry Mouth** (3%, 4%, 9%); **Somnolence** (1%, 4%, 9%); **Dizziness** (2%, 4%, 7%); **Sweating Increased** (<1%, 3%, 8%); **Constipation** (1%, 3%, 6%); **Fatigue** (2%, 2%, 6%); **Indigestion** (1%, 2%, 6%).*Adverse events with an incidence rate of at least 5% in either of the Lexapro groups and with an incidence rate in the 20 mg/day Lexapro group that was approximately twice that of the 10 mg/day Lexapro group and the placebo group. **Male and Female Sexual Dysfunction with SSRIs** Although changes in sexual desire, sexual performance, and sexual satisfaction often occur as manifestations of a psychiatric disorder, they may also be a consequence of pharmacologic treatment. In particular, some evidence suggests that SSRIs can cause such untoward sexual experiences. Reliable estimates of the incidence and severity of untoward experiences involving sexual desire, performance, and satisfaction are difficult to obtain, however, in part because patients and physicians may be reluctant to discuss them. Accordingly, estimates of the incidence of untoward sexual experience and performance cited in product labeling are likely to underestimate their actual incidence. **Table 5** shows the incidence rates of sexual side effects in patients with major depressive disorder and GAD in placebo-controlled trials. **TABLE 5: Incidence of Sexual Side Effects in Placebo-Controlled Clinical Trials** [In Males Only: **Lexapro** (N=407) **and Placebo** (N=383)]: Ejaculation Disorder (primarily ejaculatory delay) (12% and 1%); Libido Decreased (6% and 2%); Impotence (2% and <1%). [In Females Only: **Lexapro** (N=737) **and Placebo** (N=636)]: Libido Decreased (3% and 1%); Anorgasmia (3% and <1%) There are no adequately designed studies examining sexual dysfunction with escitalopram treatment. Priapism has been reported with all SSRIs. While it is difficult to know the precise risk of sexual dysfunction associated with the use of SSRIs, physicians should routinely inquire about such possible side effects. **Vital Sign Changes** Lexapro and placebo groups were compared with respect to (1) mean change from baseline in vital signs (pulse, systolic blood pressure, and diastolic blood pressure) and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. These analyses did not reveal any clinically important changes in vital signs associated with Lexapro treatment. In addition, a comparison of supine and standing vital sign measures in subjects receiving Lexapro indicated that Lexapro treatment is not associated with orthostatic changes. **Weight Changes** Patients treated with Lexapro in controlled trials did not differ from placebo-treated patients with regard to clinically important change in body weight. **Laboratory Changes** Lexapro and placebo groups were compared with respect to (1) mean change from baseline in various serum chemistry, hematology, and urinalysis variables, and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. These analyses revealed no clinically important changes in laboratory test parameters associated with Lexapro treatment. **ECG Changes** Electrocardiograms from Lexapro (N=625), racemic citalopram (N=351), and placebo (N=527) groups were compared with respect to (1) mean change from baseline in various ECG parameters and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. These analyses revealed (1) a decrease in heart rate of 2.2 bpm for Lexapro and 2.7 bpm for racemic citalopram, compared to an increase of 0.3 bpm for placebo and (2) an increase in QTc interval of 3.9 msec for Lexapro and 3.7 msec for racemic citalopram, compared to 0.5 msec for placebo. Neither Lexapro nor racemic citalopram were associated with the development of clinically significant ECG abnormalities. **Other Events Observed During the Premarketing Evaluation of Lexapro** Following is a list of WHO terms that reflect treatment-emergent adverse events, as defined in the introduction to the **ADVERSE REACTIONS** section, reported by the 1428 patients treated with Lexapro for periods of up to one year in double-blind or open-label clinical trials during its premarketing evaluation. All reported events are included except those already listed in **Tables 2 & 3**, those occurring in only one patient, event terms that are so general as to be uninformative, and those that are unlikely to be drug related. It is important to emphasize that, although the events reported occurred during treatment with Lexapro, they were not necessarily caused by it. Events are further categorized by body system and listed in order of decreasing frequency according