Experts Eager for Easing Buprenorphine Limits

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BY TIMOTHY F. KIRN Sacramento Bureau

SAN DIEGO — Despite the recent potential easing of the federal limit on the number of opiate-addicted patients a physician can treat, substance abuse experts continue to see a pressing need for more buprenorphine slots.

At a recent meeting of the American Society of Addiction Medicine, those experts complained that there were still more potential patients than they can legally treat. These experts are lobbying government officials for a further easing of the limit.

A bill recently introduced in the U.S. Senate by Sen. Arlen Specter (R-Pa.) would in essence relax the limits further. The revision would allow those who have had their buprenorphine waiver for 1 year to apply for more patients.

The Drug Addiction Treatment Act of 2000 created the office buprenorphine

prescribing program. Initially, the 30-patient limit established by the act was interpreted to mean 30 patients could be treated per site. However, in August 2005, that provision was amended to mean 30 patients could be treated per physician, regardless of the number of physicians with a waiver who were based at a particular site.

Those attending the meeting cheered and applauded when Mark L.

Kraus, cochair of the society's public policy committee, said in a statement from the society that the law "makes absolutely no sense" and "constitutes rationing of care."

"No other FDA-approved medication has an arbitrary limit as to the number of patients a physician is allowed to treat," Dr. Kraus said. "If government's major purpose is to prevent diversion, rationing of care is not reasonably related to that goal."

Currently, about 7,000 physicians have received the training and a waiver for office treatment of addiction with buprenorphine.

No one ventures to estimate the number of potential opiate-addicted individuals who are prevented from getting treatment because of the 30-patient limit. However, it has been reported that clinics in some cities have hundreds on their waiting lists.

And some physicians are known to be openly flouting the limit and exceeding it, with one physician in Massachusetts treating some 600 patients, government officials said at the meeting.

On the other hand, only 20% of 1,059 waivered physicians reported being at the 30-patient limit in a 2005 survey, said Arlene Stanton, Ph.D., of the Center for Substance Abuse Treatment, of the Substance Abuse and Mental Health Services Administration (SAMHSA).

The caveat to interpreting that number, however, is that only 67% of the waivered physicians reported having prescribed buprenorphine and, of those who had prescribed it, 38% used it only to detoxify patients, not for maintenance.

Regarding safety and effectiveness, the buprenorphine program appears to be going well, according to Dr. Stanton's report. In a survey of about 400 patients, 59% were free of all illicit drug use; 81% were free of all opioid use. At the same time, the Drug Abuse Warning Network recorded only 108 emergency department visits related to buprenorphine use in 2004.

By March 2005, 104,640 patients had been started on buprenorphine, with about 65,000 of those patients on maintenance treatment.

Diversion of buprenorphine may be occurring, but it is not considered a problem by federal authorities, said Denise Curry, deputy director of the Office of Diversion Control at the Drug En-

forcement Agency (DEA), who spoke at the meeting.

She said there are reports that Suboxone is available on the streets and goes for about \$45 a dose in Virginia, but the agency has not found any evidence of abuse and has no confirmed cases of diversion.

The DEA is much more concerned with other problems, particularly methamphetamine, Ms. Curry said. "We have bigger fish to

fry," she said. The other, equally important, solution to the lack of availability of buprenorphine for all those who need it is to encourage more physicians to get a waiver, said Dr. H. Westley Clark, the director of SAMHSA's Center for Substance Abuse Treatment.

There are about 500,000 ambulatorycare physicians in this country, but only 7,000 have a waiver. Getting a waiver takes only 8 hours of training, and most states require physicians to have 25 hours of continuing medical education a year, he said.

"We need to convince our colleagues in primary care that they, too, have a responsibility in this," he said. "We have a large number of physicians who are not willing to deal with this."

But while increasing the number of prescribers might be a solution in the cities, it may not be in rural areas, according to one person at the meeting who got up to speak.

Rural America has a big problem with illicit opioid use in general and OxyContin in particular. But most primary care physicians in rural areas are too busy already to take on treating substance abusers, said Dr. James W. Berry, of Bangor, Maine.

"As for psychiatrists, there aren't any," he added.

