

Money Matters: Managing Expenses

As important as it is to ensure that there is enough cash coming into your practice, it's just as important to watch the amount of money being spent by the practice. Your combination of fixed expenses (such as rent and insurance) and variable expenses (such as medical supplies) needs to be monitored to make certain that overspending doesn't eat into your practice profits.

Fast Facts



- ▲ *Experts recommend analyzing your expenses by Relative Value Units to measure the financial well-being of a practice and determine the true cost of providing different services. Page 74*
- ▲ *To cut the costs of converting to an electronic medical record (EMR) system, investigate whether your hospital will subsidize the costs. Page 78*
- ▲ *Managing inventory and standardizing when possible can lead to big savings on medical and office supplies. Page 81*

Managing expenses requires constant vigilance, says Barry Lycka, M.D., a cosmetic surgeon with offices in Edmonton, Alberta, Canada, and Tallahassee, Fla. Dr. Lycka monitors and minimizes overhead in his practice by keeping an eye on expenses and matching them with revenue. If revenue goes down, spending gets cut.

“In order to keep expenses down, you must have someone constantly looking at your costs and negotiating contracts. Plus, it helps to have others on your staff who are constantly thinking like owners,” says Dr. Lycka.

The principles of budgeting, expense tracking, and types of

expenses involved in running a medical office can be complicated. Expenses such as salaries, equipment, software, partnership and associate particulars, reinvestment, and retirement plans require specialized knowledge and research, says Dr. Lycka.

Although physicians' natural tendency is to focus on quality patient care rather than managing expenses, it's important to take time to understand the money side of medical care.

Tracking Expenses

Before you can cut expenses, you need to know what they are. However, many medical practices aren't tracking them in a way that lets the managers and partners see what is being spent across revenue centers, says Joe White, a healthcare principal at LarsonAllen, a Minneapolis-based accounting firm that specializes in serving physician groups and healthcare systems.

"If you ask, 'How much do you make on labs, on X-rays?' they don't know. They say, 'What are we going to do? Eliminate those services [if expenses are too high]?' But that's not the point. The point is that you can look at where expenses are high and try to do something about that," says Mr. White.

He says that physician groups that don't practice cost accounting are probably missing an opportunity to access valuable information that can benefit their practices. That information can also be a negotiating tool with insurance companies, he says. "You can say to insurance companies, 'You need to pay us more for pediatric immunization because what you're paying us doesn't even cover the cost of the drug.' That's not uncommon. But if you don't have that information, you can't make the argument."

Tab Bingamon, vice president and trust officer with Kanaly Trust Company, a Houston, Tex., financial planning firm, agrees that doctors should establish and monitor cost centers.

"The key to the cost center [is] to establish appropriate parameters in order to make sure that the costs assigned to the center are truly reflective of the activities associated with the center," says Mr. Bingamon. That way, you're not getting a skewed view of how much a particular service is generating or how much it costs to offer. After the cost center is established, there needs to be a periodic review process, he says, to keep the numbers accurate.

"The quality of the review process will improve [the quality

Helping Change the Cycle of Migraine

A RICHER UNDERSTANDING OF PATIENTS' MIGRAINE IMPAIRMENT



The renowned Diamond Headache Clinic recently hosted a meeting featuring the results of the landmark American Migraine Communication study (AMCS). The study revealed that, during office visits for migraines, patients heard mostly closed-ended or short-answer questions (91%), which prompted limited responses.¹ Such questions may tell you about frequency and severity but may fall short in clarifying the patient's total level of impairment due to migraine.

AMCS reveals prevention is often overlooked

Despite the fact that many patients met the American Migraine Prevalence and Prevention study criteria for prevention, discussions were initiated in only 50% of the office visits.¹

TOPAMAX Tablets and TOPAMAX Sprinkle Capsules are indicated for adults for the prophylaxis of migraine headache. The usefulness of TOPAMAX in the acute treatment of migraine headache has not been studied.

TOPAMAX is contraindicated in patients with a history of hypersensitivity to any component of this product.

IMPORTANT SAFETY INFORMATION

TOPAMAX has been associated with serious adverse events, including:

- Hyperchloremic, non-anion gap metabolic acidosis—lowering of bicarbonate levels in the blood. Measurement of baseline and periodic serum bicarbonate is recommended.
- Acute myopia and secondary angle-closure glaucoma—patients should be cautioned to seek medical attention if they experience

blurred vision or ocular pain.

- Oligohidrosis and hyperthermia—decreased sweating and increased body temperature, especially in hot weather. The majority of reports have been in children.
- Cognitive/psychiatric side effects including cognitive dysfunction, psychiatric/behavioral disturbances including suicidal thoughts or behavior, and somnolence and fatigue.

Most common adverse events associated with TOPAMAX 100 mg vs placebo were: paresthesia, 51% vs 6%; anorexia,* 15% vs 6%; fatigue, 15% vs 11%; nausea, 13% vs 8%; diarrhea, 11% vs 4%; weight decrease, 9% vs 1%; taste alteration, 8% vs 1%.

The possibility of decreased contraceptive efficacy and increased breakthrough bleeding should be considered in patients taking combination oral contraceptive products with TOPAMAX.

COULD LEAD TO BETTER INFORMED TREATMENT DECISIONS.¹

Improving Communication Is Important to a Broader Assessment

Open-ended questions can help you gain a richer understanding of your patients' impairment during and *in between* their attacks.

The study showed that most patients gave brief yet informative responses to questions and prompts like these:¹

- "How do migraines make you feel—even when you aren't having one?"
- "Describe the total impact migraines have on your work, family, or social life."

A Subtle Communication Shift Can Help Make a Difference

You may find asking open-ended questions leads to a broader assessment of migraine impairment, and the disruption, disability, and frustration that can come with it. In fact, your patients' level of impairment may require a different treatment option.

Finding out if your patients are feeling trapped in a cycle of suffering, treating and worrying may open up an opportunity to discuss the need for preventive therapy. TOPAMAX can help stop migraines before they start—so your patients can get fewer of them.^{2,3} TOPAMAX offers proven efficacy and is the #1 prescribed brand for migraine prevention in the U.S.⁴

When evaluating migraine, consider using open-ended questions to assess the total degree of migraine impairment. Then talk about the possibility of preventive therapy with TOPAMAX.

The Migraine Discussion Continues

Look for the next installment of *Helping Change the Cycle of Migraine*, in which we'll continue to explore important topics regarding the migraine patient and strategies to help enhance patient care.



www.TOPAMAX.com

Patients should be instructed to maintain an adequate fluid intake in order to minimize the risk of renal stone formation.

* Anorexia is defined as loss of appetite.

Please see brief summary of Prescribing Information on following page.

Rx

Important

Avoid confusion with Toprol-XL® (metoprolol succinate) by spelling out TOPAMAX® (topiramate) on your prescription. Toprol-XL is a registered trademark of the AstraZeneca group of companies.

References: 1. Hahn SR, Nelson M, Lipton RB. Provider-patient migraine discussions: Results of American Migraine Communication study (AMCS). Poster presented at: 58th American Academy of Neurology Annual Meeting, April 1–8, 2006; San Diego, California. 2. Silberstein SD, Neto W, Schmitt J, Jacobs D, for the MIGR-001 Study Group. Topiramate in migraine prevention: results of a large controlled trial. *Arch Neurol*. 2004;61:490-495. 3. Brandes JL, Saper JR, Diamond M, et al, for the MIGR-002 Study Group. Topiramate for migraine prevention: a randomized controlled trial. *JAMA*. 2004;291:965-973. 4. IMS Data. July 2006.

TOPAMAX® (topiramate) Tablets

TOPAMAX® (topiramate capsules) Sprinkle Capsules

Brief Summary of Full Prescribing Information for Migraine. CLINICAL STUDIES FOR OTHER INDICATIONS WILL HAVE DIFFERING ADVERSE EVENTS AND SAFETY CONCERNS. PLEASE SEE FULL PI FOR THIS INFORMATION REGARDING TOPAMAX® FOR EPILEPSY.

