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MEDICARE UNMASKED

Doctor 'Self-Referral' Thrives on Legal Loophole

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Daniel Dosoretz co-founded 21st Century Oncology, which has grown into a national cancer-care chain. Brian Tietz

In a letter to a friend, the manager of a Florida urology practice worried in 2010 that her company would attract federal scrutiny for its frequent use of an expensive bladder-cancer test.

The manager's concern involved a program at 21st Century Oncology Holdings Inc. — a national chain of cancer practices — that gives its urologists a financial incentive to order the test from a central in-house lab. A federal law since the 1990s has prohibited "self-referral," in which doctors can profit from Medicare-reimbursed procedures they order. But 21st Century Oncology and many physician groups around the country have found ways to do it anyway, exploiting an exception to the law in ways its writers didn't anticipate.

The manager attached an email from a 21st Century Oncology executive who touted an increase in the number of tests ordered through the central lab, and encouraged doctors in her office to direct business to the lab and share in the revenue. The surge in orders for the bladder-cancer test was so sharp, she wrote to her friend, that it would "surely bring the OIG to our door!"

The letter was prescient. The OIG, or Office of Inspector General at the U.S. Department of Health and Human Services, subpoenaed 21st Century Oncology in February, requesting records of patients it performed the bladder-cancer test on, the company disclosed in filings with the Securities and Exchange Commission this spring. The investigation focuses on whether the testing from 2007 to the present was medically necessary, according to the filings.

A 21st Century Oncology spokesman says the company is cooperating with the investigation and believes its actions "were proper and in accordance with applicable Medicare guidelines."

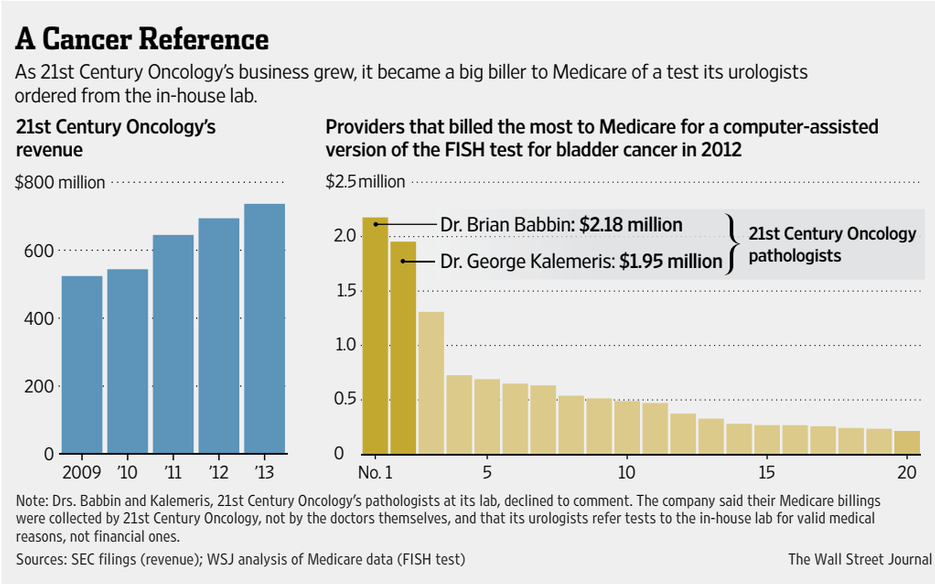
The SEC filings didn't mention self-referral. But ordering tests and treatments in-house is a pillar of 21st Century Oncology's business model. By grouping several medical specialties under the same corporate roof, it captures revenues generated when one group of doctors refers patients to another. Its 95 urologists can get a cut of the revenues generated by the Fort Myers lab to which they refer tests.

The pricey bladder-cancer test, known as FISH, has been part of that program. Urologists at 21st Century Oncology ordered it frequently, says Richard D. Fernandez, its senior pathologist from 2009 until late 2010. "There was in the background, I suppose, a financial component" to the urologists' propensity to order the test, he says.