-POLICY & PRACTICE-

Feds Seek Electronic Credentials

The ability to verify the identity and credentials of physicians after a disaster may be achieved via a chip or other technology, Anthony M. Cieri of the Department of Homeland Security said at a briefing sponsored by the Information Technology Association of America. Experts at the meeting pointed to the success of the Veterans Administration in maintaining credentialing information during the response to Hurricane Katrina. Kathryn Enchelmayer, VA director of credentialing, said she was able to "go down in [her] basement at 10:00 p.m." and verify physician credentials, and quickly send 151 displaced physicians from the area off to other jobs.

Survey: FDA Influenced by Politics

A majority of Americans-82%-believe the Food and Drug Administration is greatly influenced by politics when making decisions about the safety and efficacy of new prescription drugs, according to a Wall Street Journal online Harris Interactive poll. The finding was similar across parties, with 87% of Democrats, 77% of Republicans, and 88% of Independents saying they thought that politics outweighed science greatly or to some extent in decision making. The survey of more than 2,300 adults was conducted in mid-May. In addition, almost 60% said the agency is doing a fair or poor job in ensuring the safety and efficacy of new drugs. Only 36% said the FDA was doing an excellent or good job. That is a reversal from 2 years ago, when 56% had a positive view, and 37% a negative view, of the FDA. Opinions have not changed much on the agency's performance in bringing innovative drugs to market quickly. In 2004, 62% said the FDA was not doing well on that front, compared with 70% in the latest poll. Most of those polled said FDA advisory panel members should not be allowed to have consulting agreements with, or stock in, drug companies.

Too Many Screening Tests?

Physicians are needlessly ordering certain diagnostic tests during routine preventive health exams, which is inflating the cost of medical care, according to a study from Johns Hopkins University, Baltimore. The U.S. Preventive Services Task Force has rated such diagnostics according to level of evidence; the Hopkins researchers looked at five tests. Two tests (complete blood count and hematocrit) had "C" ratings from USPSTF, meaning there was no recommendation for or against their use; three (urinalysis, xray, and electrocardiogram) had "D" ratings with a recommendation against routine use. The study, which used National Ambulatory Medical Care Survey data for 1997-2002 for outpatient visits for nonpregnant adults aged 21 years or over, was in the May/June issue of the American Journal of Preventive Medicine, and was

led by Dr. Dan Merenstein, who is now at Georgetown University, Washington. Cost data were obtained from the Medicare fee schedule. About 37 million visits were identified as preventive by physicians and 190 million as such by patients. Most visits were to family physicians, ob.gyns., or internists. Urinalysis was performed most frequently, about 25%-33% of the time, but urine cultures were ordered only 3%-6% of the time. Annual direct costs for hematocrit and urinalysis run about \$13-\$61 million, depending on whether it was a physician- or patient-identified visit, the authors estimated. For the D-rated tests, costs were \$47-\$194 million.

J-1 Visas for Underserved Areas

J-1 visas remain the primary tool for recruiting physicians to work in underserved areas, according to a report by the U.S. Government Accountability Office. The GAO surveyed the 50 states, the District of Columbia, Guam, Puerto Rico, and the U.S. Virgin Islands regarding their waiver requests for fiscal years 2003-2005. States and federal agencies reported requesting more than 1,000 waivers in each of the 3 years, although the number requested varied by state: About one-fourth of states requested the maximum number of 30 visas, while slightly more than a quarter requested 10 or fewer. About 80% of states said the 30-waiver limit was adequate for their needs, the report noted. Nearly half of the states' waiver requests were for physicians to practice primary care exclusively.

ICD-10 Fraud Concerns

The Blue Cross and Blue Shield Association and the Medical Group Management Association are among those objecting to the planned implementation of ICD-10, the newest version of the comprehensive list of diagnostic billing codes used by health care providers. A bill currently being considered in the House would require payers to switch from the current ICD-9 codes to ICD-10 by Oct. 1, 2009. Blue Cross/Blue Shield argues in a statement that the deadline should be pushed back to 2012 "because much has to be done before a switch to ICD-10 can be started ... and providers need time to automate their offices and be trained." The Blues are particularly concerned because the switch comes at the same time that Medicare is shrinking the number of its claims processors—many of which are Blues plans—from 50 to 15. At a press briefing, the association released a report by D. McCarty Thornton, former chief counsel to the Department of Housing and Human Services Inspector General, which found that forcing the switch to occur in 2009 "will not give the contractors who administer the Medicare fee-for-service claims process and payments systems sufficient time to upgrade their antifraud tools."