INDICATIONS AND USAGE

Migraine: TOPAMAX® (topiramate) Tablets and TOPAMAX® (topiramate capsules) Sprinkle Capsules are indicated for adults for the prophylaxis of migraine headache. The usefulness of TOPAMAX® in the acute treatment of migraine headache has not been studied.

CONTRAINDICATIONS: TOPAMAX® is contraindicated in patients with a history of hypersensitivity to any component of this product.

WARNINGS: Metabolic Acidosis: Hyperchloremic, non-anion gap, metabolic acidosis (i.e., decreased serum bicarbonate below the normal reference range in the absence of chronic respiratory alkalosis) is associated with topiramate treatment. This metabolic acidosis is caused by renal bicarbonate loss due to the inhibitory effect of topiramate on carbonic anhydrase. Such electrolyte imbalance has been observed with the use of topiramate in placebo-controlled clinical trials and in the post-marketing period. Generally, topiramate-induced metabolic acidosis occurs early in treatment although cases can occur at any time during treatment. Bicarbonate decrements are usually moderate (average decrease of 4 mEq/L at daily doses of 400 mg in adults and at approximately 6 mg/kg/day in pediatric patients); rarely patients can experience severe decrements to values below 10 mEq/L. Conditions or therapies that predispose to acidosis (such as renal disease, severe respiratory disorders, status epilepticus, diarrhea, surgery, ketogenic diet, or drugs) may be additive to the bicarbonate lowering effects of topiramate. Metabolic acidosis has been observed at doses as low as 50 mg/day. Serum bicarbonate levels have not been systematically evaluated at daily doses greater than 400 mg/day. The incidence of persistent treatment-emergent decreases in serum bicarbonate in placebo-controlled trials for adults for prophylaxis of migraine was 44% for 200 mg/day, 39% for 100 mg/day, 23% for 50 mg/day, and 7% for placebo. The incidence of a markedly abnormally low serum bicarbonate (i.e., absolute value <17 mEq/L, and >5 mEq/L decrease from pretreatment) in these trials was 11% for 200 mg/day, 9% for 100 mg/day, 2% for 50 mg/day, and 0% for placebo. Some manifestations of acute or chronic metabolic acidosis may include hyperventilation, nonspecific symptoms such as fatigue and anorexia, or more severe sequelae including cardiac arrhythmias or stupor. Chronic, untreated metabolic acidosis may increase the risk for nephrolithiasis or nephrocalcinosis, and may also result in osteomalacia (referred to as rickets in pediatric patients) and/or osteoporosis with an increased risk for fractures. Chronic metabolic acidosis in pediatric patients may also reduce growth rates. A reduction in growth rate may eventually decrease the maximal height achieved. The effect of topiramate on growth and bone-related sequelae has not been systematically investigated. Measurement of baseline and periodic serum bicarbonate during topiramate treatment is recommended. If metabolic acidosis develops and persists, consideration should be given to reducing the dose or discontinuing topiramate (using dose tapering). If the decision is made to continue patients on topiramate in the face of persistent acidosis, alkali treatment should be considered. **Acute Myopia and Secondary Angle Closure Glaucoma:** A syndrome consisting of acute myopia associated with secondary angle closure glaucoma has been reported in patients receiving TOPAMAX®. Symptoms include acute onset of decreased visual acuity and/or ocular pain. Ophthalmologic findings can include myopia, anterior chamber shallowing, ocular hyperemia (redness) and increased intraocular pressure. Mydriasis may or may not be present. This syndrome may be associated with supraciliary effusion resulting in anterior displacement of the lens and iris, with secondary angle closure glaucoma. Symptoms typically occur within 1 month of initiating TOPAMAX® therapy. In contrast to primary narrow angle glaucoma, which is rare under 40 years of age, secondary angle closure glaucoma associated with topiramate has been reported in pediatric patients as well as adults. The primary treatment to reverse symptoms is discontinuation of TOPAMAX® as rapidly as possible, according to the judgment of the treating physician. Other measures, in conjunction with discontinuation of TOPAMAX®, may be helpful. Elevated intraocular pressure of any etiology if left untreated, can lead to serious sequelae including permanent vision loss. **Oligohydrosis and Hyperthermia:** Oligohydrosis (decreased sweating), infrequently resulting in hospitalization, has been reported in association with TOPAMAX® use. Decreased sweating and an elevation in body temperature above normal characterized these cases. Some of the cases were reported after exposure to elevated environmental temperatures. The majority of the reports have been in children. Patients, especially pediatric patients, treated with TOPAMAX® should be monitored closely for evidence of decreased sweating and increased body temperature, especially in hot weather. Caution should be used when TOPAMAX® is prescribed with other drugs that predispose patients to heat-related disorders; these drugs include, but are not limited to, other carbonic anhydrase inhibitors and drugs with anticholinergic activity. **Cognitive/Neuropsychiatric Adverse Events:** Adults: Adverse events most often associated with the use of TOPAMAX® were related to the central nervous system. In adults, the most frequent of these can be classified into three general categories: 1) Cognitive-related dysfunction (e.g., confusion, psychomotor slowing, difficulty with concentration/attention, difficulty with memory, speech or language problems, particularly word-finding difficulties); 2) Psychiatric/behavioral disturbances (e.g., depression or mood problems); and 3) Somnolence or fatigue. **Cognitive-Related Dysfunction:** The majority of cognitive-related adverse events were mild to moderate in severity, and they frequently occurred in isolation. Rapid titration rate and higher initial dose were associated with higher incidences of these events. Many of these events contributed to withdrawal from treatment (see **ADVERSE REACTIONS, Table 1**). In the 6-month migraine prophylaxis controlled trials using a slower titration regimen (25 mg/day weekly increments), the proportion of patients who experienced one or more cognitive-related adverse events was 19% for TOPAMAX® 50 mg/day, 22% for 100 mg/day, 28% for 200 mg/day, and 10% for placebo. These dose-related adverse reactions typically began in the titration phase and often persisted into the maintenance phase, but infrequently began in the maintenance phase. Some patients experienced a recurrence of one or more of these cognitive adverse events and this recurrence was typically in the titration phase. A relatively small proportion of topiramate-treated patients experienced more than one concurrent cognitive adverse event. The most common cognitive adverse events occurring together included difficulty with memory along with difficulty with concentration/attention, difficulty with memory along with language problems, and difficulty with concentration/attention along with language problems. Rarely, topiramate-treated patients experienced three concurrent cognitive events. **Psychiatric/Behavioral Disturbances:** Psychiatric/behavioral disturbances (depression or mood problems) were dose-related for both the epilepsy and migraine populations. In the double blind phases of clinical trials with topiramate in approved and investigational indications, suicide attempts occurred at a rate of 3/1000 patient years (13 events/3999 patient years) on topiramate versus 0 (0 events/1430 patient years) on placebo. One completed suicide was reported in a bipolar disorder trial in a patient on topiramate. **Somnolence/Fatigue:** Fatigue and somnolence were dose-related and more common in the titration phase.

PRECAUTIONS: Hyperammonemia and Encephalopathy Associated with Concomitant Valproic Acid: Concomitant administration of topiramate and valproic acid has been associated with hyperammonemia with or without encephalopathy in patients who have tolerated either drug alone.

