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OIG Leery Of Business Deals To Boost Pathology Referrals

The government is likely to pay very close attention to these business ties, said OIG official Vicki Robinson, because of the likelihood that they would lead to overutilization of pathology services and thus more unnecessary Medicare spending

The HHS Office of Inspector General is warning about the proliferation of a new type of business arrangement in which specialty physicians such as urologists, dermatologists and gastroenterologists can increase their Medicare revenue from pathology referrals.

"There's a significant fraud and abuse risk here," said Vicki Robinson, chief of the OIG industry guidance branch, who raised the issue at a recent American Bar Association meeting in New Orleans, LA, and elaborated on her concerns in an interview with the *National Intelligence Report*.

Robinson told *NIR* that multiple sources have alerted the OIG over the past few months about these arrangements. Their typical elements: a facility manager establishes a turnkey lab for physician groups; the lab is compartmentalized in a separate building, often out of state, with separate office suites or cubicles for each of 10 or 15 physician groups; the lab provides technical personnel who work in the rooms, preparing samples for pathologists. ➥ *p. 2*

San Diego Case Rattles Hospital Industry

In a move that targets business agreements common among U.S. hospitals when competing for physicians, federal prosecutors have filed criminal charges against Alvarado Hospital Medical Center (San Diego, CA) and its former chief executive Barry Weinbaum, alleging that they used "relocation packages" as bribes in exchange for referrals. Alvarado bankrolled more than 100 such packages worth a combined $10 million for over a decade, the government said.

Spearheading the case is local U.S. attorney Carol Lam who, as an assistant U.S. attorney in the early 1990s, broke new legal ground on "medical necessity" issues in the case against National Health Laboratories. Lam argued that NHL duped doctors into ordering unnecessary tests by the way it packaged and marketed an "enhanced" chemistry profile. NHL's $111 million settlement was the first of many big-buck settlements throughout the 1990s with independent labs accused of similar practices.

Tenet Healthcare Corp., which owns Alvarado, and Weinbaum deny any wrongdoing. The case is set to go to trial in October, but Tenet reportedly wants a global resolution of this and other fraud allegations that could end up costing it more than $1 billion.

INSIDE *NIR*

OIG Leery Of Business Deals, *from p. 1*

The groups take advantage of an exception to the Stark ban on self-referrals, which lets physicians perform lab services in their own space or in a separate "centralized location" they own or rent. Generally, the lab provides the pathologist, the space and the technical services, but the physician groups handle the Medicare billing as if they were doing the lab and pathology work themselves. The physicians pay a management fee to the facility manager, a discounted fee to the pathologists and keep the rest.

"There are significant kickback risks with these arrangements," Robinson emphasized. "We are hearing of over-referrals from a number of sources." The structure of these arrangements is quite varied, she said, but "a lot of the ones I have been hearing about would not comply with Stark."

Robinson declined to characterize the OIG's enforcement stance, but did say, "We are looking at this issue." She also noted that if there are violations, the OIG has a variety of enforcement options to explore on a case-by-case basis. If the violations break federal anti-kickback law, the OIG would have recourse to a host of sanctions.

Robinson urged organizations that are contemplating such arrangements to review an April 2003 special advisory bulletin on contractual joint ventures—available online at *oig.hhs.gov/fraud/docs/alertsandbulletins/042303SABJointVentures.pdf*.

"Cut A Deal Or Lose Business"

"I am getting so many distressed calls from pathologists about this," attorney Jane Pine Wood, JD, of McDonald Hopkins Co. LPA (Cleveland, OH), told *NIR*. Management companies, primarily based in Florida, have been marketing these arrangements to specialty physicians nationwide. Some physician groups have asked the pathologists they have been using to offer a similar arrangement or risk losing all of their business. "I have some pathology clients who may be forced to offer one of these arrangements" to avoid losing business.

Despite the creative method these arrangements use to comply with Stark, Wood said, "there are lots and lots of compliance issues." The specialty physicians are responsible for compliance and liability at the remote site, over which they have no real control, because the off-site lab is technically part of their office.

Wood echoed Robinson's concerns about the increased utilization among doctors who have an interest in these pathology operations. She has heard of urologists taking more prostate specimens and dermatologists removing more skin so they could profit from increased pathology billings.

Pathology Lab May Donate Its Services, OIG Says

A for-profit laboratory, partially owned by several pathologists, may provide lab services at no charge to low-income, uninsured residents as part of a countywide volunteer project without fear of violating federal anti-kickback law, the HHS Office of Inspector General concluded in an advisory opinion (No. 04-5) posted June 9.

