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Terms: **medicare & whistleblower and date(geq (08/20/1995) and leq (08/22/1995))** ([Edit Search](#))

Modern Healthcare August 21, 1995

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Modern Healthcare

August 21, 1995

SECTION: News; Pg. 34

LENGTH: 414 words

HEADLINE: THE SUIT IMPLIES A CONSPIRACY TO DECEIVE THE GOVERNMENT AND NAMES SEVERAL PROMINENT RESEARCH INSTITUTIONS.

BYLINE: Lisa Scott

BODY:

A **whistleblower** lawsuit, partially unsealed last week, charges that hospitals deliberately miscoded procedures and manipulated patient records to obtain up to \$1 billion in federal reimbursement for the use of investigational devices.

The suit lies behind the broad federal probe of hospital billing for investigational devices. Last year, subpoenas to 132 research centers shocked the industry and prompted several hospitals to discontinue or limit clinical device trials (Feb. 20, p. 34).

Under longstanding policy, **Medicare** and Medicaid classify products that don't have Food and Drug Administration marketing approval as "investigational" and, therefore, not reimbursable. Both programs, however, pay hospitals a fixed rate based on diagnosis, instead of the products used. Because of that, many hospitals say they believed reimbursement was due no matter what products were used.

In contrast, the allegations of the **whistleblower** suit imply a conspiracy to deceive the government. The suit names several prominent research institutions, including Cedars-Sinai Medical Center in Los Angeles, Mount Sinai Medical Center in New York and Johns Hopkins Hospital in Baltimore.

Len Homer, a lawyer for the hospitals, called the charges "hogwash."

The centers are part of a coalition of hospitals that has asked the U.S. District Court in Los Angeles to

declare the government policy illegal (May 15, p. 26). The court is scheduled to hear arguments on Oct. 30.

Homer said that the hospitals' lawsuit might have prompted the **whistleblower** to unseal some of the records in that case, hoping to influence the California hearing. Donald Warren, a San Diego lawyer for the **whistleblower**, didn't return calls.

Part of the suit, including the identity of the **whistleblower**, remains sealed. That probably means the Justice Department still is reviewing results of its probe and hasn't decided whether to join the **whistleblower** suit, Homer said.

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B12 THE WALL STREET JOURNAL THURSDAY, AUGUST 17, 1995

Suit Claims Research Hospitals Faked Records and Billing to Get U.S. Funds

By ANDY PASZTOR

Staff Reporter of THE WALL STREET JOURNAL

Dozens of prominent research hospitals nationwide submitted phony bills and some even falsified patients' records to obtain as much as \$1 billion in federal payments for sophisticated, but still experimental, cardiac procedures, a newly unsealed whistle-blower suit alleges.

The allegations of years of systematic fraud involving as many as 130 major medical centers nationwide — accusations that already have prompted a previously reported federal criminal investigation — are likely to shine a spotlight on the controversial issue of which cutting-edge devices and procedures currently are, or should be, eligible for Medicare or Medicaid claims.

Lawyers representing hospitals strongly denied any wrongdoing, asserting that until recently the government knew about and, at least tacitly, approved federal coverage for such diagnostic and surgical procedures. Meanwhile, Congress is wrestling with the topic amid a barrage of claims and counterclaims that threaten to disrupt the medical-devices industry.

Existing regulations say that the government generally won't pay for treatment considered to be experimental or for the use of "investigational" medical devices that haven't been formally approved for general use by the Food and Drug Administration. The lawsuit contends that physicians and hospitals, including Cedars-Sinai Medical Center in Los Angeles, Mount Sinai Medical Center in New York, Johns Hopkins Hospital in Baltimore and the University of California at Los Angeles Medical Center, devised improper procedures to get around those restrictions and hoodwink the government into paying for such treatments.

The identity of the whistle-blower, who stands to pocket tens of millions of dollars if his suit succeeds, remains secret.

Filed in federal district court in Seattle

last year but not unsealed until yesterday, the suit claims that since 1986 physicians "knowingly submitted false claims" for, among other things, the use of lasers, miniature drills and other cutting devices to remove deposits inside blood vessels.

While the existence of the nationwide investigation has been reported, the formal complaint and related documents released by the whistle-blower's lawyers spell out, for the first time, techniques allegedly used to cheat the government.

According to Phil Benson, one of the lawyers for the whistle-blower, seminars were sponsored by at least one manufacturer to help doctors and hospital administrators allegedly falsify bills for unblocking blood vessels. In an interview, Mr. Benson also claimed that some hospitals instructed staff to deceive potential federal audits by removing "consent forms" from certain patient files explicitly approving the use of experimental procedures.

