Practice Trends

New Federal Regs Aim to Grease Health IT Wheels

BY MARY ELLEN SCHNEIDER

New York Bureau

ospitals, health plans, and other health care organizations will soon Le be able to help physicians obtain health information technology without running afoul of federal fraud laws under regulations issued last month by the Department of Health and Human Services.

In two final regulations published in the Federal Register on Aug. 8, the Centers for

Medicare and Medicaid Services and the HHS Office of Inspector General carved out new exceptions to the Stark physician self-referral law and the federal antikickback statute. Under these new exceptions, certain health care entities will be able to donate interoperable electronic health record (EHR) software and training. Hospitals and other health care organizations will also be able to provide hardware, software, and training that are "necessary and used solely" for electronic prescribing.

The regulations did not cap the donations to physicians for electronic prescribing technology, but the government is requiring physicians to share some of the costs of donated EHR technology. Under the rules, physicians will be required to pay 15% of the donor's cost of the EHR technology and services. The regulations go into effect in October (60 days after publication in the Federal Register). The provisions related to EHR arrangements are slated to sunset on Dec. 31, 2013.

The regulations were widely praised by physician organizations and health IT industry groups for breaking down barriers to physician adoption. But Patrick Hope, legislative counsel for the American College of Physicians, said the changes aren't likely to do a whole lot to speed physician adoption of the technologies since few hospitals will be able to afford to donate the expensive technology to physicians.

"They are operating at the margins just as physician offices are," Mr. Hope said.

ACP officials are urging members of Congress to establish an add-on payment to the Medicare reimbursement for an office visit in an effort to help offset the ongoing costs of an electronic health record system, Mr. Hope said. While the regulations are helpful in removing some barriers, he said,

Health plans may offer electronic prescribing products, but hospitals are likely to want to help physicians acquire more comprehensive EHR systems.

an add-on payment would create a better business case for physician adoption of health IT. The jury is still out as to what impact these regulations will have on physician adoption, said Chantal Worzala, senior associate director for

policy at the American Hospital Association. Not all hospitals will have the financial resources to donate health IT services, she said, since only about a third of U.S. hospitals are making a profit.

But the regulations will give hospital administrators more options. "Hospitals really should have flexibility in working with community physicians," she said.

Although some health plans may be interested in offering electronic prescribing products, Ms. Worzala said, hospitals are likely to want to help physicians acquire more comprehensive EHR systems.

The relaxation of the Stark physician self-referral law and the antikickback statute is a good thing, said Dr. Steven E. Waldren, assistant director of the American Academy of Family Physicians' Center for Health Information Technology, since the changes will allow more health IT resources to flow to physicians. However, he cautioned physicians not to count on getting this support.

This type of support won't be available to all physicians and in some cases may not be appropriate, he said. For example, Dr. Waldren said that some hospital electronic health record systems are not designed for the ambulatory environment and may end up costing physicians more money in the long run. The bottom line is that physicians need to continue to do their "due diligence" in researching systems, he said.

The Medicare Modernization Act of 2003 mandated that the HHS Secretary create exemptions that would allow for certain health care organizations to help furnish physician practices with electronic prescribing technology. The changes were originally outlined in a proposed Continued on following page

Our della METADATE CD® (methylphenidate HCl, USP)

BRIEF SUMMARY: Please see full Prescribing Information.

INDICATION AND USAGE: Attention Deficit Hyperactivity Disorder (ADHD): METADATE CD is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

The efficacy of METADATE CD in the treatment of ADHD was established in one controlled trial of children aged 6 to 15 who met DSM-IV criteria for ADHD (see CLINICAL PHARMACOLOGY in full

children aged 6 to 15 who met DSM-IV criteria for ADHD (see CLINICAL PHARMACULOGY IN TUB
Prescribing Information).

CONTRAINDICATIONS: Agitation: METADATE CD is contraindicated in patients with marked anxiety,
tension and agitation, since the drug may aggravate these symptoms.

Hypersensitivity to Methylphenidate: METADATE CD is contraindicated in patients known to be hypersensitive to methylphenidate or other components of the product.

Glaucoma: METADATE CD is contraindicated in patients with glaucoma.

Tics: METADATE CD is contraindicated in patients with moror tics or with a family history or diagnosis of
Tourette's syndrome (see ADVERSE REACTIONS).