Clinical symptoms of hyperammonemic encephalopathy often include acute alterations in level of consciousness and/or cognitive function with lethargy or vomiting. In most cases, symptoms and signs abated with discontinuation of either drug. This adverse event is not due to a pharmacokinetic interaction. It is not known if topiramate monotherapy is associated with hyperammonemia. Patients with inborn errors of metabolism or reduced hepatic mitochondrial activity may be at an increased risk for hyperammonemia with or without encephalopathy. Although not studied, an interaction of topiramate and valproic acid may exacerbate existing defects or unmask deficiencies in susceptible persons. In patients who develop unexplained lethargy, vomiting, or changes in mental status, hyperammonemic encephalopathy should be considered and an ammonia level should be measured. **Kidney Stones:** As in the general population, the incidence of stone formation among topiramate treated patients was higher in men. Kidney stones have also been reported in pediatric patients. An explanation for the association of TOPAMAX® and kidney stones may lie in the fact that topiramate is a carbonic anhydrase inhibitor. Carbonic anhydrase inhibitors, e.g., acetazolamide or dichlorophamide, promote stone formation by reducing urinary citrate excretion and by increasing urinary pH. The concomitant use of TOPAMAX® with other carbonic anhydrase inhibitors or potentially in patients on a ketogenic diet may create a physiological environment that increases the risk of kidney stone formation, and should therefore be avoided. Increased fluid intake increases the urinary output, lowering the concentration of substances involved in stone formation. Hydration is recommended to reduce new stone formation. **Paresthesia:** Paresthesia (usually tingling of the extremities), an effect associated with the use of other carbonic anhydrase inhibitors, appears to be a common effect of TOPAMAX®. Paresthesia was more frequently reported in the monotherapy epilepsy trials and migraine prophylaxis trials versus the adjunctive therapy epilepsy trials. In the majority of instances, paresthesia did not lead to treatment discontinuation. **Adjustment of Dose in Renal Failure:** The major route of elimination of unchanged topiramate and its metabolites is via the kidney. Dose adjustment may be required in patients with reduced renal function (see **DOSE AND ADMINISTRATION**). **Decreased Hepatic Function:** In hepatically impaired patients, topiramate should be administered with caution as the clearance of topiramate may be decreased. **Information for Patients:** Patients taking TOPAMAX® should be told to seek immediate medical attention if they experience blurred vision or periorbital pain. Patients, especially pediatric patients, treated with TOPAMAX® should be monitored closely for evidence of decreased sweating and increased body temperature, especially in hot weather. Patients, particularly those with predisposing factors, should be instructed to maintain an adequate fluid intake in order to minimize the risk of renal stone formation (see **PRECAUTIONS: Kidney Stones**, for support regarding hydration as a preventative measure). Patients should be warned about the potential for somnolence, dizziness, confusion, and difficulty concentrating and advised not to drive or operate machinery until they have gained sufficient experience on topiramate to gauge whether it adversely affects their mental and/or motor performance. Additional fluid intake may be considered if the patient is losing weight while on this medication. **Laboratory Tests:** Measurement of baseline and periodic serum bicarbonate during topiramate treatment is recommended (see **WARNINGS: Drug Interactions**). **In vitro** studies indicate that topiramate does not inhibit enzyme activity for CYP1A2, CYP2A6, CYP2B6, CYP2C9, CYP2C19, CYP2D6, CYP2E1 and CYP3A4/5 isozymes. **Other Drug Interactions: Digoxin:** In a single-dose study, serum digoxin AUC was decreased by 12% with concomitant TOPAMAX® administration. The clinical relevance of this observation has not been established. **CNS Depressants:** Concomitant administration of TOPAMAX® and alcohol or other CNS depressant drugs has not been evaluated in clinical studies. Because of the potential of topiramate to cause CNS depression, as well as other cognitive and/or neuropsychiatric adverse events, topiramate should be used with extreme caution if used in combination with alcohol and other CNS depressants. **Oral Contraceptives:** In a pharmacokinetic interaction study in healthy volunteers with a concomitantly administered combination oral contraceptive product containing 1 mg norethindrone (NET) plus 35 mg ethinyl estradiol (EE), TOPAMAX® in the absence of other medications at doses of 50 to 200 mg/day was not associated with statistically significant changes in mean exposure (AUC) to either component of the oral contraceptive. In another study, exposure to EE was statistically significantly decreased at doses of 200, 400, and 800 mg/day (18%, 21%, and 30%, respectively) when given as adjunctive therapy in patients taking valproic acid. In both studies, TOPAMAX® (50 mg/day to 800 mg/day) did not significantly affect exposure to NET. Although there was a dose dependent decrease in EE exposure for doses between 200-800 mg/day, there was no significant dose dependent change in EE exposure for doses of 50-200 mg/day. The clinical significance of the changes observed is not known. The possibility of decreased contraceptive efficacy and increased breakthrough bleeding should be considered in patients taking combination oral contraceptive products with TOPAMAX®. Patients taking estrogen containing contraceptives should be asked to report any change in their bleeding patterns. Contraceptive efficacy can be decreased even in the absence of breakthrough bleeding. **Hydrochlorothiazide (HCTZ):** A drug-drug interaction study conducted in healthy volunteers evaluated the steady-state pharmacokinetics of HCTZ (25 mg q24h) and topiramate (96 mg q12h) when administered alone and concomitantly. The results of this study indicate that topiramate C_{max} increased by 27% and AUC increased by 29% when HCTZ was added to topiramate. The clinical significance of this change is unknown. The addition of HCTZ to topiramate therapy may require an adjustment of the topiramate dose. The steady-state pharmacokinetics of HCTZ were not significantly influenced by the concomitant administration of topiramate. Clinical laboratory results indicated decreases in serum potassium after topiramate or HCTZ administration, which were greater when HCTZ and topiramate were administered in combination. **Metformin:** A drug-drug interaction study conducted in healthy volunteers evaluated the steady-state pharmacokinetics of metformin and topiramate in plasma when metformin was given alone and when metformin and topiramate were given simultaneously. The results of this study indicated that metformin mean C_{max} and mean $AUC_{0-\infty}$ increased by 18% and 26%, respectively, which were mean CL/F decreased 20% when metformin was co-administered with topiramate. Topiramate did not affect metformin t_{max} . The clinical significance of the effect of topiramate on metformin pharmacokinetics is unclear. Oral plasma clearance of topiramate appears to be reduced when administered with metformin. The extent of change in the clearance is unknown. The clinical significance of the effect of metformin on topiramate pharmacokinetics is unclear. When TOPAMAX® is added or withdrawn in patients on metformin therapy, careful attention should be given to the routine monitoring for adequate control of their diabetic disease state. **Pioglitazone:** A drug-drug interaction study conducted in healthy volunteers evaluated the steady-state pharmacokinetics of topiramate and pioglitazone when administered alone and concomitantly. A 15% decrease in the $AUC_{0-\infty}$ of pioglitazone with no alteration in C_{max} was observed. This finding was not statistically significant. In addition, a 13% and 16% decrease in C_{max} and $AUC_{0-\infty}$ respectively, of the active hydroxy-metabolite was noted as well as a 60% decrease in C_{max} and $AUC_{0-\infty}$ of the active keto-metabolite. The clinical significance of these findings is not known. When TOPAMAX® is added to pioglitazone therapy or pioglitazone is added to TOPAMAX® therapy, careful attention should be given to the routine monitoring of patients for adequate control of their diabetic disease state. **Lithium:** Multiple dosing of topiramate 100 mg every 12 hrs decreased the AUC and C_{max} of Lithium (300 mg every 8 hrs) by 20% (N=12, 6 M; 6 F). **Haloperidol:** The pharmacokinetics of a single dose of haloperidol (5 mg) were not affected following multiple dosing of topiramate (100 mg every 12 hr) in 13 healthy adults (6 M, 7 F). **Amiripiline:** There was a 12% increase in AUC and C_{max} for amiripiline (25 mg per day) in 16 normal subjects (9 male; 9 female) receiving 200 mg/day of topiramate. Some subjects may experience a large