Newly released Medicare billing records, made public following a legal effort by The Wall Street Journal, show 21st Century Oncology is an outlier in billing for a computer-assisted version of the FISH test. Its two current pathologists in 2012 each billed Medicare more for that version of the test than any other pathologist or lab in the country, the data show.

The company says its urologists order the test through its two pathologists for valid medical reasons, not financial ones. Catching bladder cancer early keeps patients alive by turning the disease "into a chronic illness" instead of a death sentence, says Constantine Mantz, the company's chief medical officer.

Self-referral has become common practice among many



U.S. physician groups, which refer anything from lab services to MRIs to entities from which they benefit financially.

That wasn't the intention of Congress two decades ago, when it passed the so-called Stark Law banning self-referral when the patient is covered by Medicare or another government plan. The law, named after former Rep. Pete Stark (D., Calif.), includes an "in-office ancillary services" exception — intended for simple, routine procedures such as in-office blood tests that would let doctors make patient care more efficient.

But as technology advanced, doctors argued the exception applied to newer services they could administer in an office, such as sophisticated diagnostic tests and radiation therapy. The government didn't challenge this interpretation, leading many physician practices to buy medical equipment they could profit from.

Mr. Stark, who is 82 years old and retired, says the exception has been so expertly exploited that he probably wouldn't vote for the law today unless it were changed. "When I began to see that evolve," he says, he asked himself, "Why did we do the law in the first place?"

Regulators have gone after some hospitals. The Justice Department in March reached a settlement with Halifax Hospital Medical Center and Halifax Staffing Inc. of Daytona Beach, Fla., in which the hospital system agreed to pay $85 million, without admitting wrongdoing, to resolve allegations it violated the Stark Law by providing an incentive bonus to a number of oncologists that improperly included the value of prescription drugs and tests the oncologists ordered. Halifax declines to comment.

But regulators have largely not challenged physician

groups that can invoke the in-office exception.

Cancer specialist 21st Century Oncology owns a network of cancer centers in 16 states that specialize in radiation therapy. It had $646 million in U.S. revenue in 2013, according to a May financial filing — 55% of that from Medicare.

Doctors at 21st Century Oncology have a number of ways to benefit financially from self-referrals.

Launched by cancer doctors in 1983, the company acquired urology and radiation-oncology practices around the country. It says patients benefit from its "integrated cancer care" model, in which company urologists often refer patients with prostate cancer to their oncologist colleagues for radiation therapy. That model allows the urologists to share in the revenue generated by the radiation treatments. Medicare reimbursements for radiation therapy can reach $30,000 a case, according to Astro, the medical society for radiation oncologists.

The company entered pathology in 2009 by starting its Fort Myers lab. It encouraged its urologists to order tests from the lab, promising them a cut of testing revenues, according to the email from the 21st Century Oncology executive, Michael Tompkins, to the urology-practice manager.

One test, in particular, began to generate big revenues: a bladder-cancer test known as fluorescent in situ hybridization, or FISH.

At the time, Medicare paid from $700 to just under $1,000 for the FISH test. For an older test used for the same purpose, Medicare paid up to $84 in the 21st Century Oncology lab's region.

There is debate over the FISH test's value. Ashish Kamat, a urologic oncologist at MD Anderson Cancer Center in Houston, says it is valuable for detecting tumors in patients with aggressive bladder cancer. But a 2010 study he conducted with colleagues found the FISH test had a high rate of false positives.

Urologists at 21st Century Oncology quickly increased orders to the new lab to 942 FISH tests in October 2009 from 202 tests in May 2009, according to a table and chart contained in Mr. Tompkins' email.

"If you are interested in revisiting the financials we would love to have your group aboard," he wrote to the practice manager. "The return to the physicians is about 50% of the total revenue that is distributed out in the pools that urologist belong."

The company spokesman, addressing the increased 2009 FISH testing, says a lab's volume typically rises rapidly in

the months after it opens, as it ramps up operations.

Mr. Tompkins declines to comment about his email. The spokesman says Mr. Tompkins's phrasing incorrectly implied that urologists' pay is tied to their individual test-referral volume. Rather, the spokesman says, urologists are paid bonuses linked to the lab's overall test revenue, which he says is permitted by the Stark Law exception.

