

Los Angeles Times

SUNDAY, FEBRUARY 11, 1996

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Secret Witness to Detail Medicare Billing Fraud

■ **Hearing:** Hooded whistle-blower is expected to tell Senate of hospitals' illegal charges for experimental devices.

By RALPH VARTABEDIAN
TIMES STAFF WRITER

WASHINGTON—A secret star witness, his identity cloaked by a black hood, is scheduled to be spirited Wednesday through the marble halls of the historic Dirksen Senate Office Building to an ornate hearing room jammed with corporate attorneys and powerful lobbyists anticipating the worst.

In years past, Congress has reserved such high drama for Mafia snitches and union racketeers who had blown the whistle on corruption or mismanagement. Wednesday's masked witness, by contrast, is expected to disclose a pattern of payoffs, influence peddling and fraudulent billing practices in one of the nation's most admired applications of high technology: hospital use of lifesaving medical devices.

A probe of 131 of the nation's most prominent hospitals by federal agents at the Health and Human Services Department has uncovered evidence that illegal billings for experimental medical devices over the past decade may reach \$1 billion.

Hospitals around the nation—often with the encouragement of medical-device manufacturers—routinely billed Medicare for pacemakers, cardiac catheters and other high-tech devices while they were still undergoing clinical trials, according to documents obtained by federal investigators.

There was only one hitch: Medicare did not cover the cost of experimental devices. And many of the hospitals knew it.

"The federal agencies responsible for preventing these abuses

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MEDICARE: Senate Hearing on Illegal Billing

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were asleep at the switch," said Sen. William V. Roth Jr. (R-Del.), chairman of the Senate Permanent Subcommittee on Investigations, which is in charge of Wednesday's hearing. "It is such a major problem, and so complex."

The practice had continued for roughly a decade until a lone employee of a major institution came to the conclusion that the whole arrangement was a potential fraud and filed a sealed whistle-blower suit under the federal False Claims Act in 1994. He is the one who will be the cloaked witness.

The high-profile hearing is but one measure of the increasing federal scrutiny of Medicare fraud at a time when the program is coming under heavy pressure from congressional budget-cutters. The General Accounting Office estimates that fraud amounts to 10% of Medicare's entire budget, about \$17 billion in illegal payments this year.

The FBI has more than tripled the number of agents assigned to police Medicare fraud, and Justice Department officials have ranked it as one of their top priorities.

The dragnet is finally yielding some big fish. A week ago, a federal jury in Georgia convicted Robert "Jack" Mills, owner of the nation's largest network of home health care firms, of improperly billing Medicare for country club dues, gourmet popcorn and personal travel on corporate jets.

The probe into medical devices touches on institutions that might have been regarded as far above any suspicion of criminal activity until only a few years ago.

The medical-devices industry ranks among the most promising and fastest-growing sectors of U.S. high technology. It reports annual sales of \$57 billion, making it bigger than the steel industry. Silicon Valley has 100 device manufacturers, followed by about 50 in Southern California. The next biggest centers, Massachusetts and Minnesota, have 25 each.

The most technologically intensive firms are growing by 50% annually, said Montgomery Securities analyst Kurt Kruger, adding, "I don't see any end to it."

For federal investigators, the hospital and device industries are proving to be politically well-connected and powerful opponents. Until Roth blocked them, they nearly pushed through legislation last year that would have essentially absolved them of any past wrongdoing.

In recent weeks, Roth's staff and private attorneys representing the whistle-blower have collected compelling new evidence that hospitals have violated Medicare regulations. The subcommittee has subpoenaed a number of prominent cardiologists from major university hospitals, including the University of Washington.

"Our case focuses on the hospital, but we are talking about an entire underground of people making bad decisions . . . for enormous sums of money," said Phillip Benson, a Newport Beach, Calif., attorney who, along with Donald R. Warren of San Diego, represents the still-secret whistle-blower. "It is outright fraud."

