

# Practices Must Craft Anti-Identity Theft Plan

BY MARY ELLEN SCHNEIDER

Physicians and health care organizations will have to implement a formal identity theft prevention program to protect their patients under a little-known set of regulations called the "Identity Theft Red Flags Rule."

The rule, which was issued by the Federal Trade Commission (FTC) in 2007 but will be enforced starting in August, is aimed primarily at creditors and financial institutions. However, after publication of the rule, the FTC informed physician groups that it was interpreting the term creditor broadly to include health care professionals who regularly allow consumers to defer payment for services. Therefore, any medical practices that allow patients to defer payment while they bill insurance would be covered under the rule.

Physicians and other health care professionals were required to come into compliance with the rule as of Aug. 1.

The rule requires health care professionals to develop and implement a written identity-theft prevention and detection program to protect consumers. Specifically, organizations must conduct a risk assessment to determine their vulnerability to identity theft. Next, they

must develop and implement a written identity-theft program to identify, detect, and respond to those risks.

As part of the plan, organizations must specify how they will detect the "red flags" alerting them to potential identity theft. The program also must include how the organization will respond once a red flag is detected.

While identity theft is most commonly associated with financial transactions, there is increasing concern about identity theft in the health care sector, according to the FTC. For example, medical identity theft can occur when a patient seeks care using the name or insurance information of another person.

For most physicians in settings with a low risk for fraud, an identity-theft program could be simple, according to the FTC. For example, staff at the practice could check a photo ID at the time services are sought. Another part of a basic program would be to develop steps to take in the event that someone's identity has been misused. That might include not collecting debt from the "true consumer."

But the interpretation of physicians as creditors has raised the hackles of the American Medical Association, the American College of Cardiology, the Heart Rhythm Society, the Society for Cardio-

vascular Angiography and Interventions, the American College of Physicians, and several other physician organizations. Those groups contend that physicians are being inappropriately labeled as creditors, and that the requirements place an undue burden on physicians that could adversely affect patients' access to services.

In addition, the physician groups point out that they didn't have an opportunity to comment on the rule's impact before it was issued. Since the 2007 rule didn't explicitly mention physicians, the groups contend that the FTC must publish a new rule and put that new rule out for public comment. ■

## Tips for Red Flags Rule Compliance

Physician practices seeking to comply with the "Red Flags Rule" can begin by appointing someone who will be the officer for the identity-theft prevention program, said Sai Huda, an expert in financial services regulation. The next step is to conduct an inventory of the medical services that are covered by the rule, said Mr. Huda, chairman and CEO of Compliance Coach Inc., a provider of regulatory compliance software. Under the rule, practices also must identify the applicable "red flags" for each of their covered services and develop procedures to detect and respond to potential identity fraud.

Mr. Huda recommended tightening up hiring and retention practices

as part of the effort to reduce fraud. It's worth spending the money for a background and credit check on potential new hires, he said.

Compliance Coach sells an online tool to help in the formulation of an identity theft prevention plan, but there are also free resources that physicians can use to help set up a program. Mr. Huda advised that physicians check out the Red Flags Rule at [edocket.access.gpo.gov/2007/pdf/07-5453.pdf](http://edocket.access.gpo.gov/2007/pdf/07-5453.pdf). The FTC has resources at [www.ftc.gov/bcp/edu/pubs/articles/art11.shtm](http://www.ftc.gov/bcp/edu/pubs/articles/art11.shtm). A 30-page report from the World Privacy Forum offers compliance suggestions ([www.worldprivacyforum.org/pdf/WPF\\_RedFlagReport\\_09242008fs.pdf](http://www.worldprivacyforum.org/pdf/WPF_RedFlagReport_09242008fs.pdf)).

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** Two years of dietary administration of bosentan to mice produced an increased incidence of hepatocellular adenomas and carcinomas in males at doses as low as 450 mg/kg/day (about 8 times the maximum recommended human dose [MRHD] of 125 mg b.i.d., on a mg/m<sup>2</sup> basis). In the same study, doses greater than 2000 mg/kg/day (about 32 times the MRHD) were associated with an increased incidence of colon adenomas in both males and females. In rats, dietary administration of bosentan for two years was associated with an increased incidence of brain astrocytomas in males at doses as low as 500 mg/kg/day (about 16 times the MRHD). In a comprehensive battery of in vitro tests (the microbial mutagenesis assay, the unscheduled DNA synthesis assay, the V-79 mammalian cell mutagenesis assay, and human lymphocyte assay) and an in vivo mouse micronucleus assay, there was no evidence for any mutagenic or clastogenic activity of bosentan.

**Impairment of Fertility/Testicular Function:** The development of testicular tubular atrophy and impaired fertility has been linked with the chronic administration of certain endothelin receptor antagonists in rodents. Treatment with bosentan at oral doses of up to 1500 mg/kg/day (50 times the MRHD on a mg/m<sup>2</sup> basis) or intravenous doses up to 40 mg/kg/day had no effects on sperm count, sperm motility, mating performance or fertility in male and female rats. An increased incidence of testicular tubular atrophy was observed in rats given bosentan orally at doses as low as 125 mg/kg/day (about 4 times the MRHD and the lowest doses tested) for two years but not at doses as high as 1500 mg/kg/day (about 50 times the MRHD) for 6 months. Effects on sperm count and motility were evaluated only in the much shorter duration fertility studies in which males had been exposed to the drug for 4-6 weeks. An increased incidence of tubular atrophy was not observed in mice treated for 2 years at doses up to 4500 mg/kg/day (about 75 times the MRHD) or in dogs treated up to 12 months at doses up to 500 mg/kg/day (about 50 times the MRHD).