to the following definitions: frequent adverse events are those occurring on one or more occasions in at least 1/100 patients; infrequent adverse events are those occurring in less than 1/100 patients but at least 1/1000 patients. Cardiovascular - *Frequent:* palpitation, hypertension. *Infrequent:* bradycardia, tachycardia, ECG abnormal, flushing, varicose vein. Central and Peripheral Nervous System Disorders - *Frequent:* light-headed feeling, migraine. *Infrequent:* tremor, vertigo, restless legs, shaking, twitching, dysequilibrium, tics, carpal tunnel syndrome, muscle contractions involuntary, sluggishness, coordination abnormal, faintness, hyperreflexia, muscular tone increased. Gastrointestinal Disorders - *Frequent:* heartburn, abdominal cramp, gastroenteritis. *Infrequent:* gastroesophageal reflux, bloating, abdominal discomfort, dyspepsia, increased stool frequency, belching, gastritis, hemorrhoids, gagging, polyposis gastric, swallowing difficult. General - *Frequent:* allergy, pain in limb, fever, hot flushes, chest pain. *Infrequent:* edema of extremities, chills, tightness of chest, leg pain, asthenia, syncope, malaise, anaphylaxis, fall. Hemic and Lymphatic Disorders - *Infrequent:* bruise, anemia, nosebleed, hematoma, lymphadenopathy cervical. Metabolic and Nutritional Disorders - *Frequent:* increased weight. *Infrequent:* decreased weight, hyperglycemia, thirst, bilirubin increased, hepatic enzymes increased, gout, hypercholesterolemia. Musculoskeletal System Disorders - *Frequent:* arthralgia, myalgia. *Infrequent:* jaw stiffness, muscle cramp, muscle stiffness, arthritis, muscle weakness, back discomfort, arthropathy, jaw pain, joint stiffness. Psychiatric Disorders - *Frequent:* appetite increased, lethargy, irritability, concentration impaired. *Infrequent:* jitteriness, panic reaction, agitation, apathy, forgetfulness, depression aggravated, nervousness, restlessness aggravated, suicide attempt, amnesia, anxiety attack, bruxism, carbohydrate craving, confusion, depersonalization, disorientation, emotional lability, feeling unreal, tremulousness nervous, crying abnormal, depression, excitability, auditory hallucination, suicidal tendency. Reproductive Disorders/Female* - *Frequent:* menstrual cramps, menstrual disorder. *Infrequent:* menorrhagia, breast neoplasm, pelvic inflammation, premenstrual syndrome, spotting between menses. *% based on female subjects only: N= 905 Respiratory System Disorders - *Frequent:* bronchitis, sinus congestion, coughing, nasal congestion, sinus headache. *Infrequent:* asthma, breath shortness, laryngitis, pneumonia, tracheitis. Skin and Appendages Disorders - *Frequent:* rash. *Infrequent:* pruritus, acne, alopecia, eczema, dermatitis, dry skin, folliculitis, lipoma, furunculosis, dry lips, skin nodule. Special Senses - *Frequent:* vision blurred, tinnitus. *Infrequent:* taste alteration, earache, conjunctivitis, vision abnormal, dry eyes, eye irritation, visual disturbance, eye infection, pupils dilated, metallic taste. Urinary System Disorders - *Frequent:* urinary frequency, urinary tract infection. *Infrequent:* urinary urgency, kidney stone, dysuria, blood in urine. **Events Reported Subsequent to the Marketing of Escitalopram** - Although no causal relationship to escitalopram treatment has been found, the following adverse events have been reported to have occurred in patients and to be temporally associated with escitalopram treatment during post marketing experience and were not observed during the premarketing evaluation of escitalopram: abnormal gait, acute renal failure, aggression, akathisia, allergic reaction, anger, angioedema, atrial fibrillation, choreoathetosis, delirium, delusion, diplopia, dysarthria, dyskinesia, dystonia, ecchymosis, erythema multiforme, extrapyramidal disorders, fulminant hepatitis, hepatic failure, hypoaesthesia, hypoglycemia, hypokalemia, INR increased, gastrointestinal hemorrhage, glaucoma, grand mal seizures (or convulsions), hemolytic anemia, hepatic necrosis, hepatitis, hypotension, leucopenia, myocardial infarction, myoclonus, neuroleptic malignant syndrome, nightmare, nystagmus, orthostatic hypotension, pancreatitis, paranoia, photosensitivity reaction, priapism, prolactinemia, prothrombin decreased, pulmonary embolism, QT prolongation, rhabdomyolysis, seizures, serotonin syndrome, SIADH, spontaneous abortion, Stevens Johnson Syndrome, tardive dyskinesia, thrombocytopenia, thrombosis, torsade de pointes, toxic epidermal necrolysis, ventricular arrhythmia, ventricular tachycardia and visual hallucinations.

