

Regulatory Ins & Outs of Self-Referral for CT Scans

By Andrew Holtz

One morning last spring, Thomas A. Conley, RRPT, CHP, got an early-morning surprise when reading the newspaper: "There was a huge color four-page ad for screening all over Kansas. That was the first I'd heard of it." As the Director of the Radiation and Asbestos Control Section of

the Kansas Department of Health and Environment, he is supposed to know about all the CT scanning operations in his state.

What made the ad especially surprising, he said, is that it promoted a mobile CT screening operation that does not employ on-site physicians.

"In Kansas, screening is illegal," Mr. Conley explained. "The regulations

basically say that any human exposure has to be specifically and individually ordered by a physician after an examination." As elsewhere, mammography is exempted from the Kansas screening ban.

Mr. Conley ordered an inspection of the mobile screening operation. "People would call in and schedule it and then they'd have a doctor in Flor-

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ida electronically sign an order that they faxed to the truck that the scanner was on."

The scanning operation was run by technicians. "They electronically sent the images back to Florida to be read by their radiologist and then they would mail a report," he said.

What's more, the mobile scanner would not accept customers with symptoms or other indications suggesting disease, a position diametrically opposite to that of the Kansas rules that say individuals should be exposed to CT radiation only when there is reason to suspect something is awry.

Last August, Kansas regulators and CATScan 2000, the company running the mobile screening centers, signed a consent agreement. CATScan 2000 paid a \$5,000 fine and rolled out of Kansas. The company still operates six mobile CT scanners in 14 states. Radiation control officials also sent notice to CT scanner operators around the state that

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Whole-Body CT

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have toured the site and they say, 'I've looked at this and I don't think this is of value.'

"It'll be better than if they just say 'No,' but they have very little knowledge. I think we still need to remember that at least from the point of view of the American College of Radiology, we don't recommend these examinations."

The impact of screening CT on patient-physician relationship bears some similarity to issues relating to alternative or complementary medicine. Whether or not whole-body CT screening is recommended or accepted by physicians, patients are aware of the test and some are undergoing it.

Increasingly the question for physicians is not whether CT screening is good or bad, but how to counsel curious patients, and then support and care for those patients who get screened... only to be given results that raise questions and fears.

ARANESP® (darbepoetin alfa) For Injection

INDICATIONS AND USAGE
ARANESP is indicated for the treatment of anemia in patients with end-stage renal disease (ESRD) who are receiving hemodialysis or peritoneal dialysis.

CONTRAINDICATIONS
ARANESP is contraindicated in patients with a potential hypersensitivity or known hypersensitivity to the active ingredient or any of the excipients.

WARNINGS
Cardiovascular Events (Hypertension, and Risk of Thrombotic Complications)
ARANESP and other erythropoietin analogs may increase the risk of thrombotic events, including stroke. The higher the hemoglobin level, the greater the risk of thrombotic events. Higher hemoglobin levels may be associated with higher mortality. The hemoglobin level should be managed carefully to avoid increasing the risk of thrombotic events.

PRECAUTIONS
Warnings and Precautions
Patients with end-stage renal disease (ESRD) who are receiving hemodialysis or peritoneal dialysis should be monitored for signs and symptoms of hypertension, including headache, dizziness, and blurred vision. If hypertension is detected, the dose of ARANESP should be reduced. If hypertension persists, antihypertensive therapy should be initiated. The early stage of hypertension may be asymptomatic. Hypertension may be associated with an increased risk of thrombotic events.

ADVERSE REACTIONS
The most common adverse reactions in patients receiving ARANESP are hypertension, headache, dizziness, and blurred vision. Other adverse reactions include back pain, muscle cramps, and fatigue. In patients receiving ARANESP, the risk of thrombotic events, including stroke, is increased. The risk of thrombotic events is increased in patients with a history of thrombotic events, including stroke, and in patients with a history of cardiovascular disease.

DRUG INTERACTIONS
There are no known drug interactions with ARANESP.

USE IN SPECIFIC POPULATIONS
Pregnancy
There are no data on the use of ARANESP in pregnant women. ARANESP should be used with caution in pregnant women.

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HOW TO USE
ARANESP should be administered intravenously or subcutaneously. The dose should be adjusted based on the patient's hemoglobin level and clinical response.

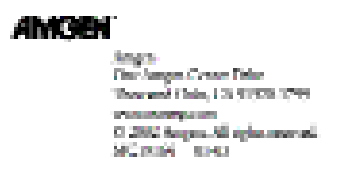
HOW TO STORE
ARANESP should be stored at 20°C to 25°C (68°F to 77°F). Excursions permitted to 15°C to 30°C (59°F to 86°F). Do not freeze. Do not shake.

USING WITH OTHER PRODUCTS
ARANESP may be administered with other medications. However, the use of ARANESP with other erythropoietin analogs is not recommended.

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Self-Referral

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screening is not an approved use in Kansas.

"It was a complete administrative misunderstanding," says CATScan 2000 CEO Gina Johnson. "Kansas has a requirement of a physical examination by a doctor before a preventive CT scan can be performed; and our protocol was not set up in such a way that we could make that happen in a cost-effective manner."



Thomas A. Conley, RRPT, CHP

Despite the Kansas incident, and the skeptical view of leading medical groups, Ms. Johnson's faith is unshaken

that her mobile CT screening improves the health and increases the longevity of customers.

"Absolutely and without question," she said in an interview. But she added that the CATScan 2000 screening trucks and promotional materials claiming "New Technology Could Save Your Life!" won't roll into states that require on-site physicians or otherwise restrict self-referrals.

Each State Has Own Regulations

National statistics regarding self-referred CT screening are difficult to come by. Each state has its own regulations, ranging from those like Kansas that act to restrict CT scanning to diagnosis and treatment to a handful of states that have no rules prohibiting self-referred screening. (In general, the Food and Drug Administration regulates only the manufacturers of CT scanners.)