Monoamine Oxidase Inhibitors: METADATE CD is contraindicated during treatment with monoamine
oxidase inhibitors, and also within a minimum of 14 days following discontinuation of a monoamine oxidase inhibitor (hypertensive crises may result).

Hypertension and Other Cardiovascular Conditions: METADATE CD is contraindicated in patients with
severe hypertension, angina pectoris, cardiac arrhythmias, heart failure, recent myocardial infarction, hyperthyriodism or thyrotoxicosis (see WARNINGS).

WARNINGS: Serious Cardiovascular Events: Sudden Death and Pre-existing Structural Cardiac
Abnormalities or Other Serious Heart Problems.

WARNINGS: Serious Cardiovascular Events: Sudden Death and Pre-existing Structural Cardiac Abnormalities or Other Serious Heart Problems.
Children and Adolescents: Sudden death has been reported in association with CNS stimulant treatment at usual doses in children and adolescents with structural cardiac abnormalities or other serious heart problems although some serious heart problems alone carry an increased risk of sudden death, stimulant products generally should not be used in children or adolescents with known serious structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, or other serious cardiac problems that may place them at increased vulnerability to the sympathormimetic effects of a stimulant drug (see CONTRAINDICATIONS).

lems that mainly place them at increased vulnerability to the sympathomimetic effects of a stimulant drug (see CONTRAINDICATIONS).

Adults: Sudden deaths, stroke, and myocardial infarction have been reported in adults taking stimulant drugs at usual doses for ADHD. Although the role of stimulants in these adult cases is also unknown, adults have a greater likelihood than children of having serious structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, coronary artery disease, or other serious cardiac problems. Adults with such abnormalities should also generally not be treated with stimulant drugs (see CONTRAINDICATIONS). Hypertension and Other Cardiovascular Conditions: Stimulant medications cause a modest increase in average blood pressure (about 2-4 mmHg) and average heart rate (about 3-6 bpm), and individuals may have larger increases. While the mean changes alone would not be expected to have short-term consequences, all patients should be monitored for larger changes in heart rate and blood pressure. Caution is indicated in treating patients whose underlying medical conditions might be compromised by increases in blood pressure or heart rate, e.g., those with pre-existing hypertension, heart failure, recent myocardial infarction, or ventricular arrhythmia (see CONTRAINDICATIONS). Assessing Cardiovascular Status in Patients Being Treated with Stimulant Medications: Children, adolescents, or adults who are being considered for treatment with stimulant medications should have a careful history (including assessment for a family history of sudden death or ventricular arrhythmia) and physical exam to assess for the presence of cardiac disease, and should receive further cardiac evaluation if findings suggest such disease (e.g., electrocardiogram and echocardiogram). Patients who develop symptoms suggestive of cardiac disease during stimulant treatment should undergo a prompt cardiac evaluation.

Psychiatric Adverse Events: Pre-Existing Psychosis; Administration of stimulants may

should include a detailed psychiatric history, including a family history of suicide, bipolar disorder, and depression.

Emergence of New Psychotic or Manic Symptoms; Treatment emergent psychotic or manic symptoms, e.g., hallucinations, delusional thinking, or mania in children and adolescents without prior history of psychotic illness or mania can be caused by stimulants at usual doses. If such symptoms occur, consideration should be given to a possible causal role of the stimulant, and discontinuation of treatment may be appropriate. In a pooled analysis of multiple short-term, placebo-controlled studies, such symptoms occurred in about 0.1% (4 patients with events out of 3482 exposed to methylphenidate or amphetamine for several weeks at usual doses) of stimulant-treated patients compared to 0 in placebo-treated patients. Aggression: Aggression: Aggression: Aggression: Aggression stopping there is no systematic evidence that stimulants cause aggressive behavior or hostility, patients beginning treatment for ADHD should be monitored for the appearance of or worsening of aggressive behavior or hostility. Careful follow-up of weight and height in children ages 7 to 10 years who were randomized to either methylphenidate or non-medication treatment groups over 11 denoths, as well as in naturalistic subgroups of newly methylphenidate-treated and non-medication treatment (i.e., treatment for 7 days per week throughout the year) have a temporary slowing in growth rated children over 36 months (to the ages of 10 to 13 years), suggests that consistently medicated children over 36 months (to the ages of 10 to 13 years), suggests that consistently medicated children whether chronic use of amphetamines may cause a similar suppression of growth, however, it is anticipated that they likely have this effect as well. Therefore, growth should be monitored during treatment with stimulants, and patients who are not growing or gaining highly or seizures, and patients with or EEG abnormalities in absence of seizures, and key are

ug should be discontinued.

isual Disturbance: Difficulties with accommodation and blurring of vision have been reported with stim-

ulant treatment. **Use in Children Under Six Years of Age:** METADATE CD should not be used in children under six years, since safety and efficacy in this age group have not been established.