increase in amitriptyline concentration in the presence of topiramate and any adjustments in amitriptyline dose should be made according to the patient's clinical response and not on the basis of plasma levels. **Sumatriptan:** Multiple dosing of topiramate (100 mg every 12 hrs) in 24 healthy volunteers (14 M, 10 F) did not affect the pharmacokinetics of single dose sumatriptan either orally (100 mg) or subcutaneously (6 mg). **Risperidone:** There was a 25% decrease in exposure to risperidone (2 mg single dose) in 12 healthy volunteers (6 M, 6 F) receiving 200 mg/day of topiramate. Therefore, patients receiving risperidone in combination with topiramate should be closely monitored for clinical response. **Propranolol:** Multiple dosing of topiramate (200 mg/day) in 34 healthy volunteers (17 M, 17 F) did not affect the pharmacokinetics of propranolol following daily 160 mg doses. Propranolol doses of 160 mg/day in 39 volunteers (27M, 12F) had no effect on the exposure to topiramate at a dose of 200 mg/day of topiramate. **Dihydroergotamine:** Multiple dosing of topiramate (200 mg/day) in 24 healthy volunteers (12 M, 12 F) did not affect the pharmacokinetics of a 1 mg subcutaneous dose of dihydroergotamine. Similarly, a 1 mg subcutaneous dose of dihydroergotamine did not affect the pharmacokinetics of a 200 mg/day dose of topiramate in the same study. **Others:** Concomitant use of TOPAMAX[®], a carbonic anhydrase inhibitor, with other carbonic anhydrase inhibitors, e.g., acetazolamide or dichlorophenamide, may create a physiological environment that increases the risk of renal stone formation, and should therefore be avoided. **Drug/Laboratory Tests Interactions:** There are no known interactions of topiramate with commonly used laboratory tests. **Carcinogenesis, Mutagenesis, Impairment of Fertility:** An increase in urinary bladder tumors was observed in mice given topiramate (20, 75, and 300 mg/kg) in the diet for 21 months. The elevated bladder tumor incidence, which was statistically significant in males and females receiving 300 mg/kg, was primarily due to the increased occurrence of a smooth muscle tumor, considered histomorphologically unique to mice. Plasma exposures in mice receiving 300 mg/kg were approximately 0.5 to 1 times steady-state exposures measured in patients receiving topiramate monotherapy at the recommended human dose (RHD) of 400 mg, and 1.5 to 2 times steady-state topiramate exposures in patients receiving 400 mg of topiramate plus phenytoin. The relevance of this finding to human carcinogenic risk is uncertain. No evidence of carcinogenicity was seen in rats following oral administration of topiramate for 2 years at doses up to 120 mg/kg (approximately 3 times the RHD on a mg/m² basis). Topiramate did not demonstrate genotoxic potential when tested in a battery of *in vitro* and *in vivo* assays. Topiramate was not mutagenic in the Ames test or the *in vitro* mouse lymphoma assay; it did not increase unscheduled DNA synthesis in rat hepatocytes *in vitro*; and it did not increase chromosomal aberrations in human lymphocytes *in vitro* or in rat bone marrow *in vivo*. No adverse effects on male or female fertility were observed in rats at doses up to 100 mg/kg (2.5 times the RHD on a mg/m² basis). **Pregnancy: Pregnancy Category C.** Topiramate has demonstrated selective developmental toxicity, including teratogenicity, in experimental animal studies. When oral doses of 20, 100, or 500 mg/kg were administered to pregnant mice during the period of organogenesis, the incidence of fetal malformations (primarily craniofacial defects) was increased at all doses. The low dose is approximately 0.2 times the recommended human dose (RHD=400 mg/day) on a mg/m² basis. Fetal body weights and skeletal ossification were reduced at 500 mg/kg in conjunction with decreased maternal body weight gain. In rat studies (oral doses of 20, 100, and 500 mg/kg or 0.2, 2.5, 30, and 400 mg/kg), the frequency of limb malformations (ectrodactyly, micromelia, and amelia) was increased among the offspring of dams treated with 400 mg/kg (10 times the RHD on a mg/m² basis) or greater during the organogenesis period of pregnancy. Embryotoxicity (reduced fetal body weights, increased incidence of structural variations) was observed at doses as low as 20 mg/kg (0.5 times the RHD on a mg/m² basis). Clinical signs of maternal toxicity were seen at 400 mg/kg and above, and maternal body weight gain was reduced during treatment with 100 mg/kg or greater. In rabbit studies (20, 60, and 180 mg/kg or 0, 35, and 120 mg/kg orally during organogenesis), embryofetal mortality was increased at 35 mg/kg (2 times the RHD on a mg/m² basis) or greater, and teratogenic effects (primarily rib and vertebral malformations) were observed at 120 mg/kg (6 times the RHD on a mg/m² basis). Evidence of maternal toxicity (decreased body weight gain, clinical signs, and/or mortality) was seen at 35 mg/kg and above. When female rats were treated during the latter part of gestation and throughout lactation (0.2, 4, 20, and 100 mg/kg or 2, 20, and 200 mg/kg), offspring exhibited decreased viability and delayed physical development at 200 mg/kg (5 times the RHD on a mg/m² basis) and reductions in pre- and/or postweaning body weight gain at 2 mg/kg (0.05 times the RHD on a mg/m² basis) and above. Maternal toxicity (decreased body weight gain, clinical signs) was evident at 100 mg/kg or greater. In a rat embryofetal development study with a postnatal component (0.2, 2.5, 30, or 400 mg/kg during organogenesis; noted above), pups exhibited delayed physical development at 400 mg/kg (10 times the RHD on a mg/m² basis) and persistent reductions in body weight gain at 30 mg/kg (1 times the RHD on a mg/m² basis) and higher. There are no studies using TOPAMAX[®] in pregnant women. TOPAMAX[®] should be used during pregnancy only if the potential benefit outweighs the potential risk to the fetus. In post-marketing experience, cases of hypohidrosis have been reported in male infants exposed *in utero* to topiramate, with or without other anticonvulsants; however, a causal relationship with topiramate has not been established. **Labor and Delivery:** In studies of rats where pups were allowed to deliver pups naturally, no drug-related effects on gestation length or parturition were observed at dosage levels up to 200 mg/kg/day. The effect of TOPAMAX[®] on labor and delivery in humans is unknown. **Nursing Mothers:** Topiramate is excreted in the milk of lactating rats. The excretion of topiramate in human milk has not been evaluated in controlled studies. Limited observations in patients suggest an extensive secretion of topiramate into breast milk. Since many drugs are excreted in human milk, and because the potential for serious adverse reactions in nursing infants to TOPAMAX[®] is unknown, the potential benefit to the mother should be weighed against the potential risk to the infant when considering recommendations regarding nursing. **Pediatric Use:** Topiramate is associated with metabolic acidosis. Chronic untreated metabolic acidosis in pediatric patients may cause osteomalacia/rickets and may reduce growth rates. A reduction in growth rate may eventually decrease the maximal height achieved. The effect of topiramate on growth and bone-related sequelae has not been systematically investigated (see **WARNINGS**). Safety and effectiveness in pediatric patients have not been established for the prophylaxis treatment of migraine headache. **Geriatric Use:** In clinical trials, 3% of patients were over 60. No age related difference in effectiveness or adverse effects were evident. However, clinical studies of topiramate did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently than younger subjects. Dosage adjustment may be necessary for elderly with impaired renal function (creatinine clearance rate \leq 70 mL/min/1.73 m²) due to reduced clearance of topiramate (see **CLINICAL PHARMACOLOGY AND DOSAGE AND ADMINISTRATION** in the full PI). **Race and Gender Effects:** Evaluation of effectiveness and safety in clinical trials has shown no race or gender related effects.

ADVERSE REACTIONS: The data described in the following section were obtained using TOPAMAX[®] (topiramate) Tablets. **Migraine:** In the four multicenter, randomized, double-blind, placebo-controlled, parallel group migraine prophylaxis clinical trials, most of the adverse events with topiramate were mild or moderate in severity. Most adverse events occurred more frequently during the titration period than during the maintenance period. Table 1 includes those adverse events reported for patients in the placebo-controlled trials where the incidence rate in any topiramate treatment group was at least 2% and was greater than that for placebo patients.