The hearing is also expected to show evidence that medical-device makers paid kickbacks to major hospitals that performed the clinical trials on their devices. And it is scheduled to unveil memorandums showing explicitly that hospitals sought to hide illegal billings from federal regulators.

"There were some hospitals that not only violated Medicare rules, but they did so knowingly," Roth said in an interview. "I want to know why this problem was not known earlier and why nothing was done for such a long time."

Indeed, federal investigators have turned up a few memos that leave little doubt about what hospitals were doing. For example, federal agents obtained a document showing that Sutter Hospital in Sacramento had implanted several dozen cardiac defibrillators and pacemakers that were not covered by Medicare.

In a bizarre April 1994 memo, a Sutter administrator, Mark W. Rieger, remarked that the hospital faced a "conundrum" because it was clearly billing Medicare for experimental procedures. The administrator went on to say that the hospital "could potentially be audited" and that "by the letter of the law we are at risk."

But he determined that "there is obviously no communication" among government agencies that would disclose the practice. Therefore he concluded that "our overall risks are small."



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February 15, 1996, Thursday, Late Edition - Final

SECTION: Section B; Page 13; Column 3; National Desk

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HEADLINE: Health Executive Tells Senators **Medicare Fraud** Is Widespread

BYLINE: Reuters

DATELINE: WASHINGTON, Feb. 14

BODY:

A health industry executive, testifying at a Senate hearing with his identity concealed, said today that **Medicare fraud** by doctors and hospitals was widespread, especially on the use of experimental medical devices.

"**Medicare** abuse is rampant in the medical industry," the executive told a hearing of the Senate Permanent Subcommittee on Investigations. He spoke behind a screen with his voice electronically altered and wore a hood when he entered and left the hearing room.

He said he feared that if his identity became known, his career in the industry would be over.

The witness said hospitals were filing false claims and performing unnecessary procedures to get **Medicare** payments for devices that have not been approved for use by the Food and Drug Administration after clinical tests. **Medicare** pays only for procedures performed with approved devices.

The executive is providing information to a Department of Health and Human Services investigation of **Medicare fraud** and has filed a false-claim suit against 132 hospitals on behalf of the Government. If the suit is successful, he will get a percentage of the money.

John Hartwig, a deputy inspector general with the department, said the investigation was still in progress, but added, "It is clear that **Medicare** was misled into paying millions of dollars to hospitals for procedures using these experimental devices."

Financing of the **Medicare** health insurance program for older Americans has been a major issue in budget negotiations between the White House and Republican Congressional leaders. Last week, the Clinton Administration said the system was losing money more quickly than expected.

The witness said he had seen dozens of unnecessary invasive balloon angioplasty procedures performed on patients after experimental devices were used to remove plaque from arteries because **Medicare** would pay for angioplasty but not for the experimental treatment.

"Physician training sessions sponsored by the medical industry promoted this falsification as the 'reimbursement balloon,' " he said.

The witness also said he had seen \$60,000 experimental heart defibrillators billed as pacemakers and single-use catheters reused up to 20 times and billed as new.


The executive was critical of the Department of Health and Human Services, which administers the **Medicare** program, saying the department was "too connected to the medical industry to prosecute the major abusers."

A spokesman for the department, Victor Zonana, disputed the contention that the department was lax about **Medicare** abuse, saying, "H.H.S. has zero tolerance for **fraud**." He said the department had recovered millions of dollars in improper payments and brought many prosecutions for **fraud**.

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The San Diego Union-Tribune

Wednesday
February 14, 1996

Hospitals target of lawsuit over Medicare billing

*UCSD, 2 Scripps
facilities among
132 facing probe*

By REX DALTON
Staff Writer

Three San Diego hospitals are among a group of 132 elite facilities nationwide that are under investigation by federal agencies for alleged false billing of Medicare for experimental heart procedures.

UCSD Medical Center in Hillcrest, Scripps Memorial Hospital in La Jolla and Scripps' Green Hospital in La Jolla have been subpoenaed to provide records to the U.S. Department of Health and Human Services, which is leading the investigation.