DRUG DEPENDENCE: METADATE CD should be given cautiously to patients with a history of drug dependence or alcoholism. Chronic abusive use can lead to marked tolerance and psychological dependence with varying degrees of abnormal behavior. Frank psychotic episodes can occur, especially with parenteral abuse. Careful supervision is required during withdrawal from abusive use since severe depression may occur. Withdrawal following chronic therapeutic use may unmask symptoms of the underlying disorder that may require follow-up.

Information for Patients: Patients should be instructed to take one dose in the morning before breakfast. The patients should be instructed to take one dose in the morning before breakfast. The patients should be instructed that the capsule may be swallowed whole, or alternatively, the capsule may be opened and the capsule contents sprinkled onto a small amount (tablespoon) of applesauce and given immediately, and not stored for future use. The capsules and the capsule contents must not be crushed or chewed. To assure safe and effective use of METADATE CD, the information and instructions provided in the patient information section should be discussed with patients.

Drug Interactions: Because of possible effects on blood pressure, METADATE CD should be used cautiously with pressor agents.

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Human pharmacologic studies have shown that methylphenidate may inhibit the metabolism of coumarin anticoagulants, anticonvulsants (e.g., phenobarbital, phenytoin, primidone), and some antidepressants (tricyclics and
selective serotonin reuptake inhibitors). Downward dose adjustment of these drugs may be required when given
concomitantly with methylphenidate. It may be necessary to adjust the dosage and monitor plasma drug concentrations (or, in the case of coumarin, coagulation times), when initiating or discontinuing concomitant
methylpheni/date

Serious adverse events have been reported in concomitant use with clonidine, although no causality for the combination has been established. The safety of using methylphenidate in combination with clonidine or other centrally acting alpha-2 agonists has not been systematically evaluated. Carcinogenesis, Mutagenesis, and Impairment of Fertility: In a lifetime carcinogenicity study carried out in B6C3F1 mice, methylphenidate caused an increase in hepatocellular adenomas and, in males only, an increase in hepatoblastomas, at a daily dose of approximately 60 mg/kg/day. This dose is approximately 30 times and 4 times the maximum recommended human dose of METADATE CD on a mg/kg and mg/m² basis, respectively. Hepatoblastoma is a relatively rare rodent malignant tumor type. There was no increase in total malignant hepatic tumors. The mouse strain used is sensitive to the development of hepatic tumors, and the significance of these results to humans is unknown.

Methylphenidate did not cause any increases in tumors in a lifetime carcinogenicity study carried out in F344 rats; the highest dose used was approximately 45 mg/kg/day, which is approximately 22 times and 5 times the maximum recommended human dose of METADATE CD on a mg/kg and mg/m² basis, respectively.

and 3 times the inaximum recommended normal base on the IADATE CD on a highing and highin basis, respectively. In a 24-week carcinogenicity study in the transgenic mouse strain p53+/-, which is sensitive to genotoxic carcinogens, there was no evidence of carcinogenicity. Male and female mice were fed diets containing the same concentration of methylphenidate as in the lifetime carcinogenicity study, the high-dose groups were exposed to 60 to 74 mg/kg/day of methylphenidate. Methylphenidate was not mutagenic in the *in vitro* Ames reverse mutation assay or in the *in vitro* mouse lymphoma cell forward mutation assay. Sister chromatid exchanges and chromosome aberrations were increased, indicative of a weak clastogenic response, in an *in vitro* assay in cultured Chinese Hamster Ovary cells. Methylphenidate was negative *in vivo* in males and females in the mouse bone marrow micronucleus assay.