A draft statement from the Conference of Radiation Control Program Directors (CRCPD) urges, "Until large-scale clinical trials have been performed and analyzed thoroughly and effectively, insufficient scientific evidence exists for the efficacy and safety of the self-referral whole-body CT process. Unnecessary radiation exposure during medical procedures should be avoided at all costs."

Ron Fraass, Executive Director of CRCPD, which is an association of the 50 state directors of radiation use, says a resolution calling on members to

JAMA Study: Little Value for Lung Cancer CT Screens

CT scans do not appear to be useful for mass screening for lung cancer, according to a study by Johns Hopkins researchers published in the Jan. 5 issue of the *Journal of the American Medical Association*.

"Direct-to-consumer marketing and media coverage has encouraged demand for lung cancer screening despite a lack of evidence for its efficacy," lead author Parthiv J. Mahadevia, MD, MPH, said in a news release.

"These scans are not risk-free.

There is a downside, including high costs and possible harm to individuals who may unnecessarily get invasive procedures if the scan detects a benign lung nodule."

The NCI has begun an eight-year trial comparing CT scans with chest x-rays in the diagnosis of lung cancer.

"We're not down on the technology--just its injudicious use," said coauthor Neil R. Powe, MD, MPH. "CT can be a very useful tool, but only when recommended by a physician for a specific clinical purpose."

actively discourage self-referral CT screening was one of the few such measures to pass unanimously.

Scanning center operators in Oregon say that state's self-referral ban does reduce the number of people who request a whole-body CT screen. However, radiologist James Borgstede, MD, Chair of the Patient Safety Task Force of the American College of Radiology, has doubts about the effectiveness of self-referral bans.

"A lot of those laws are really paper tigers, because there are a lot of ways to circumvent the intent of that law; so I'm not really sure that it really protects the patient," he said.

For instance, a radiologist at a scanning center can write a prescription for

a scan, as long as it doesn't run afoul of the Medicare and Medicaid bans against physicians referring patients to scanning centers they have an interest in.

Dr. Borgstede predicts conclusive research into the pros and cons of CT screening will ultimately have more influence than regulations.

For now, he urges people to be skeptical about marketing claims for CT screening. "Have a 'buyer beware,' 'caveat emptor' type of approach and let people know what they are getting into here. It's a free country and people can do what they want, but I think they should understand what the potential consequences are of getting one of these scans," he says.

CT Screening Exams: Official Statements

ACR Statement on CT Screening Exams: www.aacr.org

"The American College of Radiology recognizes that an increasing number of computed tomography screening examinations are being performed in the United States. Much CT screening is targeted at specific diseases, such as lung scanning for cancer in current and former smokers, coronary artery calcium scoring as a predictor of cardiac events, and CT colonography (virtual colonoscopy) for colon cancer.

"Early data suggest that these targeted examinations may be clinically valid. Large, prospective, multicenter trials are currently under way or in the planning phase to evaluate whether these screening exams reduce the rate of mortality.

"The ACR, at this time, does not believe there is sufficient evidence to justify recommending total-body CT screening for patients with no symptoms or a family history suggesting disease. To date, there is no evidence that total body CT screening is cost efficient or effective in prolonging life.

"In addition, the ACR is concerned that this procedure will lead to the discovery of numerous findings

that will not ultimately affect patients' health but will result in unnecessary follow-up examinations and treatments and significant wasted expense.

"The ACR will continue to monitor scientific studies concerning these procedures."

American Association of Physicists in Medicine: www.aapm.org

"The use of computed tomography for total body screening of asymptomatic patients has not currently been found to be scientifically justifiable or clinically efficacious.

"The greatest concerns surrounding this procedure are: (1) that the procedure will lead to the discovery of minor anomalies that have no influence on patient health, but their identification will lead to added medical examinations with associated risks and unnecessary medical expenses, and (2) the wide-scale use of significant radiation exposures from total body screening CT for a yet unproven screening procedure.

"Total body CT screening should not be confused with the scientific CT studies of screening for lung cancer in

high-risk patients or cardiac scoring to identify calcification in coronary vessels. Scientists in the AAPM will continuously assess the scientific literature as to the efficacy of total body CT screening and make revisions to this policy statement when appropriate."

Food and Drug Administration: www.fda.gov/cdrh/ct

"At this time the FDA knows of no data demonstrating that whole-body CT screening is effective in detecting any particular disease early enough for the disease to be managed, treated, or cured and advantageously spare a person at least some of the detriment associated with serious illness or premature death. Any such presumed benefit of whole-body CT screening is currently uncertain, and such benefit may not be great enough to offset the potential harms such screening could cause.

"Statements by CT imaging facilities that imply FDA 'approval,' 'clearance,' or 'certification' of CT for screening procedures misrepresent the actual situation. FDA has never approved or cleared or certified any

CT system specifically for use in screening (i.e., of individuals without symptoms), because no manufacturer has ever demonstrated to the FDA that their CT scanner is effective for screening for any disease or condition."

Conference of Radiation Control Program Directors: www.crcpd.org

"No scientific studies have demonstrated that CT screening of individuals without symptoms provides a greater probability of benefit than harm.

"The main risks of CT screening scans for an individual are: (1) abnormal test results for a benign or incidental finding, leading to unneeded and possibly invasive follow-up tests that may present additional risks; (2) normal findings that carry the possibility of inaccuracy and false reassurance which may lead the patient to conclude that further routine screening tests such as for breast cancer, cervical cancer, colon cancer, hypertension, diabetes, etc. are unnecessary; and (3) the increased possibility of cancer induction from x-ray radiation exposure."