In addition, Mr. Benson said that his client, who attended some of the seminars and training sessions at which purportedly bogus billing schemes were discussed, has data showing that some hospitals used the same catheter on as many as 20 patients. But Mr. Benson claims that Medicare was billed as though each of procedures used a new catheter.

Russell Hayman, a Los Angeles attorney representing 25 of major hospitals that have filed a separate civil suit seeking to block any sanctions against them, said "the government was billed in a straightforward manner" and "paid for these [procedures] year after year" until the whistle-blower's complaints prompted a sudden policy change. Mr. Hayman, who denied that his clients authorized file-tampering or any other steps to mislead government auditors, asserted that "it's fraudulent on the part of the government" to belatedly demand refunds of hundreds of millions of dollars. The hospitals' suit was filed in Los Angeles federal district court.

Los Angeles Times

A20

THURSDAY, AUGUST 17, 1995 ★

L.A. TIMES

Suit Cites 21 Hospitals for False Billing

■ **Law:** Medicare fraud is alleged in whistle-blower filing. Institutions, including 5 in California, charged for experimental devices, complaint says.

By ROBERT A. ROSENBLATT
TIMES STAFF WRITER

WASHINGTON—At least 21 major hospitals and research centers—including five California institutions—have falsely billed Medicare for more than \$1 billion for the use of experimental devices and equipment, according to portions of a whistle-blower lawsuit made available Wednesday.

The lawsuit, which has been sealed from public view, claims the hospitals routinely violated government standards by billing the Medicare system for devices still deemed experimental, including heart valves, pacemakers, catheters and equipment used to regulate fast heart rates.

Even before the Food and Drug Administration approved the use of the equipment, the lawsuit alleges, the hospitals charged the government for reimbursement "through the knowingly false use of existing Medicare and Medicaid billing codes."

For the installation of a replacement heart valve, for example, the lawsuit said hospitals charged \$40,000 and doctors charged \$5,000 for equipment not yet approved by the FDA—a violation of Medicare rules.

Some details of the alleged abuses have been unsealed by a federal court in response to a countersuit by the hospitals against the federal government.

The lawsuit has touched off a government investigation of more than 130 hospitals, although the number identified in the lawsuit is unknown. The portions of the lawsuit made available Wednesday named 21 institutions, including several in California: UCLA Medical Center, Cedars-Sinai Medical Center, Loma Linda University Medical Center, UC San Francisco Medical Center and UC San Diego.

Those California hospitals are among 25 that have responded to the government inquiry by filing a lawsuit against the government. In it, they say they acted correctly, using equipment and procedures needed to save patients' lives, and that their bills were reviewed and approved.

The whistle-blower complaint was filed in federal court in Washington state under a legal procedure commonly used by whistle-blowers in the defense industry to bring fraud charges. Under those procedures, and if the allegations are confirmed by government investigators, the whistle-blower is awarded a share of the money recovered. The name of the person filing the suit, the defendants and the details are normally kept confidential until the government inquiry is complete.

In this case, there are vast financial issues at stake: If the hospitals lose, they will have to repay the government money for bills they have already collected. And the whole system of clinical trials in hospitals for new medical devices could be drastically altered.

If the government investigation proves that the hospitals have violated the rules, they will be deemed guilty of some of the biggest financial misdeeds in the recent history of the Medicare program.

The opportunity for the fraud alleged in this case exists at hospitals because they routinely are the sites where new procedures and equipment are tested. Clinical trials are required before the FDA certifies that a device is safe and effective.

In December, the federal government, prompted by the whistle-blower lawsuit, issued a ruling saying that experimental equipment lacking FDA approval had never been covered for reimbursement. This led to investigations at the more than 130 hospitals.

The disclosed sections of the whistle-blower lawsuit say the hospitals have submitted false claims, receiving payments during the last eight years "totaling at least \$800 million to \$1 billion or more."

Although the FDA has yet to approve artificial vascular grafts to repair or replace diseased vessels, the lawsuit said, the hospitals routinely billed Medicare for the operation with the grafts.

The hospitals charged \$40,000 and the doctor charged \$2,000 for the procedures, the lawsuit said.

The suit asks for the hospitals to make refunds to the federal government for any bills improperly submitted to Medicare, and for reimbursement to California for improper charges for the treatment of Medi-Cal patients. It also calls for penalties equal to three times the losses to the federal and state governments.