Methylphenidate did not impair fertility in male or female mice that were fed diets containing the drug in an 18-week Continuous Breeding study. The study was conducted at doses up to 160 mg/kg/day, approximately 80-fold and 8-fold the highest recommended human dose of METADATE CD on a mg/kg and mg/m² basis, respectively.

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Pregnancy: Teratogenic Effects: Pregnancy Category C. Methylphenidate has been shown to have stand 40 times the maximum recommended human dose on a mg/kg and mg/m² basis, respectively.

A reproduction study in rats revealed no evidence of teratogenicity at an oral dose of 58 mg/kg/day. However, this dose, which caused some maternal toxicity, resulted in decreased postnatal put weights and survival when given to the dams from day one of gestation through the lactation period. This dose is approximately 30 fold and 6 fold the maximum recommended human dose of METADATE CD on a mg/kg and mg/m² basis, respectively.

There are no adequate and well-controlled studies in pregnant women. METADATE CD should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is not known whether methylphenidate is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised if METADATE CD is administered to a nursing woman.

woman.

Pediatric Use: The safety and efficacy of METADATE CD in children under 6 years old have not been established. Long-term effects of methylphenidate in children have not been well established (see WARNINGS).

ADVERSE REACTIONS: The premarketing development program for METADATE CD included exposures in a total of 228 participants in clinical trials (188 pediatric patients with ADHD, 40 healthy adult subjects). These participants received METADATE CD 20, 40, and/or 60 mg/day. The 188 patients (ages 6 to 15) were evaluated in one controlled clinical study, one controlled, crossover clinical study, and one uncontrolled clinical study. Safety data on all patients are included in the discussion that follows. Adverse reactions were assessed by collecting adverse events, results of physical examinations, vital signs, weights, laboratory analyses, and ECCs.

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 listings that follow, COSTART terminology has been used to classify reported adverse events.

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mate of the proportion of individuals experiencing adverse events without first grouping similar types or events into a smaller number of standardized event categories. In the tables and listings that follow, COSTART 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 for 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 Findings in Clinical Trials with METADATE CD: Adverse Events Associated with Discontinuation of Treatment. In the 3-week placebo-controlled, parallel-group trial, two METADATE CD-treated patients (1%) and no placebo-treated patients discontinued due to an adverse event (rash and pruritus; and headache, abdominal pain, and dizziness, respectively).

Adverse Events Occurring at an Incidence of 5% or More Among METADATE CD-Treated Patients: Table 1 enumerates, for a pool of the three studies in pediatric patients with ADHD, at METADATE CD doses of 20, 40, or 60 mg/day, the incidence of treatment-emergent adverse events. One study was a 3-week place-bo-controlled, parallel-group trial, one study was a controlled, crossover trial, and the third study was an open titration trial. The table includes only those events that occurred in 5% or more of patients treated with METADATE CD where the incidence in patients treated with METADATE CD 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 tre

Body System General	Preferred Term Headache Abdominal pain (stomach ache)	METADATE CD (n=188) 12% 7%	Placebo (n=190) 8% 4%
Digestive System	Anorexia (loss of appetite) Insomnia	9%	2%
Nervous System		5%	2%

most common adverse reactions reported with other methylphenidate products. Other reactions include hypersensitivity (including skin rash, urticaria, lever, arthralgia, exfoliative dermatitis, erythema multiforme with histopathological findings of necrotizing vascultis, and thrombocytopenic purpura); anorexia, nausea; dizziness; palpitations; headache; dyskinesia; drowsiness; blood pressure and pulse changes, both up and down; tachycardia, angina; cardiac arrhythmia; abdominal pain; weight loss during prolonged therapy. There have been are reports of fourette's Syndrome. Toxic psychosis has been reported. Although a definite causal relationship has not been established, the following have been reported in patients taking this drug; instances of abnormal liver function, ranging from transaminase elevation to hepatic coma; isolated cases of cerebral arteritis and/or occursion; leucopenia and/or anemia; transient depressed mood; a few instances of scalp hair loss. Very rare reports of neuroleptic malignant syndrome (NMS) have been reported, and, in most of these, patients were concurrently receiving therapies associated with NMS. In a single report, a ten year old boy who had been taking methylphenidate for approximately 18 months experienced an NMS-like event within 45 minutes of ingesting his first dose of venlataxine. It is uncertain whether this case represented a drug-drug interaction, a response to either drug alone, or some other cause.