Scripps officials say the experimental procedures were done to offer patients the most advanced technology and that improper billing to Medicare and other government programs did not occur. The UCSD official involved in the probe was unavailable yesterday for comment, but a UCSD spokeswoman said the university has given the federal government the documen-

tation it needs.

The investigation stems from a whistle-blower lawsuit filed in 1994 in Seattle by a San Diego attorney. The lawsuit, which was filed on behalf of a Washington man, alleges at least \$1 billion in false billing of Medicare, Medicaid (Medi-Cal in California) and CHAMPUS.

The unidentified whistle-blower contends in the lawsuit that many of the nation's leading hospitals — including the three here — routinely billed government health programs from 1984-94 for the use of experimental devices in cardiac procedures.

Federal officials say that in those years, Medicare and the other programs would not pay for devices that weren't approved by the U.S. Food and Drug Administration (FDA) for marketing.

Medicare officials did this because they wanted patients to receive only those devices the FDA had found safe and effective. In November, however, this policy was slightly revised to allow billing for some experimental devices. The investigation focuses on allegations

See Probe on Page A-21

Probe

Senate panel will hear whistle-blower today

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that hospitals charged the federal government for approved procedures, but physicians either substituted a procedure that made use of an experimental device or added the device to the approved operation, officials say.

A number of the devices in question have since been approved by the FDA, officials say, although some have not.

Cardiac devices involved in the billing probe at the San Diego hospitals, and since approved by the FDA, include:

— The Rotablator, a catheter with a rapidly spinning head that unclogs coronary arteries; and the Schatz stent, a mesh, steel tube placed in coronary arteries to prevent their closure.

“This is a real hidden cost in devices that hospitals don’t want anyone to know about,” said Donald R. Warren, the San Diego attorney

representing the man who filed the whistle-blower lawsuit in U.S. District Court in Seattle. Warren’s co-counsel is Phillip E. Benson of Newport Beach.

Under federal law, a whistle-blower lawsuit remains sealed while government agencies investigate whether it has merit. If the government decides to take over the case, it can sue for recovery of the falsely obtained funds, plus penalties. The whistle-blower also receives a share of the government’s award. The government continues to investigate this lawsuit, and it will be unsealed in August.

Today in Washington, the whistle-blower will testify anonymously — he will wear a hood, like those used for criminal informants — at a hearing of the Senate Permanent Subcommittee on Investigations.

“Medicare abuse is rampant in the medical industry,” says a copy of his planned testimony. “I have witnessed this fraud from inside the medical industry: in major hospitals, in medical device seminars and in operating rooms around the country.

“What I have seen is an industry that believes it is not bound by the law and Medicare rules.”

Sen. William V. Roth Jr., R-DeI.,

chairman of the subcommittee on investigations, said in a written statement.

“Our investigators have obtained clear evidence that some hospitals billed Medicare for investigational (experimental) medical devices despite knowledge of Medicare’s policy prohibiting such charges. This concerns me, especially in light of recent reports that the Medicare Trust Fund may be bankrupt even sooner than we feared.”

At the Scripps hospitals, spokesman Michael D. Bardin insisted there was no fraudulent billing.

After being subpoenaed in June 1994 for information, Bardin said the two hospitals provided five filing boxes of patient billing and medical records on procedures by cardiologists. The doctors were working under the overview of Institutional Review Boards, which monitor experimental procedures to protect patients.

As an example of a case, Bardin said, the hospital may have billed Medicare for a balloon angioplasty to open a coronary artery, but the physician also may have placed a then-experimental Schatz stent into the vessel. Medicare would not have known that the stent was

used.

In another type of case, he said, a then-experimental Rotablator may have been used to open a coronary artery clogged with fatty deposits, then a balloon angioplasty would be undertaken, with the bill listing an angioplasty.

“We billed under the closest (Medicare) classification we could find for the procedure,” Bardin said. “If you looked at stent (cases), we would do an angioplasty; we just added a stent.”