The 21st Century Oncology lab collected $7.8 million from Medicare in 2010 through the identification number of Dr. Fernandez, its senior pathologist at the time. Of that, nearly $5 million was for the FISH test, the company says.

Dr. Fernandez says he merely executed his urologist colleagues' frequent orders for the test. He says the high reimbursements may have driven that heavy order flow.

"If you're going to be the beneficiary of testing that you order, and you're going to order a test for $50 and get an answer ... or maybe somewhat justifiably order a similar test for $1,000," he says, "it might be reasonable to think that some individuals would be swayed by the test that is more highly compensated."

The company, in response, says its urologists order tests for medical reasons, not financial ones.

In 2011, Medicare cut the reimbursement to a maximum of about $430 for the computer-assisted version of the FISH test 21st Century Oncology uses. The 2012 Medicare data released in April after the Journal's legal effort show it continued to use the test extensively.

Brian Babbin and George Kalemeris, the pathologists who now head its Fort Myers lab, performed the computer-assisted version of the test 12,180 times in 2012. Through the two pathologists' identification numbers, 21st Century Oncology collected $4.13 million — 21% of what Medicare paid out nationwide to 379 pathologists and labs for that version of the test in 2012.

The spokesman says the pathologists' billings reflect the lab's total Medicare billings for all the tests ordered by 21st Century Oncology doctors. Dr. Babbin and Dr. Kalemeris decline to comment.

A report the OIG released this summer cited questionable Medicare billings by laboratories, including 21st Century Oncology's. The report didn't discuss the FISH test or self-referral, but it showed the lab stood out among its peers.

The agency analyzed 94,609 labs and found 1,025 of them exceeded its thresholds for five or more measures of questionable billing. It highlighted, without naming them, six of those labs.

It cited a nonindependent laboratory in Florida for having an average Medicare reimbursement per ordering physician of $107,700 in 2010 — 24 times the average for all nonindependent labs. The lab's average reimbursement per Medicare patient was $1,193 — 16 times the average for such labs.

The lab is 21st Century Oncology's, the company confirms.

The OIG found the company met three other criteria for questionable Medicare billing: In 2010, it had a high percentage of claims for beneficiaries who lived more than 150 miles from the ordering physician, a high percentage of duplicate lab tests and a high percentage of claims with a "compromised" patient-identification number.

Dr. Mantz, 21st Century Oncology's chief medical officer, discussing the OIG report, says its lab's billings are unusual because the company specializes in treating more elderly patients with cancer than average. "We do serve a very different population," he says. The company spokesman says it counts snowbirds who winter in Florida among its patients, which might explain the rate of beneficiaries who live far from their ordering physicians.

The OIG is conducting its civil investigation with the U.S. attorney's office for the middle district of Florida, 21st Century Oncology said in its spring SEC filing. In an August SEC filing it said it recorded a liability of about $5 million on its balance sheet to account for how much it may have to pay should it decide not to litigate. It estimated its maximum financial exposure at $10 million.

"Our recording of a liability related to this matter is not an admission of guilt," it said. "We believe we have a meritorious position."

The College of American Pathologists and some other medical societies advocate narrowing the scope of the Stark Law's in-office ancillary-services exception. In its last two budgets, the White House recommended doing so, estimating it would save Medicare $6 billion over 10 years by eliminating medical overutilization the exception can foster.

When the White House made the proposal last year, 21st Century Oncology and seven other radiation-oncology groups sent the Senate leadership a letter opposing it. The company's political-action committee has spent nearly $440,000 over the past three election cycles. The family of Daniel Dosoretz, its co-founder and chairman, has made about $200,000 in political donations since 2009.

The 21st Century Oncology spokesman says its PAC's "ef-

forts are designed to protect and promote the patients that we serve." Dr. Dosoretz declines to comment.

Mr. Stark says when he hears his namesake law mentioned when visiting a doctor, "I just look the other way and pretend that I had a lot of cousins."

Tom McGinty and Christopher S. Stewart contributed to this article.