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come to our clinic and use this type of insurance for the first time are often surprised at their coverage, or rather the lack thereof," says Harold D. Brandt, MD, FACP, an internist at a Baton Rouge, La., multispecialty clinic. "They are under the impression that they are fully insured and then learn otherwise when we verify their benefits. Some can become quite angry when they realize they are responsible for their first dollar of coverage, and that their deductible is $1,000, $1,500, or more, and they have no medical savings account."

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Practices need to prepare for the changes brought about by CDHC plans by training staff, revamping policies and procedures, and upgrading information systems.

The Reality of CDHC Reimbursement

Here's how the CDHC model works, at least in theory: When a CDHC plan member arrives for an office visit or outpatient procedure, an office staff member must attempt to verify whether the patient's deductible has been satisfied. That may not be possible right away. If the patient does not have an HSA, most practices request payment upfront. However, the patient may ask to be billed or, as a self-payer, may request a reduced fee. Office staff must then follow up both to determine whether the deductible is satisfied and to process the billing.

If the patient has an HSA, the situation is easier. Most HSA plans are linked to automated bank and credit card processing companies that provide a healthcare debit card or special checks for payment of covered expenses. The staff person swipes the patient's debit card, determines that HSA funds are available, and completes the transaction. At least that's the ideal.

The patient who presents an HSA card or check is simply authorizing the processing company to debit the HSA account after the claims adjudication process is complete. Payment may

still take a long time, depending on the insurance companies.

Some, like United Healthcare, offer "real-time" adjudication while the patient is at the office. The availability of online statements can also help. But not all plans offer these services. Physicians may have to wait several weeks—and staff may need to follow up—before the claim is processed. Physicians may receive a notice about the amount of money the HSA payment plan is holding. At the time the claim is finally adjudicated, the plan issues an explanation of the transaction and releases the funds. Case closed? Perhaps not, if the explanation shows that HSA funds were insufficient to cover the billed charges. Once again, practice staff must follow up to ensure payment.

"From what my staff tells me, it's quite simple," says Dr. Johnson, a diagnostic radiologist. "Our tests are big-ticket MRIs and CTs, but if the patient has a debit card set-up, as many people have, that's very simple. Pass the card through and that's the end of the story. If they're paying with a check, that's working very well, too," he says.

It's also important to realize that those debit and credit card swipes may come at a per-transaction price to the practice, plus monthly or annual statement and maintenance fees. The cost with credit cards is typically expressed as a discount rate that runs between 1.5 and 3 percent of the transaction, higher when the card number is keyed in for a phone, mail, or online transaction. The higher the practice's total dollar volume and the higher the average transaction, the better the chance of getting a lower rate. Similar rates apply for debit cards run through a terminal, but transaction fees can be lower if the patient enters his PIN.

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However, other physicians are distressed by long delays in determining payments, and so are their CDHC patients. For patients with concurrent healthcare expenses to various providers, it can be difficult to determine whether they have remaining HSA funds.

The job of explaining, managing, and collecting from CDHC plans may fall to physicians and their staff, often at considerable cost, including staff time, more billing statements, and payments that slip through the cracks. "Many health plans simply have not invested the energy to connect with their CDHP subscribers on their health issues, nor have they been willing to make their own plans' administrative processes (eligible services, claims management, etc.) more accessible and easier for subscribers to understand," writes Jeff Goldsmith, PhD, president of Health Futures, Inc., in Charlottesville, Va., in a *Healthcare Financial Management* article.

Dr. Goldsmith notes, "CDHPs are a good idea since they represent a thoughtful attempt to sort out, at the consumer's direction, the subsidy flows in health insurance, with the goals of getting people to buy the right amount of health insurance for their needs, use health services more conservatively, and take better care of themselves." However, he admits that "CDHPs are extraordinarily complicated, with a lot of moving parts. You cannot explain them in a couple of sentences."