Table 1: Incidence of Treatment-Emergent Adverse Events in Placebo-Controlled, Migraine Trials Where Rate Was \geq 2% in Any Topiramate Group and Greater than the Rate in Placebo-Treated

Patients.^b **Body System/Adverse Event** followed by Placebo (N=445) first, TOPAMAX[®] Dosage (mg/day) 50 (N=235) second, 100 (N=386) third, 200 (N=514) fourth. **Body as a Whole - General Disorders:** Fatigue 11, 14, 15, 19; Injury 7, 9, 6, 6; Asthenia 1, <1, 2, 6; Fever 1, 1, 1, 2; Influenza-Like Symptoms <1, <1, <1, 2; Allergy <1, 2, <1, <1, 2. **Central & Peripheral Nervous System Disorders:** Paresthesia 6, 35, 51, 49; Dizziness 10, 8, 9, 12; Hypoaesthesia 2, 6, 7, 8; Language Problems 2, 6, 7; Involuntary Muscle Contractions 1, 2, 2, 4; Ataxia <1, 1, 2, 1; Speech Disorders/Related Speech Problems <1, 1, <1, 2. **Gastro-Intestinal System Disorders:** Nausea 8, 9, 13, 14; Diarrhea 4, 9, 11, 11; Abdominal Pain 3, 6, 6, 7; Dyspepsia 3, 4, 5, 3; **Gastro-Intestinal System Disorders:** Gastrointestinal Disturbance 2, 3, 5; Vomiting 2, 1, 2, 3; Gastroenteritis 1, 3, 3, 2. **Hearing and Vestibular Disorders:** Tinnitus <1, <1, <1, 2. **Metabolic and Nutritional Disorders:** Weight Decrease 1, 6, 9, 11; Thirst <1, 2, 2, 1. **Musculoskeletal System Disorders:** Arthralgia 2, 7, 3, 1; **Neoplasms:** Neoplasm NOS <1, 2, <1, <1. **Psychiatric Disorders:** Anorexia 6, 9, 15, 14; Somnolence 5, 8, 7, 10; Difficulty with Memory NOS 2, 7, 7, 11; Difficulty with Concentration/Attention 2, 3, 6, 10; Insomnia 5, 6, 7, 6; Anxiety 3, 4, 5, 6; Mood Problems 2, 3, 6, 5; Depression 4, 4, 6; Nervousness 2, 4, 4, 4; Confusion 2, 2, 3, 4; Psychomotor Slowing 1, 3, 4; Libido Decreased 1, 1, 1, 2; Aggravated Depression 1, 2, 2, 2; Agitation 1, 2, 2, 1; Cognitive Problems NOS 1, <1, 2, 2. **Reproductive Disorders, Female:** Menstrual Disorder 2, 3, 2, 2. **Reproductive Disorders, Male:** Ejaculation Premature 0, 3, 0, 0. **Resistance Mechanism Disorders:** Viral Infection 3, 4, 4, 3; Otitis Media <1, 2, 1. **Respiratory System Disorders:** Upper Respiratory Tract Infection 12, 13, 14, 12; Sinusitis 6, 10, 6, 8; Pharyngitis 4, 5, 6, 2; Coughing 2, 2, 4, 3; Bronchitis 2, 3, 3, 3; Dyspnea 2, 1, 3, 2; Rhinitis 1, 2, 2. **Skin and Appendages Disorders:** Pruritus 2, 4, 2, 2. **Special Sense Other Disorders:** Taste Perversion 1, 15, 8, 12; Taste Loss <1, 1, 1, 2. **Urinary System Disorders:** Urinary Tract Infection 2, 4, 2. **Renal Calculus 0, 0, 1, 2. Vision Disorders:** Vision Abnormal <1, 1, 2, 3; Blurred Vision 2, 4, 2, 4; Conjunctivitis 1, 1, 2, 1. ^aValues represent the percentage of patients reported for an adverse event. Patients may have reported more than one adverse event during the study and can be included in more than one adverse event category. Blurred vision was the most common term considered as vision abnormal. Blurred vision was an included term that accounted for > 50% of events coded as vision abnormal, a preferred term.

Of the 1,135 patients exposed to topiramate in the placebo-controlled studies, 25% discontinued due to adverse events, compared to 10% of the 445 placebo patients. The adverse events associated with discontinuing therapy in the topiramate-treated patients included paresthesia (7%), fatigue (4%), nausea (4%), difficulty with concentration/attention (3%), insomnia (3%), ataxia (2%), and dizziness (2%). Patients treated with topiramate experienced mean percent reductions in body weight that were dose-dependent. This change was not seen in the placebo group. Mean changes of 0%, -2%, -3%, and -4% were seen for the placebo group, topiramate 50, 100, and 200 mg groups, respectively. Table 2 shows adverse events that were dose-dependent. Several central nervous system adverse events, including some that represented cognitive dysfunction, were dose-related. The most common dose-related adverse events were paresthesia, fatigue, nausea, anorexia, dizziness, difficulty with memory, diarrhea, weight decrease, difficulty with concentration/attention, and somnolence.

Table 2: Incidence (%) of Dose-Related Adverse Events From Placebo-Controlled, Migraine Trials.^a Adverse Event followed by Placebo (N=445) first, TOPAMAX[®] Dosage (mg/day) 50 (N=235) second, 100 (N=386) third, 200 (N=514) fourth. Paresthesia 6, 35, 51, 49; Fatigue 11, 14, 15, 19; Nausea 8, 9, 13, 14; Anorexia 6, 9, 15, 14; Dizziness 10, 8, 9, 12; Weight decrease 1, 6, 9, 11; Difficulty with Memory NOS 2, 7, 7, 11; Diarrhea 4, 9, 11, 11; Difficulty with Concentration/Attention 2, 3, 6, 10; Somnolence 5, 8, 7, 10; Hypoaesthesia 2, 6, 7, 8; Anxiety 3, 4, 5, 6; Depression 4, 4, 6; Mood Problems 2, 3, 6, 5; Dry Mouth 2, 2, 3, 3, 5; Confusion 2, 2, 2, 4; Involuntary Muscle Contractions 1, 2, 2, 4; Abnormal Vision 1, 1, 2, 3. **Renal Calculus 0, 0, 1, 2.** The incidence rate of the adverse event in the 200 mg/day group was \geq 2% than the rate in both the placebo group and the 50 mg/day group. **Other Adverse Events Observed During Migraine Clinical Trials:** Topiramate, for the treatment of prophylaxis of migraine headache, has been administered to 1,367 patients in all clinical studies (includes double-blind and open-label extension). During these studies, all adverse events were recorded by the clinical investigators using terminology of their own choosing. To provide a meaningful estimate of the proportion of individuals having adverse events, similar types of events were grouped into a smaller number of standardized categories using modified WHOART dictionary terminology. The following additional adverse events that were not described earlier were reported by greater than 1% of the 1,367 topiramate-treated patients in the controlled clinical trials: **Body as a Whole:** Pain, chest pain, allergic reaction. **Central & Peripheral Nervous System Disorders:** Headache, vertigo, tremor, sensory disturbance, migraine aggravated. **Gastrointestinal System Disorders:** Constipation, gastroesophageal reflux, tooth disorder. **Musculoskeletal System Disorders:** Myalgia, Platelet, Bleeding, and Clotting Disorders: Epistaxis. **Reproductive Disorders, Female:** Intermenstrual bleeding. **Resistance Mechanism Disorders:** Infection, genital moniliasis. **Respiratory System Disorders:** Pneumonia, asthma. **Skin and Appendages Disorders:** Rash, alopecia. **Vision Disorders:** Abnormal accommodation, eye pain. **Postmarketing and Other Experience:** In addition to the adverse experiences reported during clinical testing of TOPAMAX[®], the following adverse experiences have been reported worldwide in patients receiving topiramate post-approval. These adverse experiences have not been listed above and data are insufficient to support an estimate of their incidence or to establish causation. The listing is alphabetized: bullous skin reactions (including erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis), hepatic failure (including fatalities), hepatitis, pancreatitis, pemphigus, and renal tubular acidosis.

DRUG ABUSE AND DEPENDENCE: The abuse and dependence potential of TOPAMAX[®] has not been evaluated in human studies.

OVERDOSAGE

Experiences with TOPAMAX[®] have been reported. Signs and symptoms included convulsions, drowsiness, speech disturbance, blurred vision, diplopia, mentation impaired, lethargy, abnormal coordination, stupor, hypotension, abdominal pain, agitation, dizziness and depression. The clinical consequences were not severe in most cases, but deaths have been reported after poly-drug overdoses involving TOPAMAX[®].

Topiramate overdose has resulted in severe metabolic acidosis (see **WARNINGS**).

A patient who ingested a dose between 96 and 110 g topiramate was admitted to hospital with coma lasting 20-24 hours followed by full recovery after 3 to 4 days.