UCSD’s Leslie Franz acknowledged that the university received a subpoena for records in 1994 and that officials provided the necessary documents to Health and Human Services investigators. But she said the UC attorney handling the case was unavailable for comment yesterday.

Franz noted that other hospitals involved in the investigation are some of the nation’s finest. They include: Cedars-Sinai in Los Angeles, UCLA and UC San Francisco.

Led by Cedars-Sinai, 25 of the 132 hospitals are suing the Department of Health and Human Services in U.S. District Court in Los Angeles seeking relief, arguing that Medicare’s policies were vague on

the use of such devices.

But top officials from Medicare and the HHS Office of the Inspector General will be testifying at the Senate hearing today that the government’s policies were well known and understood.

Other devices involved in the questioned billing practices nationwide include pacemakers, lasers, equipment for diagnosing electrical heart ailments, implantable defibrillators for shocking faulty hearts into action and catheters used for a procedure known as radio frequency ablation, which cuts cardiac nerves to correct heart pumping.

One San Diego biotech firm, InterVentional Technologies Inc., is the maker of an artery-cleaning catheter for which Medicare reportedly was billed when it was still experimental and undergoing testing at Scripps’ Green Hospital and other institutions. The firm’s TEC catheter — which cuts coronary artery deposits and sucks them out — was approved by the FDA in 1993.

Rob Michiels, president of the privately owned InterVentional Technologies, said Medicare’s policy was never clarified and that billing for the use of his firm’s device prior to 1993 was appropriate.

USA TODAY Washington

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Secret witness tells senators of Medicare fraud

WASHINGTON - A secret witness told a Senate panel Wednesday that some hospitals illegally, and with little fear of getting caught, bill Medicare for experiments with new medical devices.

"Physicians go so far as to joke of the government's ineptness to investigate and prosecute the fraud," said the man, who could be seen by senators but was screened off from the public, with his voice electronically altered. When he left the room he wore a hood and dark trench coat with the collar turned up.

"I know that when my name becomes known, my career is over," said the man, who described himself as an expert in cardiac care devices.

He said he watched for 10 years as hospitals and physicians defrauded the Medicare and Medicaid billing system.

"I have witnessed this fraud from inside the medical industry: in major hospitals, in medical device seminars and in operating rooms around the country," he told the Senate Governmental Affairs investigations subcommittee.

The fraud he described has been under investigation by the Health and Human Services inspector general's office since 1993. It's getting even greater attention as Congress searches for ways to reduce Medicare costs as part of overall budget tightening.

Medicare losses caused by fraud have totaled \$17 billion, according to the General Accounting Office, an investigative unit of Congress. That's 10% of total Medicare spending, said Sen. William Roth (R-Del.), subcommittee chairman.

"It is clear that Medicare was misled into paying millions of dollars to hospitals for procedures using these experimental devices," said John Hartwig, deputy inspector general, who also testified but would not name the hospitals because the investigation is ongoing.

He said the government has issued more than 130 subpoenas to hospitals in 30 states to determine the extent of improper billing.

At issue are experiments with devices not yet approved by the Food and Drug Administration.

The hearing concentrated on heart devices such as implantable defibrillators, used to regulate the heart's rhythm.

Only a few physicians at about 2% of the nation's hospitals have been approved to conduct clinical trials of new medical devices. The costs are supposed to be absorbed by the manufacturers and hospitals.

But, as the Senate subcommittee hearing revealed, the government has discovered that some of the hospitals have found a way to get Medicare to pay.

Hartwig said most of the hospitals his office subpoenaed knew they were not supposed to bill Medicare and about 30 took steps to conceal it.

The secret witness said hospitals would falsely bill their experiments as other surgery or implants of already approved devices that could legally be billed to Medicare.

Los Angeles Times

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Medicare Fraud Rampant, Secret Witness Claims

By RALPH VARTABEDIAN
TIMES STAFF WRITER

WASHINGTON — Major research hospitals have routinely violated Medicare rules and jeopardized the lives of patients by using experimental medical devices in pursuit of illegal profits, a secret industry witness told a Senate hearing Wednesday.