New Office Procedures Needed

Managing the challenges of CDHC plans and HSAs requires increased attention to insurance issues, information gathering, billing, collections, and record keeping. Practices that haven't done so already should start by creating policies and systems for handling each of these management functions. They'll also need to develop a budget for possible expenses for staffing positions, consultants, and information technology support.

Practice staff must be sure to obtain complete and accurate financial information from each patient at every visit. It's up to the physician and other staff members to record all tests and procedures that have been provided, in addition to checking that codes are entered correctly. If these steps are done right, claims submitted for insurance payment are less likely to be sent back for additional information.

In addition, billing statements that physicians provide to patients must be clear and easily understandable to patients. "Bills for medical services should be as straightforward and accurate as credit card statements to avoid confusing con-

sumers," says Jeffrey C. Bauer, PhD, senior vice president and partner in the management consulting practice at ACS Healthcare Solutions in Dearborn, Mich., in an article published in the July 2006 issue of *Healthcare Financial Management*.

"Our policy is to collect co-payments at the time of service," Dr. Brandt says. "Paying for the visit, immunizations, and other charges can be a challenge, especially when they have not budgeted for this large deductible. At our clinic we do our best to work with the patients. We recognize their frustration and are sensitive to the cost factor."

To meet this standard, medical practices and especially hospitals often contract with outside billing companies, many of which also offer payment tracking, reports on accounts payable and receivable, and even collection services. However, in-office staff members still need to monitor the process.

With self-pay patients, the chances of full collection are greatly increased if they receive a bill in person at the conclusion of an office visit. While most offices have gotten used to asking for the co-pay upfront, now they must also be ready to present the bill before the patient leaves the office. Staff must strike the right balance between encouraging immediate payment and being sensitive to the patient's financial constraints.

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Dr. Brandt is willing to extend credit to reduce the impact of paying the entire bill at one time. "Interestingly, these patients are usually slower to pay their outstanding obligations versus those patients we care for who have no insurance at all," he says. "Often they are more difficult to work with when being called to make arrangements to pay off any outstanding balance, compared with any other patient, whether insured or uninsured."

When cash is tight, people are likely to pay their rent and utility bills first, while putting medical bills at the bottom of their list. As Massachusetts obstetrician-gynecologist B. Dale Magee,

MD, MS, finds, "Patients with high-deductible plans may not pay their doctor bills, leading us to subsidize the system."

One way around this is to talk to patients about their deductible requirements before their visit or surgery, advises L. Michael Fleischman, FAAHC, principal at Gates, Moore & Co., a consulting firm in Atlanta, Ga. "If patients pay their deductible upfront, they're likely to show up, and you won't have a cancellation or a no-show because they've already paid for it," he says. He sees this as a good way to improve cash flow.

For physicians whose training and motivation focus on patient care, that's a difficult message to appreciate. "I wasn't a business major in college, and I haven't improved a heck of a lot in that area," admits New Jersey internist Alan K. Felsen, MD. "I don't keep track of what they pay me for various services yet, because I am still running a positive balance."

But consultants urge physicians to take a closer look at their finances, or to hire staff professionals to do it for them before the bottom line drops into the red. Some local and national medical associations may provide help in this area. For example, the American Academy of Family Physicians (AAFP) through its TransforMED initiative is evaluating a new model of patient-centered care aimed at improving patient care and satisfaction while enhancing business performance.

Catering to Cost-conscious Patients

There are other patient-care and financial issues to consider, according to J. Max Reiboldt, CPA, managing partner and CEO of The Coker Group in Alpharetta, Ga. Staff members may need additional training to handle increasingly cost-conscious CDHC patients. Speaking at a 2006 audioconference hosted by HCPro, Inc., Mr. Reiboldt noted, "First and foremost, providers should face the fact that cost-conscious patients will not want to visit the office unless it's absolutely necessary."

He suggests that physicians create policies that help their staff to be proactive in getting patients to see their physicians, an effort that can ensure quality care. Many patients don't realize that their plans may include some first-dollar preventive care coverage, or they think they'll have to pay for any tests associated with prevention. By communicating with patients, your

staff can help ensure that CDHC patients use all of their first-dollar benefits. For example, since many practice management information systems generate reports on patients due for annual physicals and other preventive care, staff can schedule well visits proactively instead of waiting for patients to call.