**Pregnancy, Teratogenic Effects: Category X** (See **CONTRAINDICATIONS**).

**Nursing Mothers:** It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, breastfeeding while taking TRACLEER® is not recommended. **Pediatric Use:** Safety and efficacy in pediatric patients have not been established. **Use in Elderly Patients:** Clinical experience with TRACLEER® in subjects aged 65 or older has not included a sufficient number of such subjects to identify a difference in response between elderly and younger patients.

**ADVERSE REACTIONS: Adverse Events:** See **BOX WARNING** for discussion of liver injury and **PRECAUTIONS** for discussion of hemoglobin and hematocrit abnormalities. Safety data on bosentan were obtained from 12 clinical studies (8 placebo-controlled and 4 open-label) in 777 patients with pulmonary arterial hypertension, and other diseases. Doses up to 8 times the currently recommended clinical dose (125 mg b.i.d.) were administered for a variety of durations. The exposure to bosentan in these trials ranged from 1 day to 4.1 years (N = 89 for 1 year; N = 61 for 1.5 years and N = 39 for more than 2 years). Exposure of pulmonary arterial hypertension patients (N = 235) to bosentan ranged from 1 day to 1.7 years (N = 126 more than 6 months and N = 28 more than 12 months). Treatment discontinuations due to adverse events other than those related to pulmonary hypertension during the clinical trials in patients with pulmonary arterial hypertension were more frequent on bosentan (5%; 8/165 patients) than on placebo (3%; 2/80 patients). In this database the only cause of discontinuations >1%, and occurring more often on bosentan was abnormal liver function. The adverse drug reactions that occurred in ≥ 3% of the bosentan-treated patients and were more common on bosentan in placebo-controlled trials in pulmonary arterial hypertension at doses of 125 or 250 mg b.i.d. are shown in Table 1:

**Table 1.** Adverse events\* occurring in ≥ 3% of patients treated with bosentan 125-250 mg b.i.d. and more common on bosentan in placebo-controlled studies in pulmonary arterial hypertension

Adverse Event	Bosentan (N = 165)		Placebo (N = 80)	
	No.	%	No.	%
Headache	36	22%	16	20%
Nasopharyngitis	18	11%	6	8%
Flushing	15	9%	4	5%
Hepatic function abnormal	14	8%	2	3%
Edema, lower limb	13	8%	4	5%
Hypotension	11	7%	3	4%
Palpitations	8	5%	1	1%
Dyspepsia	7	4%	0	0%
Edema	7	4%	2	3%
Fatigue	6	4%	1	1%
Pruritus	6	4%	0	0%

\*Note: only AEs with onset from start of treatment to 1 calendar day after end of treatment are included. All reported events (at least 3%) are included except those too general to be informative, and those not reasonably associated with the use of the drug because they were associated with the condition being treated or are very common in the treated population.

In placebo-controlled studies of bosentan in pulmonary arterial hypertension and for other diseases (primarily chronic heart failure), a total of 677 patients were treated with bosentan at daily doses ranging from 100 mg to 2000 mg and 288 patients were treated with placebo. The duration of treatment ranged from 4 weeks to 6 months. For the adverse drug reactions that occurred in ≥ 3% of bosentan-treated patients, the only ones that occurred more frequently on bosentan than on placebo (≥ 2% difference) were headache (16% vs. 13%), flushing (7% vs. 2%), abnormal hepatic function (6% vs. 2%), leg edema (5% vs. 1%), and anemia (3% vs. 1%).

**Post-Marketing Experience:** Hypersensitivity, Rash, Thrombocytopenia, Jaundice, Anemia requiring transfusion: There have been several post-marketing reports of angioneurotic edema associated with the use of bosentan. The onset of the reported cases occurred within a range of 8 hours to 21 days after starting therapy. Some patients were treated with an antihistamine and their signs of angioedema resolved without discontinuing TRACLEER®. In the post-marketing period, in the setting of close monitoring, rare cases of unexplained hepatic cirrhosis were reported after prolonged (> 12 months) therapy with TRACLEER® in patients with multiple co-morbidities and drug therapies. There have also been rare reports of liver failure. The contribution of TRACLEER® in these cases could not be excluded (see **BOX WARNING**).

**References for previous pages:** 1. Data on file, Actelion Pharmaceuticals. 2. Rubin LJ, Badesch DB, Barst RJ, et al. Bosentan therapy for pulmonary arterial hypertension. *N Engl J Med.* 2002;346:896-903. 3. Channick RN, Simonneau G, Sitbon O, et al. Effects of the dual endothelin-receptor antagonist bosentan in patients with pulmonary hypertension: a randomised placebo-controlled study. *Lancet.* 2001;358:1119-1123.

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