Seated behind a screen and talking through a voice modulator, the anonymous witness said that he watched one patient die when an experimental cardiac catheter unraveled inside the patient's heart and shredded an artery.

Medicare, the federal health insurance program for the elderly and disabled, does not cover the cost of such experimental devices as newly developed pacemakers, implantable defibrillators and cardiac catheters.

Hospital officials defended the use of the devices, saying that they were intended to give patients the benefit of the latest technological advances even if they are not yet covered by Medicare. But the witness said that manufacturers of the devices give doctors tremendous financial rewards for using the experimental technology.

Sen. William V. Roth Jr. (R-Del.), who presided over Wednesday's hearing as chairman of the Senate Government Affairs permanent subcommittee on investigations, said his committee's work shows that hospitals have found ways to defraud Medicare out of millions of dollars by disguising their use of experimental devices.

The secret witness, an employee of a major medical institution, said that hospitals sometimes substitute approved devices for experimental ones in their requests to Medicare for payment. For example, they might disguise an experimental cardiac catheter, which is not cov-

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MEDICARE: Secret Witness Claims Fraud

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ered by Medicare, as an angioplasty balloon, which is covered.

In fact, the witness said he had seen doctors insert angioplasty balloons as well as catheters solely to create a paper trail for subsequent Medicare billings. The practice was cynically called a "reimbursement balloon," he said.

"They would run the balloon up into the patient's artery, expand it and take an X-ray for the patient file in the event of a Medicare audit," the witness said. "A bill would then be submitted to Medicare, hiding the experimental device procedure and instead claiming reimbursement" for a Food and Drug Administration-approved angioplasty.

The witness said that he had personally seen such practices "dozens of times in dozens of places," an assertion that left the Senate panel stunned. Sen. Carl Levin (D-Mich.) said that the practices amounted to a virtual "criminal assault" on patients.

Investigators for the Department of Health and Human Services testified that, after issuing subpoenas to 132 major hospitals, they have collected evidence that most, if not all, of them submitted improper bills for experimental medical devices and that at least half of them did so knowing it was illegal.

The witness has filed a sealed whistle-blower lawsuit under the federal False Claims Act. If the suit is successful, he will get a percentage of the money.

In a separate action, it was announced Wednesday that the government has settled the first civil case stemming from the investigation, collecting \$1.3 million from Sutter Hospital in Sacramento.

Sutter chief executive Patrick Fry acknowledged at the hearing that his hospital had submitted improper billings to Medicare but said it was done in the interest of patient care and that the costs for experimental devices did not exceed what the hospital would have spent for care using older technology.

The billing practices of the University of Washington Medical Center in Seattle and Allegheny General Hospital in Pittsburgh, Pa., also were called into question by Roth, who displayed blown-up copies of internal memos from the hospitals showing that they were fully aware of Medicare rules and elected to bill the agency nonetheless.

Anthony Sanzo, president of Allegheny, said that Medicare rules were unclear and that they were never promulgated correctly under federal rule-making procedures. "Superior patient care" dictated

the hospital's decision to use the devices, he said.

But the secret witness told a much different story, maintaining that hospitals and doctors respond to the potential for financial rewards. As incentives to use the devices frequently, doctors who are clinical investigators for experimental devices are often granted stock options, royalty contracts and cash by manufacturers, he said. In the end, many of the devices prove unsafe and are withdrawn from the market, he added.

Jack Hartwig, deputy inspector general at Health and Human Services, told the subcommittee that the agency is committed to recovering all the money that was improperly paid out, calling the hospitals' practices "outrageous" in an interview after the hearing.

Nonetheless, Roth said that the department is not doing enough to stop fraud and that Medicare remains more open to fraud and abuse than any other federal program.

Hartwig said, however, that his budget for investigations has been repeatedly cut in recent years, leaving him with "greatly diminished" resources for audits, travel and other investigation costs. He has 175 criminal investigators to cover the entire Medicare program, he said.