In acute TOPAMAX[®] overdose, if the ingestion is recent, the stomach should be emptied immediately by lavage or by induction of emesis. Activated charcoal has been shown to adsorb topiramate *in vitro*. Treatment should be appropriately supportive. Hemodialysis is an effective means of removing topiramate from the body.



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of the information] and allow better decisions to be made as to whether costs can be eliminated, reduced, or outsourced.”

But how do you do it? Janet Ruth, C.P.A. and tax manager for Kerber, Eck & Braeckel, a St. Louis, Mo., accounting firm, recently conducted a cost analysis for a nephrology practice.

Physicians should regularly analyze their practice financials to ensure that the business is healthy, since it's possible to have a great deal of money coming in, but also to be earning less than they should after expenses are tallied. Mr. White recommends using Relative Value Units (RVUs) as a measurement tool.

She says that the doctor was providing immunizations for his patients, but didn't understand what that service was costing him, she says. He was trying to decide whether to discontinue the service to his patients and instead refer them to the hospital.

Ms. Ruth's firm looked at how much each vial was costing the practice, as well as how many shots were given per vial. She

also looked at the level of the staff needed to give the shots and how much time it took on average. She used those figures to determine the labor cost involved. Once she added up all of the costs, including the cost to store the vials, she compared that total cost with the insurance reimbursement.

“The practice was coming out ahead, but not by much,” she says. However, once the physician considered that this was also a service to clients—who preferred to have the shot administered at the doctor's office instead of the hospital—he decided to keep providing it.

Physicians should regularly analyze their practice financials to ensure that the business is healthy, since it's possible to have a great deal of money coming in, but also to be earning less than they should after expenses are tallied. Mr. White recommends using Relative Value Units (RVUs) as a measurement tool. RVUs are values that represent the amount that Medicare will pay for each CPT code, he explains.

Looking at a practice's revenue per RVU and expenses per RVU (including physician compensation per RVU) gives physicians good benchmarks by which to measure the financial well-being of their practices, says Mr. White. Once a practice

analyzes the average income that it receives per RVU, it can compare itself with other practices in the same specialty, he says. That information is available through specialty societies or the Medical Group Management Association, he says.

“That gives you a meaningful number. Without it, it’s like one physician making \$200,000 and the other making \$100,000. The guy who makes \$200,000 might work 10 hours a day, not taking any lunches, breaks, or vacation, so he makes \$20 per RVU. The other guy works 3.5 days a week, takes 10 weeks vacation, and works 8 to 4 with an hour for lunch, so he earns \$30 per RVU. [The ability to use RVUs as a benchmarking tool] is an accountant’s dream.”

C.P.A. Dan Kushner agrees that RVUs can be useful. “What they did was figure out the value of a particular medical procedure in relation to other services—so if an office visit was 1, then heart surgery might be 7. So it goes by difficulty, the length of time, the whole nine yards,” says the accountant with Gerson, Preston, Robinson & Co., an accounting firm based in Miami, Fla. However, he suggests that physicians also work out their own versions of RVUs.

“I like to have my physicians work out their own RVU method, based on their own specialty, their own office,” he says. Physicians can take the most frequently used or applicable codes and examine how many the doctor has done, then use that information to determine “production numbers,” he says. Determine how much that revenue center is worth to the practice by examining its income, costs, and frequency. By focusing on a smaller universe of codes, Mr. Kushner says, you can

Sharing the Cost of Malpractice Insurance

Medical malpractice insurance is one of the biggest expenses of any medical practice. A report in the July 23, 2004, issue of *Medical Practice Management* said that some enterprising physicians have asked their patients to help foot the bill, charging annual fees ranging from \$10 to \$125 per year or a smaller per-visit stipend. One physician reported that he received more than \$5,000 in “donations” from his patient base after he explained the rising cost of malpractice insurance.

get a clearer picture of how your practice runs and where the money is generated.

Controlling Expenses

Once you have an accurate understanding of what your expenses are, you can take steps to control and reduce them. However, cutting costs shouldn't impact patient care, says Judy Capko, founder of Capko & Company, a medical practice management company in Thousand Oaks, Calif., and author of *Secrets of the Best-Run Practices* (Greenbranch Publishing, 2005). In fact, she says, sometimes the physician can improve patient service and decrease expenses at the same time. In addition, the financial resources that are saved can be reinvested in the business. Our experts advise looking at these areas closely:

Staffing

✔ **Manage staff scheduling carefully** and set overtime policies. Sloppy staff scheduling can lead to unnecessary overtime. Mr. White advises having policies that do not allow overtime unless it is specifically authorized.

✔ **Review your staffing needs regularly.** Your practice may have grown and may need new staff members to operate more efficiently, or you may have streamlined your operations or adopted new technology that requires fewer staff members in your office. Dr. Lycka also advises monitoring your staff for employees who are difficult or who contribute negatively to your culture, since they can drain resources, create an unpleasant work environment, and cost you money through lost productivity.

✔ **Build strong relationships with payers.** It costs money to get reimbursed from health insurers, but Mr. White says that expense can be reduced by having a strong team in your business office. "Having individuals assigned to particular insurance companies can help," he says. "Relationships are important, and someone who handles one company regularly is more familiar with the claims."

✔ **Look at outsourcing.** Another way that some practices can save money is through outsourcing. One example is hiring reliable home-based transcription services in the community. In July 2003, *Healthcare Management News* reported that the St. Barnabus Health Care System found that using home-based, pro-

duction-based transcription services cost the healthcare system nearly 37 percent less per character than total department outsourcing and 31 percent less than full-time, department-based transcription, with an increased productivity rate of nearly 40 percent over office-based transcriptionists.

Location

✔ **Don't be afraid to negotiate.** Landlords like physician-tenants. Don't hesitate to ask for the amenities you need to make your practice work in that location.

✔ **Share space.** Some physicians share office space and front-office staff, especially in the start-up phase or in satellite locations, says Ms. Ruth. She sees her physician clients structuring this in a number of ways, sometimes sharing just the office space and sometimes sharing staffing costs, too.

Some practices can save money by hiring reliable home-based transcription services in the community. St. Barnabus Health Care System realized savings of nearly 37 percent compared with total department outsourcing and 31 percent less than full-time department-based transcription, with an increased productivity rate of nearly 40 percent.

✔ **Consider what needs to be custom—and what doesn't.**

While your exam rooms should be as efficient as possible, why spend big bucks on brand-new office furniture and filing cabinets? Ms. Ruth says that many practices can easily save money by furnishing their business offices with desks, chairs, filing cabinets, and the like that are purchased second hand. "If you have a very high-end practice, like an upscale plastic surgery practice, you might want to opt for expensive furniture and artwork, but most offices can get by just fine with used furniture," she says.

Technology and Equipment

✔ **Automate as much as possible.** Mr. White tells physicians to submit claims electronically and to authorize electronic remittance directly to the practice's bank account. "In some cases, you can even integrate that information from the bank with your billing system so that you don't have to post payments manually. That's a big cost savings," he says. Registration kiosks reduce

the number of front-desk staff needed and may increase compliance with HIPAA, since patients can enter their information without reciting their personal information to a staff person.

✔ **Work with your hospital.** Your hospital may help subsidize your EMR transition, says Mr. White, to encourage a close working relationship with the physician. “[Hospitals] like to integrate their medical records with the physicians in the area,” he says. The hospital may pay up to 85 percent of the cost of the system, and provide support during the transition. However, Mr. White cautions that it’s more important that the EMR system be appropriate for the practice. Since EMRs are not one-size-fits-all technology, you need to be sure that the hospital’s system matches the needs of your practice. If it does, take advantage of the savings, says Mr. White. You may also be able to access other buying programs through your hospital, cutting costs on supplies and other necessities.

✔ **Buy rather than lease equipment.** “Most of the time, I see people purchasing their equipment because the lease cost makes it almost not feasible,” says Ms. Ruth. “You’re basically buying it anyway, and your bank can usually give you a better rate than the capital lease companies can.”