Physicians may also see an increase in calls from CDHC patients who have questions about their health but want to avoid the cost of an office visit. Mr. Reiboldt says it's important to create a policy for how staff members handle such calls. "Take a look at first-answer protocols and how you transfer calls to others within the organization," he advises. "Do patients already have an immediate option to speak with or leave a message for their doctor or nurse?" It's also important to document what each call involved, as this may become relevant to questions about the physician's quality of care.

"When medically appropriate, we want the physician to see the patient and have that patient visit no more or no less than [he or she] would do today without an HSA," Mr. Reiboldt says. "It's just good planning [and] good health management to be proactive and have wellness checkups even if you have an HSA."

Tackling these touchy issues may require a new kind of front-office professional, according to healthcare consultant Dr. Bauer. "This staff member will not only need to be able to explain the technical details of upfront payment; he or she will also need to help patients identify and evaluate all viable financial options, including the possibility of eligibility for free medications, participating in clinical trials, and in some cases qualifying for charity care," he writes in *Healthcare Financial Management*. A business office employee like this who combines the roles of admitting clerk, personal financial counselor, reimbursement specialist, and salesperson "is definitely not your father's (or mother's) admitting clerk," he adds.

The Price of Transparency

The idea behind CDHC is that consumers who must pay for their own healthcare will become more price conscious, seeking out and comparing true costs of the services they require. Insurance companies call this "price transparency."

This means physicians need to review their pricing practices

to provide standard, predetermined, consistent, "consumer-centric" pricing. "Open-ended pricing will be acceptable only in the case of unpreventable complications and life-saving emergency care," Mr. Bauer says in his 2006 article. In response to these demands, hospitals are starting to develop bundled pricing.

Providing access to those prices is another story. Patients cannot simply call up several providers and ask about costs. "It's tremendously difficult for people to find out the cost of treatment over the phone," says Maryann Napoli, associate director of the Center for Medical Consumers in New York City. "They're usually told, 'You can't get information on how much it will cost until you see the doctor.' So it winds up costing the patient money to make an appointment just to find out the treatment cost." She cites one case of a cancer patient who had to pay $750 out-of-pocket for a price-shopping consultation. "Who can afford that?" she says.

New Role for Physicians?

The challenges of caring for patients who are forced to be cost conscious can make physicians question their role as healers and advisers. When CDHC patients pay for many medical costs out-of-pocket, physicians must decide whether to recommend what is medically best, as if costs were no object, or tailor their advice to the patient's financial needs.

Writing in the July/August 2006 issue of *The American Journal of Bioethics*, G. Caleb Alexander, MD, MS, and colleagues at the University of Chicago explain, "On the one hand, it seems wrong for physicians to recommend second-rate treatments for poorer patients or those with worse insurance, than they do for their wealthier or better insured patients. On the other hand, it seems naïve and self-defeating for physicians to recommend treatments that patients will never use, especially if cheaper, acceptable alternatives are available."

At the height of the managed-care era, physicians and insurers worked—or fought—together to decide which treatment options were both medically and financially effective. In the CDHC era, many of these decisions will fall to the patient. "This gradual change in the locus of financial responsibility requires a reexamination of the fundamentals of bedside ethics," Dr. Alexander and his colleagues say.

In reality, it's not always possible to predict a patient's total costs. "Costs involved are often not apparent at the start," says Dr. Magee. "For example, my wife needed surgery for a minor problem. The overall cost was six times higher than the surgeon's fee. How could one put together even a rough estimate of costs with so many different providers sending bills that are often fractionated into professional and technical components?" He adds, "Neither doctors nor patients have adequate quality and cost information to inform decisions."

"No one has developed a method to inform patients what their out-of-pocket expenses will be for the services that providers want to deliver," says Dr. Monnig. "Most of the data that has been provided by hospitals, physicians, and other providers is charge data that has no relevance to patients' cost for services."

On the other hand, commercial competitors are already providing access to healthcare prices. According to a 2006 report from Michael F. Cannon of the Cato Institute, firms such as MinuteClinic and RediClinic that have opened in retail stores clearly post their prices, which are usually less than the cost of a standard doctor's visit. Services such as *CashDoctor.com* are used by "cash-friendly" physicians to post their prices online to attract patients. For a fee, the online service *HealthGrades.com* provides consumers with average prices for hospital services.