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Modern Healthcare February 19, 1996

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SECTION: News; Pg. 3

LENGTH: 744 words

HEADLINE: THE WEEK IN HEALTHCARE; CONGRESSIONAL HEARING EXPLORES
MEDICARE FRAUD

BYLINE: Eric Weissenstein and Lisa Scott

BODY:

Half the 132 hospitals targeted in a federal probe of **Medicare** billing practices knew that the claims they were submitting for the use of non-Food and Drug Administration approved medical devices weren't covered by **Medicare**, a government investigator told Congress last week.

Also last week, one hospital agreed to pay the government about \$1.3 million to settle charges that it falsely billed **Medicare** for the use of nonreimbursable medical devices.

The hearing testimony, which featured a hooded secret witness, and the settlement were the latest developments in the festering legal dispute over hospital **Medicare** billing practices. The dispute also has spawned a "whistleblower" lawsuit against an unspecified number of hospitals and a countersuit against HHS over **Medicare** payment policies for investigational medical devices.

At the hearing, Jack Hartwig, HHS deputy inspector general, told the Senate Governmental Affairs investigations subcommittee that about 30 of the 132 hospitals involved in the billing probe not only improperly billed **Medicare** but took steps to hide it.

"We believe these hospitals intentionally defrauded the **Medicare** program," he said.

Prior to November 1995, **Medicare** and Medicaid did not reimburse for procedures using devices not approved by the Food and Drug Administration. The programs had the option of denying all or part of a hospital admission that involved an investigational device.

Although the policy had been in effect for years, it was rarely enforced. But in 1994, the government subpoenaed records of 132 hospitals. Since then, HCFA has changed its policy and now covers about 70% of all investigational devices.

Hartwig said the HHS probe found that nearly all the hospitals examined had improperly billed **Medicare** for services involving investigational devices. The amount of false claims ranged from less than 10 cases at one hospital to more than 400 at another, representing millions of dollars in payments.

Last week's hearing was highlighted by testimony from the whistleblower, who charges that hospitals participated in a scheme to defraud the government of as much as \$1 billion in **Medicare** reimbursements.

Details of the whistleblower case were revealed last year when the suit was partially unsealed (Aug. 21, 1995, p. 34). But, the plaintiff's identity has been kept secret, and he testified last week behind a screen and had his voice electronically altered. The mystery witness also wore a hood and large overcoat when leaving the hearing to conceal his identity.

In one alleged scheme, doctors would use an investigational cardiac procedure that would not be covered by **Medicare** and would perform a second, unneeded angioplasty procedure to ensure payment from **Medicare**. The whistleblower said the first, non-reimbursable procedure would then be covered-up by hospital personnel who would remove the consent forms for the use of the investigational cardiac device from patient files.

Meanwhile, the first casualty of the probe is Sutter Memorial Hospital in Sacramento, Calif. Under a settlement announced last week by the U.S. attorney's office in Sacramento, the hospital agreed to pay a \$1.3 million civil penalty to avoid prosecution under the federal False Claims Act.

According to the government, cardiac patients at the hospital regularly received investigational devices in the course of operations performed as part of clinical trials from 1988 through 1994. Sutter billed **Medicare** for the operations even though it was told the program didn't cover procedures involving investigational devices.

"We regret that we continued to bill for the devices after we learned about the **Medicare** manual policy," said Penny Westfall, Sutter assistant general counsel. But, Westfall added that Sutter may have been entitled to payment. Several hospitals involved in the investigation have sued the government, arguing that the revised 1995 **Medicare** payment policy was illegal because it didn't go through rule-making procedures.

The lawsuit is pending in U.S. District Court in Los Angeles (Jan. 22, p. 21). Sutter isn't one of the plaintiffs.

As part of the settlement, the federal government will dismiss Sutter from the pending whistleblower lawsuit and won't take other civil actions against the hospital. Sutter, in turn, agreed to implement an internal **Medicare** billing compliance program to avoid similar problems in the future.

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