his first dose of venlafaxine. It is uncertain whether this case represented a drug-drug interaction, a response to either drug alone, or some other cause. In children, loss of appetite, abdominal pain, weight loss during prolonged therapy, insomnia and tachycardia may occur more frequently; however, any of the other adverse reactions listed above may also occur. Postmarketing Experience: In addition to the adverse events listed above, the following have been reported in patients receiving METADATE CD worldwide. The lists alphaetized: abnormal behavior, aggression, anxiety, cardiac arrest, depression, fixed drug eruption, hyperactivity, irritability, sudden death, suicidal behavior (including completed suicide), and thrombocytopenia. Data are insufficient to support an estimation of

incidence or establish causation.

DRUG ABUSE AND DEPENDENCE: Controlled Substance Class: METADATE CD, like other methylphenidate products, is classified as a Schedule II controlled substance by federal regulation.

Abuse, Dependence, and Tolerance: See WARNINGS for boxed warning containing drug abuse and

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Circumcision Pain Relief Is Taught but Underused

BY JOHN R. BELL Associate Editor

significant portion of neonates still do not receive effective pain relief when undergoing circumcision, according to the findings of a study by Dr. Daniel Yawman and his colleagues.

This is true despite the substantial increase over the last few years in the percentage of residency programs in which effective anesthesia for this procedure is taught. Moreover, the most commonly reported surgical technique taught in these programs is not the method associated in the literature with less pain, reported Dr. Yawman of the University of Rochester (N.Y.) and his colleagues (Ambul. Pediatr. 2006;6:210-4).

Following up on a 1998 study by other researchers, they found that the percentage of all family practice, ob.gyn., and pediatric residency programs in the United States that reported teaching effective (local or topical) anesthesia for the procedure rose from a previously reported 71% for the mid-1990s to 97% in 2003; however, only 84% of programs in 2003 reported actually practicing effective anesthesia in neonatal circumcision always or frequently. Overall, 82% of the programs reported teaching circumcision.

Data were collected via a survey mailed to all directors of family practice, ob.gyn., and pediatric residency programs in the United States. There was an 86% response rate involving 811 programs.

The investigators considered effective anesthesia to be either local methods (subcutaneous or dorsal penile nerve block) or topical anesthesia (a combination of lidocaine and prilocaine [EMLA] or other anesthetic cream). They also collected data on other forms of analgesia taught for and used during circumcision, such as pacifiers or parental comforting. The most commonly taught and most frequently used method was the dorsal penile nerve

Continued from previous page

rule issued last October.

Under the provisions related to electronic prescribing technology, hospitals can donate hardware, software, and services to members of their medical staffs; group practices can donate to physician members; and Medicare prescription drug plan sponsors and Medicare Advantage plans can donate to pharmacies and prescribing physicians. The Stark law exemption and antikickback safe harbors have slightly different definitions of who can donate the comprehensive electronic health record system software and training.

The electronic prescribing safe harbors and exemptions allow organizations to donate hardware, software, Internet connectivity, and training and support services. The provisions for electronic health records are slightly different and do not include hardware. For EHRs, organizations can donate software, which must include an electronic prescribing component. Also, donated information technology and training can include Internet connectivity.

block; this method was taught in 81%, and used frequently in 35%, of the residency programs that teach neonatal circumcision. Overall, local anesthesia was taught in 91% of the residency programs, and topical anesthesia was taught in only 44% of the programs.

The researchers also collected data on the surgical technique used in each program. Despite the fact that the Mogen clamp "may provide a less painful procedure, compared with the Gomco clamp or the Plastibell method," use of the Mogen clamp was taught in only 38% of the programs, vs. 95% for the Gomco clamp and % for the Plastibell technique.

Pediatric residency programs reported teaching circumcision much less often (49%) than did family practice residencies (95%) or ob.gyn. programs (86%).

The authors concluded that although education regarding pain relief in circumcision has improved, "a significant number of newborns may not receive appropriate analgesia, despite the fact that effective analgesic techniques are taught to residents.'

Dr. Yawman and his colleagues noted that since the 1998 study, the professional organizations for each of the included specialties (the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, and the American Academy of Pediatrics) have issued recommendations for universal use of local or topical anesthetic.



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Please see brief summary of full Prescribing Information on next page.

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