Counseling Your Patients

If it's a challenge for practice staff to understand new CDHC plan requirements, imagine how difficult it is for patients. Since these patients are paying a higher percentage of their healthcare costs, they're going to need full financial information and even counseling. But while staff may initially see this new responsibility as a burden, providing healthcare and cost information to patients can provide opportunities for important discussions.

"A problem for patients is that if they don't follow the exact rules, they can be stuck with huge bills," Dr Felsen finds. "Frequently my staff has to appeal to the insurance companies to get some of these situations covered."

Financial worries and unpaid claims can lead to anger and frustration on the part of patients—and physicians and their staff

may have to deal with the fallout. Dr. Magee had a situation like this recently. "I had a patient refuse to pay her co-pay for a visit because she had a high coinsurance for her mammogram [done at a hospital] and did not think this was fair," he recounts.

Carol Pryor, senior policy analyst at the Access Project, calls this problem "the illusion of coverage." As she explains: "When patients find that their CDHC insurance won't cover what they've expected, they're as angry with the hospital or the doctors as they are with the insurance company, because they're shocked at how much they've been charged."

The lack of upfront pricing information compounds the problem, says William Monnig, MD, a urologist in Kentucky. "No one has developed a method to inform patients what their out-of-pocket expenses will be for the services that providers want to deliver," he contends. "Most of the data that has been provided by hospitals, physicians, and other providers is charge data that has no relevance to patients' cost for services."

Dr. Brandt says the situation is difficult for his reception staff, who are often the first ones to explain the details of the coverage. "They can be perceived as the 'bad guy,' which makes their job most uncomfortable."

Negotiating Prices With Patients

With patients using CDHC plans, physicians find themselves talking more about prices and finances, which are often subject to negotiation.

Many physicians dislike the idea of negotiations. According to Mr. Reiboldt, "You might say to yourself, 'I've been negotiating with managed-care companies, the insurance side of business, the third-party payers for years. Now you mean to tell me I'm going to have to start negotiating directly with patients?' And of course, the answer is yes."

Negotiating doesn't necessarily mean discounting services. Even the more cost-conscious consumers judge physicians by reputation and quality, and are often willing to pay more, particularly for specialty care. "Consumers don't always shop at the closest supermarket, or buy the lowest-priced brand of an item in convenience or luxury categories," says Karen Corrigan, CEO of The Strategy Group™ in Norfolk, Va., in a 2006 *Marketing*

Health Services article.

However, surveys show that an increasing number of patients do shop around for the lowest prices. A recent *Minneapolis Star Tribune* article featured one patient who compared cataract surgery prices at the Mayo Clinic ($20,000 for both eyes) and Fairview Red Wing Medical Center ($18,000), but finally chose Minnesota Eye Consultants, which charged just $10,000. According to this article, one Minnesota hospital reduced prices for MRI and CT scans by 10 to 30 percent after patients called to complain that they were finding lower prices elsewhere. A medical service group also cut prices across the board by 10 to 15 percent, bringing them closer to the rates insurers pay.

"If we could get rid of the networks and get rid of those middle folks doing all that negotiation, we could have direct negotiations with the patient," Dr. Johnson says. "Now all of the savings get passed on to the middle folks."

When physicians decide to negotiate on price, Mr. Reiboldt advises them to "maintain confidence [and] privacy in those discussions," to protect both the patients as well as what Mr. Reiboldt calls "the so-called deal" arranged with them.

Physicians should not offer a discount lower than that of their lowest payer. In addition, if a patient's contract says it's the physician's responsibility to collect deductibles and co-pays, this is a contractual obligation that can't be waived, even for selected patients. Dr. Brandt reports, "In my personal experience, I have had only one patient who felt the need to negotiate fees after a procedure was completed, to 'save' their medical savings account dollars."

Dr. Johnson explains that his radiology practice is having some challenges in situations where the practice has already negotiated discounts for PPO members. "We've had some patients who want to get a discount off that negotiated rate," he says, "but they don't realize that there's already been a discount made on the rate. If we could get rid of the networks and get rid of those middle folks doing all that negotiation, we could have direct negotiations with the patient. Now all of the savings get passed on to the middle folks."