The hospitals that sued the gov-

ernment strongly defend their behavior. "The government knew what it was paying for," said Russell Hayman, a lawyer with Latham & Watkins in Los Angeles, representing the 25 hospitals that have sued the government. "Every bill went through a standard chain of review and the bills were paid," he said.

The hospital suit and the government investigation places "in jeopardy the fiscal integrity of over 100 of the nation's leading research and cardiac medical institutions," Hayman said. "The government paid for devices, and now eight years later, it says, 'we made a mistake, and we will go back and say, you owe \$5 million and you own \$10 million.'"

97/A18 THURSDAY, AUGUST 17, 1995

THE WASHINGTON POST

Hospital Medicare Fraud Alleged

21 Sites Falsely Billed \$1 Billion in Experimental Treatment, Suit Says

By Robert A. Rosenblatt
21st Avenue, New York

At least 21 major hospitals and research centers nationwide have falsely billed Medicare for more than \$1 billion for the use of experimental devices and equipment, alleges a whistle-blower lawsuit made available yesterday.

The lawsuit, which has been sealed from public view, claims the hospitals routinely violated government standards by billing Medicare for devices still deemed experimental and not approved by the Food and Drug Administration, including

heart valves, pacemakers, catheters and equipment used to regulate fast heart rates.

Some details of the alleged abuses have been unsealed by a federal court in response to a countersuit by some of the hospitals against the federal government. The initial lawsuit touched off a government investigation of more than 150 hospitals, although the number identified in the whistle-blower complaint, filed in federal court in Washington state, is unknown.

There are vast financial issues at stake: If the hospitals lose, they will have to repay the government mon-

ey for bills they have already collected. And the whole system of clinical trials in hospitals for new medical devices could be drastically altered.

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Healthcare FINANCIAL VENTURES REPORT

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Editor
Nina Youngstrom

Managing Editor
Phoebe Eliopoulos



Feds to File False Claims Lawsuits Over Medicare Billings for Attending MDs

As the feds take aim at attending physicians' billing practices, teaching hospitals and faculty practice plans should tighten billing procedures and beef up documentation.

The controversy over Medicare reimbursement for the services of attending physicians is exploding on two fronts, with the feds set to file a false claims lawsuit and provider groups gearing up to fight a proposed regulation that would stiffen resident supervision requirements.

False claims cases will be filed one-by-one by the U.S. Attorney in Philadelphia starting Oct. 1. The prosecution will be "ongoing" and multiple providers will be prosecuted, says Philadelphia-based assistant U.S. Attorney Jim Sheehan.

Sheehan says billing abuses over attending physicians' services have been repeatedly brought to providers' attention, but some allegedly continue the illegal practice.

continued on p. 6

Experimental Device Case Whistleblower Describes Alleged Misdeeds Behind Probe

At the heart of the federal probe into Medicare claims for experimental medical devices are charges of providers manipulating Medicare to maximize earnings by miscoding and by falsifying records.

For the first time, details of the false claims and kickback allegations in the feds' experimental medical device investigation are emerging, and they paint a picture of an industry whose research is said to be wrongly subsidized by Medicare and of providers accused of cheating Medicare and endangering patients for financial gain.

In an exclusive interview with HFVR, Donald Warren, the San Diego lawyer representing the whistleblower who set the earthshaking device probe in motion, described some examples of alleged shenanigans in clinical trials:

◆ At some hospitals, Warren claims, physicians did experimental atherectomies but billed them as angioplasties. To cover themselves in case of a Medicare audit, the MDs inserted a balloon in the patients' arteries, blew it up and took an x-ray to put in the files. MDs called these "reimbursement balloons," he charges.

◆ Medical device makers allegedly gave physicians and hospitals royalty contracts, stock options or cash to do a clinical trial with only the device maker's experimental product, instead of comparing it with a drug therapy and/or an approved device. Device makers gave providers incentives to bill Medicare as much as possible and meet FDA quotas as fast as possible, Warren charges.

continued

◆ Some providers allegedly reused single-use-only catheters.

"No one was watching the cookie jar at Medicare," which should not have been paying for experimental devices at all, says Warren, with the law firm of Monaghan & Warren.

Lawyers representing providers dismiss Warren's claims as off-base and in some cases flat-out wrong.

"Maybe that happened at one hospital. It has nothing to do with [the larger issue of coverage for experimental devices]," says Los Angeles lawyer Russell Heymann, with Latham & Watkins.