Purchasing

✔ **Be stingy with inventory orders.** As Edward Gulko, administrator of Englewood Orthopedic Associates in Englewood, N.J., noted in Chapter 2, it’s important to have as much standardization in inventory as possible and to streamline ordering from a central location. This gives you the ability to order greater quantities of some standardized items, such as printer cartridges, and prevents your practice from incorrectly estimating the stock on hand. Overstocking ties up unnecessary financial resources while having insufficient stock can negatively impact your ability to serve your patients, says Mr. Gulko.

✔ **Review health insurance costs annually.** One area in which physicians are often generous with employees is health insurance, says Mr. White. “Physicians tend to pay 100 percent of employee coverage and sometimes part of the family coverage, and they absorb the increase every year,” he says. Mr. White suggests asking employees to participate in health insurance costs

by contributing part of their own premium cost, or at least paying part or all of their family members' insurance premiums.

✔ **Keep other annual expenses in check.** From legal fees to lab services, virtually everything on which your practice spends money is subject to increasing prices, says Ms. Ruth. It's a good idea to review your primary spending areas and any price increases that have occurred. "We worked with one practice that found that offering lab services in house was getting out of control," she says. "They found it much more cost-effective to outsource them." Have someone in your office meet with service providers, consultants, and salespeople to negotiate prices.

Your hospital may help subsidize your EMR transition, says Mr. White, to encourage a close working relationship with the physician. "[Hospitals] like to integrate their medical records with the physicians in the area," he says. The hospital may pay up to 85 percent of the cost of the system, and provide support during the transition.

David P. Schmiege of Med-strategies Management Group, Ltd., a practice management group based in Burr Ridge, Ill., writes in an article for the Illinois Chapter of the American Academy of Pediatrics that physicians should examine ancillary expenses, and suggests watching for cost creep on supplies, advertising, repairs, and maintenance contracts. He advises bidding out maintenance and vendor contracts on an annual basis and taking advantage of prompt-payment discounts.

✔ **Check on your retirement plan contributions.** "Some physicians still have the old 'We'll put 15 percent of employee compensation into our retirement plan,'" says Mr. White. Instead, he suggests adjusting contributions based on what is appropriate for the business. Set a manageable contribution, which can be adjusted if the practice has a good year, he says.

Finally, don't be seduced by "keeping up with the Joneses" when it comes to spending on your practice. "Doctors deny themselves the finer things in life for so long while in medical school and in residency that once the income starts flowing, they [want to] catch up as quickly as they can," says Gregory L. Reed, director of planning at Smith, Frank & Partners, L.L.C., a financial planning firm based in Dallas, Tex. Oversized office space, lux-

ury cars leased through the business, and unnecessary equipment can put tight constraints on the practice's ability to save and reinvest in itself, so tracking expenses accurately becomes crucial.

If your practice pays for your car, don't automatically take that as a license to go luxe, says Ms. Ruth. "Every physician wants a car through the business, but [according to the Internal Revenue Code] it has to be used at least 50 percent for business," she says. It can be costly to pay for perks through your business if they're not really for business, both through their expense and through issues with the IRS if you deduct an expense that isn't really for the business. "A common one is taking the spouse along for a business trip, then extending the trip and writing the whole thing off," she says. "You can't do that. You need to carve out only the portion of the trip that was for business."

Risky Business

Practices can cut current and possible expenses by engaging in appropriate risk management, says Paul D. Weinberg, C.P.A., a partner with DeMarco, Kinnaman, Lewis & Co., an accounting firm in Lincolnshire, Ill. Risk management includes everything from maintaining proper records and documentation for medical malpractice and taxation issues to following safe workplace practices to ensure that employees are not at risk.

Mr. Weinberg says that practices should "balance the scorecard," or review their own practices and see where potential for risk lies. He advises practice administrators to make lists of the potential areas of risk for the practice and develop written policies and procedures to minimize those risks as much as possible. Some of these areas might include the following:

■ **Office safety.** Make sure that you abide by Occupational Health and Safety Administration (OSHA) guidelines, especially their bloodborne pathogen guidelines for medical businesses. In addition, says Dionne Williams, team leader and industrial hygienist for OSHA, make sure that you conduct safety checks. Is your office run in a manner that does not create safety issues for employees or patients? OSHA offers free guidelines and consultation to make your office a safer place. Increased safety can lead to greater productivity, decreased downtime and absenteeism due to accidents, and fewer accident- and workplace-

related lawsuits, not to mention lower worker's compensation rates, says Mr. Weinberg.

■ **Patient relations:** Medical malpractice suits cost money as well as the time it takes to defend the suit, says Mr. Weinberg. By keeping good records, obtaining proper consent and authorization, and dealing fairly and appropriately with patients, you can decrease the possibility of a lawsuit, he says.

■ **Compliance:** Your office needs to periodically review the requirements it must meet to comply with its obligations under its business structure, such as corporate filings, as well as various regulatory requirements with state and Federal agencies. Failure to keep on top of the laws, rules, and guidelines that apply to your business could lead to fines and penalties from the overseeing agencies. From filing incorrect tax remittance to weathering a Medicare audit unscathed, you need to ensure that your office practices can protect you from liability, says Ms. Ruth.

■ **Reporting structure:** By far, the area of risk and exposure

Inventory Control

Can you cut spending just by moving your inventory? Edward Gulko, practice administrator, says yes. He is an advocate of consolidation and inventory management as a key area to reduce wasteful spending.

"Too many practices I see will take the entire inventory and scatter it out into each exam room," he explains. But with this system, exam rooms that get used less often might have supplies that expire before they are used, which is a total waste of money. "Instead, I recommend a stock inventory in the storeroom and just putting what I need for a day or two in each exam room, then restock as necessary," he advises. This gives the practice a more accurate method of evaluating inventory levels. It also allows more control. Mr. Gulko points out that a central supply area allows you to rotate inventory to ensure that products close to their expiration date get used first.

Inventory ties up capital that could be used elsewhere in the practice, he adds. If you don't have a good sense of the supplies that you have, you could be purchasing more than you need. "You could have a policy that you will maintain a one-month supply, but you might find that if [the inventory is] scattered, you have a two-or three-month supply, or you run the risk of running out, which is just as bad," he explains.

that Ms. Ruth sees most among her medical practice clients is allowing one employee to have too much control over the business. “Usually it’s the office manager,” she says. “The doctor doesn’t want to deal with the day-to-day running of the business,

By far, the area of risk and exposure that Ms. Ruth sees most among her medical practice clients is allowing one employee to have too much control over the business. “I’ve seen fraud result from this,” she says. “I’m constantly telling doctors that you need to watch this.”

so he hands over too much control. The office manager is signing checks, running the office. I’ve seen fraud result from this, and I’m constantly telling doctors that you need to watch this.”

If you’re not able to personally oversee the financial end, then hire your accountant to do regular audits of the books. That will provide an additional

review of your financial records to ensure that they are appropriate, as well as ensure that no one is spending your practice’s money inappropriately.

If your staff can’t manage the task, a medical practice consultant or even your accountant can help you draft policies and procedures to mitigate risk. Dr. Adan Rios of Oncol Therapeutics, an oncology practice in Houston, Tex., says that his oncology practice has written policies and procedures to cover all aspects of operations to comply with Federal and state laws.

“Particularly important are the policies and procedures pertaining to safety and follow-up of patients undergoing chemotherapy,” says Dr. Rios. Nursing and pharmacy policies include more than one safety checkpoint to avoid errors in orders, dispensing, and administration of chemotherapy agents. Careful training and education of personnel in these areas are fundamental to the success of the practice, he says.

Malpractice Insurance

One of the biggest expenses for physicians is malpractice or liability insurance. Medical malpractice insurance requirements vary from state to state. However, even in states that don’t mandate coverage, most physicians opt for it to protect themselves in case a patient sues. In addition, physicians usually need malpractice coverage in order to treat patients who are in the hospital.

According to a 2006 report by the Robert Wood Johnson Foundation, “Understanding Medical Malpractice Insurance: A Primer,” the malpractice insurance industry has experienced significant shifts in the cost and availability of policies. Policy premiums vary with the determined risk of the provider’s practice area (the higher the risk of the practice area, the higher the premium) and location. So, for instance, a high-risk obstetrician will pay more than a podiatrist. Generally, the report says, malpractice is not experience rated, as automobile insurance often is, based on a motorist’s driving record. The physician’s record doesn’t usually play a part in premiums, says the report.