Adapting Information Systems

With payers and patients now requiring more detailed cost and quality data and many patients expecting online access to their medical records and e-mail contact with their healthcare providers, medical practices may need to develop new information systems—if not immediately, then at least in the near future, says Elizabeth Woodcock, an independent consultant with MGMA Health Care Consulting Group in a May 2007 article in *Dermatology Times*. Although this can be a costly proposition, especially for small practices, electronic systems definitely save time for physicians and for financial staff members by improving patient flow, clinical tracking, and the payment process.

The 2006 Institute on Medicine (IOM) report *Preventing Medication Errors* recommends greater use of the Internet to improve medical practitioners' and patients' communications and their access to quality information about prescribed medications. The report also encourages physicians to use electronic prescriptions (e-prescriptions). The report committee recommended that by 2008, all prescribers should have plans in place to implement electronic prescribing, and that by 2010, all prescribers should write—and all pharmacies should be able to receive—prescriptions electronically.

In 2007, America's Health Insurance Plans (AHIP) issued recommendations to improve medical quality and safety. The AHIP report also urged health providers to use electronic health records (EHR) to provide consumers with real-time access to their personal health records. Despite these recommendations, recent studies indicate that only about 20 percent of physicians' offices have installed the EHR systems that are needed for electronic prescribing and patient access to personal records.

Physicians who have made the switch to computer-based practice management and medical records have seen tangible benefits. "What I have done to make things better is, I've gotten a computer billing system," Dr. Felsen says. He notes that he recently had to upgrade it to manage new information and HIPAA requirements.

Those who go for complete electronic medical records systems (EMRs) see additional benefits in streamlining medical practices. These "paperless" systems hold patient charts, pre-

scription records, and other information in electronic form and, in some cases, also permit patients to access their records, schedule appointments, renew prescriptions, and even have secure e-mail contact with the physician and office staff. As pointed out previously, automatic reminders for patients who are due for preventive care can improve health outcomes and boost the practice's bottom line. By contracting with consultants or IT companies, many practices can have their new software products modified to interface with payers.

The Legal Picture

CDHC may also change the legal landscape of medical practice. CDHC gives patients great control over the medical spending and treatment choices, but physicians still bear the responsibility to deliver appropriate care. Do cost considerations change what is appropriate?

"Since transformative changes in social and economic arrangements often lead to litigation, we can anticipate that the courts will be deeply involved in resolving challenges to how these new [CDHC] products are implemented," writes Peter D. Jacobson, JD, MPH, professor of health law and policy at University of Michigan School of Public Health, and Michael Tunick in a recent *Health Affairs* article.

Historically, in fee-for-service liability cases, U.S. courts allowed physicians to determine the standard of usual and customary care. According to the "unitary standard of care" principle, the same level of care must be provided to all patients, regardless of resource constraints.

When managed care became popular, legal experts believed the courts would rule against the cost-containment strategies of managed care organizations. They didn't. In one of the most notable cases, prominent lawyers filed a multi-billion-dollar class action suit against Humana, claiming that the health insurer failed to honor its promise to pay for medically necessary care. According to a 2004 *Health Affairs* article written by Georgetown University's M. Gregg Bloche, MD, JD, and Harvard's David M. Studdert, ScD, MPH, the suit also alleged that Humana's financial rewards to doctors for frugal practice violated federal laws governing employees' fringe benefits. A fed-

eral court dismissed the Humana lawsuit three years later, along with similar class action suits.

Although many complainants lost in the legal system, they won in the court of public opinion. Negative press coverage made angry consumers think twice about buying MCO coverage and led MCO investors to press for improvements. According to Drs. Bloche and Studdert, today's MCOs rely less on "aggressive utilization management, selective contracting with caregivers, and financial incentives to physicians to limit care." Indeed, most health insurance plans now give consumers more freedom to choose among doctors and hospitals and to obtain costly tests and treatments.

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"For physicians, consumer-directed care does not change the responsibility to meet the skill and knowledge aspects of the legal standard of care," Dr. Jacobson and Mr. Tunick write. However, CDHC changes the judicial equation, since patients' willingness and ability to pay didn't factor into pre-CDHC lawsuits.

In CDHC plans, consumers, rather than physicians, are empowered to make the choice of which doctors, hospitals, tests, and treatments they want and are willing to pay for. Dr. Jacobson and Mr. Tunick ask, "If patients use their autonomy to decide on a course of treatment different from that recommended by their physician or even to forgo care (perhaps considering the costs to be too high), who bears the risk of harm resulting from a patient's erroneous decision—the patient or the physician?"