Baltimore attorney Len Homer also disputes Warren's allegations of a billing scheme. Referring to the angioplasty allegation, Homer notes "there is no code for atherectomies," so billing the procedure as an angioplasty was reasonable. "[Warren] is trying to make that sound sinister."

The feds began investigating Medicare claims for experimental devices after a private citizen filed a whistleblower lawsuit under the false claims act. To decide

whether to take over the lawsuit, the feds subpoenaed 135 hospital cardiac catheterization labs. At issue is whether Medicare claims for experimental devices and for related physician and hospital services are false claims, now that HCFA says it has never covered medical devices that lack FDA pre-marketing approval. The industry has been shaken by the probe because it has been acting on the assumption Medicare covers such devices and services.

So far, no hospital, physician or device maker has been charged with false claims or kickbacks, although members of the provider community have been in ongoing talks with the feds. In May, 25 hospitals asked a federal court to order Medicare to cover experimental devices because HCFA never finalized regulations denying Medicare payments.

The Justice Department has not yet exercised its right to take over the whistleblower lawsuit more than a year after it was filed. It remains sealed. Justice has no comment.

Kristen Morris, head of government affairs at the Health Industry Manufacturers' Assn., says "this whole [lawsuit] seems to be weak on every ground."

Meanwhile, a bill (HR 1744) introduced in June by House Ways and Means Health Subcommittee Chair Bill Thomas (R-Calif) and Senate Judiciary Chair Orrin Hatch (R-Utah) would let Medicare pay for experimental devices in FDA-approved clinical trials.

In a June letter to Congress, Warren calls the bill "an ill-advised mistake" that will "excuse criminal fraud."

Device makers and some lawyers again dismiss Warren's charges.

"He's digging up instances of [alleged] fraud unrelated to the nature of the bill," Morris says. She notes the bill just says Medicare won't refuse to cover a device solely because it's investigational. ◆

Merging Hospitals May Gain By Cooperating with State AGs

A cooperative approach to resolving state enforcers' antitrust concerns works better in hospital merger cases than an adversarial one. But cutting deals with your state attorney general won't immunize providers from federal antitrust watchdogs.

After agreeing to limit price increases and open their doors to any managed care plan for the next five years, two Harrisburg, Pa. hospitals got the green light

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Medical Industry Today August 18, 1995, Friday

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August 18, 1995, Friday

SECTION: PAYER & PROVIDER NEWS

LENGTH: 568 words

HEADLINE: Whistle-blower Says Hospitals Profiting from Billing Scam

BODY:

A whistle-blower suit filed in federal district court in Seattle alleges that dozens of prominent research hospitals nationwide submitted phony bills and falsified patient records to obtain as much as \$1 billion in federal payments for sophisticated, experimental cardiac procedures, according to a report filed by the Wall Street Journal. The allegations of years of systematic fraud involving as many as 130 major U.S. medical centers have prompted a federal criminal investigation and are expected to direct attention toward the controversial issue of which cutting-edge devices and procedures currently are, or should be, eligible for **Medicare** or Medicaid claims. Hospital lawyers reportedly vigorously deny wrongdoing, asserting that, until recently, the government knew about and, at least tacitly, approved federal coverage for such diagnostic and surgical procedures. Existing regulations say that the government generally won't pay for treatment considered to be experimental or for the use of "investigational" medical devices that haven't been formally approved for general use by the FDA. The lawsuit contends that doctors and hospitals including CEDARS SINAI MEDICAL CENTER (Los Angeles, CA), MOUNT SINAI MEDICAL CENTER (New York, NY), JOHNS HOPKINS HOSPITAL (Baltimore, MD), and the UNIV. OF CALIF. at LOS ANGELES MEDICAL CENTER devised improper procedures to circumvent those restrictions and hoodwink the government into paying for such treatments, the Journal wrote. The identity of the whistle-blower, who could be awarded tens of millions of dollars if his suit succeeds, remains secret. The formerly sealed action was filed last year, but was unsealed Wednesday. It claims that since 1986 "physicians knowingly submitted false claims" for the use of lasers, miniature drills and other surgical devices to remove deposits inside blood vessels. The complaint, released by the whistle-blower's lawyers, reportedly specifies the techniques allegedly used to cheat the government.

Phil Benson, a lawyer for the whistle-blower, said seminars were sponsored by at least one manufacturer to help doctors and hospital administrators allegedly falsify bills for unblocking blood vessels. Benson told the Journal that some hospitals instructed staff to deceive potential federal audits by removing

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