In some states, malpractice insurance is difficult and expensive to obtain. The report cites market shifts, including the demise of some commercial carriers and physician-owned insurance providers, called mutuals, as well as the growth of joint underwriting associations (JUAs) and patient compensation funds (PCFs). JUAs are last-resort insurance carriers mandated by states, which provide insurance for physicians who cannot find insurance on the open market. PCFs are state funds that cover any overages of awards beyond what a physician’s policy will cover. Both are funded through other insurers, as well as fees and surcharges on the policies of other physicians and hospitals, the report explains.

However, there are some ways to save on your premiums. Dr. Suvak advises examining your coverage requirements carefully.

“One way [to cut costs] is to simply pay attention to what you are applying for in coverage,” says Dr. Suvak. She cautions that each “procedure category” impacts the cost.

“For instance,” says Dr. Suvak, “as a primary care provider, I got coverage for minor surgical procedures, as I had performed them quite frequently. As my practice evolved, I found that I simply wasn’t doing those types of procedures as I originally thought I would, so dropping that from my malpractice insurance resulted in significant savings.”

Dr. Suvak thinks a good time to review your policy is when it’s up for renewal. “In the high-risk areas, it’s important to take the time to do a cost analysis. If the cost of coverage for a procedure exceeds the revenue for the procedure, then it merits closer evaluation as to its necessity within the context of the overall practice,” she says. “An accountant is a great asset here

and well worth it if you haven't had your practice's financial health reviewed in recent years."

Your policy will generally cover investigation of claims; legal representation, if necessary; and up to a predetermined amount, usually \$1 million per case, not to exceed a certain amount per year.

In addition to limiting covered services, you may be able to save on your premiums if you purchase a policy with a higher deductible. The more you're willing to pay out of your pocket in the case of a medical malpractice judgment, the less you will have to pay the insurance company. In addition, the Robert Wood Johnson report states some physicians have been able to find lower-cost insurance by affiliating with hospitals and taking advantage of their buying power to reduce premiums.

The Tax Man

Whenever a business makes money, a portion of it goes to the Internal Revenue Service. In addition, you may owe state and local agencies, depending on your location.

While everyone has to pay his or her fair share, there are ways to minimize your burden, says Barbara Gates of Gates, Moore and Company, a medical practice management and accounting firm based in Atlanta, Ga.

While some physicians or office managers become familiar enough with their business structure and tax codes to do their taxes themselves, it is generally better to have a skilled professional handle them, especially in the early years. Federal and state tax codes change frequently, and a certified public accountant (CPA) keeps up to date on those changes, which may affect the amount of tax that you owe.

Ms. Gates says that many physicians choose C-corporation structure for their businesses, making them qualified personal service corporations, or QPSCs. A personal service corporation is a C-corporation that is engaged in the performance of personal services that are performed by employee-owners, such as in the medical, legal, and accounting fields. This type of company pays taxes on profits to the company, rather than on income to the partners.

In order to minimize your tax liability, it's important to do some planning before the end of the year, says Ms. Gates. If you're a partner in a privately owned practice, she says, you have

several areas to consider under C-corporation structure. First, your taxes will be affected by whether you use an accrual or cash method of accounting. While most corporations are required to use the accrual method, where income is counted when a billable event occurs, a QPSC that has gross receipts under \$5 million may use cash accounting, where income is only counted when it is received. Ms. Gates says that accounts receivable are a big part of assets, which can take as long as two or more months to collect, especially when you're working with third-party billing. Using cash-based accounting allows you to forego paying taxes on money that you haven't yet received. Most S-corporations and Limited Liability Companies (LLCs) and partnerships can use cash-based accounting, as well.

Ms. Gates says that cash-method taxpayers also generally deduct and expense when paid. "This general rule, however, is subject to some qualifications when the expense paid is a prepayment, one that, under ordinary accounting concepts, would be allocable to a later year, or that represents the cost of acquiring an asset that is not consumed during the course of the year," she says.

In this case, the "three-prong test" applies. She says that payment of an otherwise current expense will be deductible if it is not a refundable deposit, if the timing of the payment has a business purpose, and if the deduction does not materially distort income.

Of course, you need to seek reliable counsel when it comes to determining how cash versus accrual accounting methods will affect your state taxes.

Whether the practice is structured as a C-corporation, S-corporation, LLC, or partnership, there are some other tax advantages that doctors should review with their tax advisors, says Ms.

Limiting Liability

In *The Doctor's Wealth Preservation Guide* (Selah Publishing Group, 2003), Rocco M. DeFrancesco, Jr., suggests savvy asset-protection strategies, including creating limited liability companies or family limited partnerships as ownership entities of the practice's real estate and equipment, which eliminate them from risk if a practice is sued for malpractice.

Gates. She suggests that physicians consider the following:

■ **Election to Expense Certain Capital Assets:** According to Internal Revenue Code section 179, a business can elect to count as an expense up to \$112,000 for qualified section 179 property. The IRS says this includes most tangible property (except land), including buildings, machinery, vehicles, furniture, equipment, and even EMR systems and packaged software, which you placed in service during the tax year. There are some value restrictions, so it's wise to have your accountant advise you whether it's best to take the full value of the property as an expense or to depreciate it over time.

The IRS says that you begin to depreciate your property when you place it in service for use in your trade or business or for the production of income. You stop depreciating property either when you have fully recovered your cost or other basis or when you retire it from service, whichever happens first. However, if you have a high-income year, Ms. Gates says that this approach may help offset some expense.

■ **Capitalizing Business Start-up Expenses:** If your practice is new, in order to deduct your business start-up expenses, they must be amortized, or distributed in equal installments over a period of time, says Ms. Gates. The IRS says that a corporation may elect to amortize costs paid or incurred before October 23, 2004, over a period of 60 months or more. For costs paid or incurred after October 22, 2004, the corporation can elect to

No Deduction Allowed

Ms. Gates says that certain expenses incurred by a professional corporation are not deductible for tax purposes, including these:

- Penalties
- Federal income taxes
- Premiums paid for officers' life insurance
- Club dues
- Political contributions
- Any gift cost beyond \$25
- Corporate auto lessee inclusion amounts
- Excess of capital losses over capital gains
- Passive activity losses

deduct up to \$5,000 of such costs for the year the corporation begins business operations. That amount is reduced (but not below zero) by the amount the total costs exceed \$50,000. If the total costs are \$55,000 or more, the deduction is reduced to zero.

■ **Making Charitable Contributions:** Donating money to a registered 501(c)3 organization is a deductible expense. However, for C-corporations, charitable deductions for a tax year can't exceed 10 percent of its taxable income for the year, she says. Taxable income for this purpose is computed without deductions for charitable contributions and certain other special items. To the extent contributions in any year exceed this limit, the excess can be carried forward and deducted over five years. Other business structures do not have the 10-percent restriction.

■ **Deducting Contributions to Qualified Retirement Plans on an Accrual Basis:** Ms. Gates says that one notable exception to the cash-basis rules relates to contributions to qualified deferred compensation plans. The Internal Revenue Code says that a payment made for the preceding taxable year is deductible if the payment is made before the due date of the employer's return, including extensions. So, for example, if you haven't written a check to your employees' qualified retirement plan by December 31, you can still deduct the payment as long as it's made before you file your tax return, including any filing extensions.

■ **Accumulated Earnings on QPSCs:** Ms. Gates says that a qualified personal service corporation may accumulate up to \$150,000 of undistributed earnings and profits without penalty and won't be penalized for accumulating additional amounts if it has a "reasonable business need" for doing so. The accumulated earnings (penalty) tax is 39.6 percent of the excess accumulated earnings, so you'll want to carefully monitor the undistributed earnings of the corporation.

While the experts have concerns that too many practices don't analyze cost centers closely enough, Mr. White believes this is changing, and that as practices continue to face a challenging reimbursement climate, more will be closely examining where and how they are spending their money.