"Doctors may face liability for prescribing the diminished level of care that patients ask for," Dr. Bloche says. "But we don't know how the courts are going to address this—they haven't done it yet." As of now, CDHC plans cover only a small proportion of Americans, but the possibility of litigation could increase if CDHC enrollment increases.

In their article, Dr. Jacobson and Mr. Tunick describe the possible scenario of a CDHC patient who presents with head pain. The physician explains two alternatives: (1) an x-ray costing

New Problems Spawn New Products

While physicians fret over increased costs related to CDHC patients, many companies that work with CDHC plans are watching their profits grow. "Consumers and employers can expect a lot of innovation from healthcare companies and financial services firms," says Aamer Baig, a partner in Diamond Management & Technology Consultants, Inc. In a 2007 report, *Seismic Shifts in the Health/Wealth Landscape*, Mr. Baig describes seven specific insurance-related needs that are expected to "generate an aggregate $40 billion worth of demand for new products and services over the next five years." A few examples:

- A $10.4 billion opportunity: provision of integrated benefits administration services and enabling electronic health records portability
- A $6.2 billion opportunity: supplying clinical-decision support and financial- planning tools to help consumers pick out the right health plan and save for health expenses
- A $5.6 billion opportunity: payment processing systems to speed collections from HSAs
- A $4.9 billion opportunity: providing lines of credit, bridge loans, and new credit instruments to help consumers meet their near-term financial obligations until they accumulate funds in an HSA

As just one example, a recent *Wall Street Journal* article highlighted a new offering from Highmark Inc., a Pittsburgh health insurer. Highmark is now selling a Healthcare Visa Gift Card, available in denominations from $25 to $5,000, which can be used to cover anything from elective surgery to prescription co-payments, contact lenses, or even gym membership. Highmark is promoting the cards as stocking stuffers and birthday gifts.

$50, the low-cost choice, and (2) a computed tomography (CT) scan costing $500, which is the physician's recommended treatment. The patient rejects the recommendation because the CT scan is too costly, but the x-ray does not detect a tumor, which then goes untreated.

If the patient alleges that the physician should have provided a higher level of service, the authors say that the physician's legal defense could be assumption of risk—that is, the patient's deliberate and voluntary choice to assume the known risk of a lower level of care. The physician can argue that he or she does not have a duty to provide more care than the patient is willing

to finance.

Alternatively, Dr. Jacobson and Mr. Tunick explain, the defense could emphasize comparative negligence, meaning that the patient, by accepting a lower level of care, is partially at fault for any injury that resulted. Comparative negligence would reduce the patient's monetary award proportionally to his degree of fault in causing the damage.

Would these defenses get the physician off the hook? According to Dr. Jacobson and Mr. Tunick, the courts could still rule that physicians have a duty to maintain the unitary standard of care, regardless of patients' choices. Another possible argument is that physicians' fiduciary duties to act in the patient's best interest supersede the provisions of CDHC insurance plans.

Do Insurers Share the Blame?

Now assume that the patient decides to have the $500 CT scan her physician recommends, but her insurance company refuses to cover it. Not willing or able to assume payment herself, she goes with the x-ray; and the scenario unfolds as before. If the patient sues, where will the courts place the blame? On the physician, for not serving the patient's interests by insisting on the CT scan? On the patient for not pursuing other remedies sooner? Or on the insurance company, for "bad faith" in unfounded denial of benefits or for failure to provide adequate advance information about coverage limits?

All of the above are possible, according to Dr. Jacobson and Mr. Tunick. Based on the Supreme Court's prior use of the 1974 Employee Retirement Income Security Act (ERISA) rules, they say CDHC might be treated "like any other consumer commodity, as opposed to a product that reflects healthcare's inherent differences from other market goods." For physicians, the courts may place less emphasis on "the expert-determined standard of care" and more emphasis on balancing economic risks and benefits. Since the patient is the one responsible for selecting a CDHC plan with a certain level of coverage, the insurer is less likely to be subject to punitive damages for its denial. However, greater emphasis on standard contract law issues would increase insurers' responsibility for "ensuring the transparency, accuracy, and completeness of information provided to patients."