The project coordinates volunteer physician and hospital care, diagnostic services and medication assistance for county residents who have no medical insurance, are not eligible for government medical aid and have income that does not exceed 150% of the federal poverty level.

The lab noted that while there will be no remuneration among the parties, some of the project's volunteer physicians may make referrals outside the scope of the project, and some of these referrals may be payable under a federal health program. The lab further certified that its participation in the project is not related to its other business.

The OIG determined that the lab's voluntary participation results in no economic value to any party in a position to refer federal program business. "Rather, the economic benefit [of the lab's role] inures to the public good in the form of increased availability of services for an underserved population."

Payment Change Looms For Certain Rural Hospital Labs

The number and name of affected hospitals was not available from CMS at press time, but agency officials say that fiscal intermediaries will make notations in their provider-specific file to flag eligible hospitals with less than 50 beds

Beginning July 1 of this year, rural hospital laboratories serving sparsely populated areas of the country will be no longer be paid for outpatient work via the Medicare Part B lab fee schedule, but will be reimbursed for 100% of reasonable costs (with no co-insurance or deductible applicable). This exception was mandated by the Medicare Modernization Act of 2003. It will extend over a two-year cost reporting period.

The exception applies to hospitals that have less than 50 beds and are located in "qualified" rural areas—those that have the lowest 25% quartile population density. The Centers for Medicare & Medicaid Services has identified eligible areas in a postal zip code file sent to local fiscal intermediaries.

In the map below, each dot represents one of the 7,826 zip codes eligible. The greatest concentration is along the Mississippi River Valley and in the Great Plains states, but there also is a broad swath of qualified areas in states from the Rocky Mountains westward.

In calculating reasonable-cost reimbursement for the outpatient lab work, CMS will use the ratio of costs to charges for the lab cost centers times the charges billed. The Congressional Budget Office has estimated that the payment methodology change will increase Medicare outlays to the rural hospitals by some $100 million. To see if your hospital's zip code is eligible, download and unzip the "Zip Code to Carrier Locality File" at *cms.hhs.gov/providers/pufdownload/default.asp?#zipcodeclf*. Then open the Microsoft Excel file, "ZPLC0704," and scroll or keyword search to find your zip code. It is eligible if there is a "B" indicator in the "Rural Ind" column.

Rural Areas Eligible For Higher Medicare Lab Payments, by zip code

HHS Panel Concerned Over Genetic Test Ads To Consumers

The HHS Secretary's Advisory Committee on Genetics, Health & Society wants a more concerted federal effort against the potential for false and misleading advertising of genetic tests to consumers. While the panel, at its June 14-15 meeting in Bethesda, MD, did back away from approving a resolution against such direct-to-consumer marketing, it agreed to urge Secretary Tommy Thompson to get the agencies within his Department to work with the Federal Trade Commission on the issue. The committee also said it will continue to gather information on the subject.

The panel discussed at length a draft report on genetic test coverage and reimbursement, the issue that it had ranked highest at its previous meeting in March (*NIR, 25, 10/Mar. 8, '04, p. 4*). Much of the talk centered on the idea of developing a process for identifying and filling the gaps in scientific evidence regarding the clinical utility of genetic tests. As Steve Furroughs, an ex officio member from the Centers for Medicare & Medicaid Services noted, "We need an evidentiary base that is really not there for the Medicare population." The committee agreed to try to finalize the coverage and payment report at its next meeting, scheduled for Oct. 18-19.

Early results from Myriad Genetics' five-month trial ad campaign in selected cities, touting its BRACAnalysis predictive test for breast and ovarian cancer, show an increase in utilization vs. control sites, underscoring the importance of test accuracy, CDC official Muin Khoury, MD, PhD, told the advisory committee. Khoury is director of CDC's Office of Genomics & Disease Prevention

The advisory committee got some discouraging news on pending legislation that would ban discrimination by employers and insurers based on genetic information. Despite widespread support in Congress, the prospects for action this year appear slim, lamented Joann Boughman, PhD, executive vice president of the American Society of Human Genetics (Bethesda). The Senate last fall passed a genetic anti-discrimination bill (S. 1053) by a vote of 95-0 vote. The House has passed two bills: H.R. 1910, which the Society supports, and H.R. 3636, which it opposes. "Our hope had been to get S. 1053 to the floor or get H.R. 1910 through committee, with S. 1053 as a compromise," she said.

The White House has signaled that the President would sign a measure like the Senate-approved one if the full Congress would enact it. Geneticists and a host of other distinguished scientists have urged lawmakers to act, and even leading health insurers have indicated they have no problem with the legislation, Boughman noted. But "there has been nothing happening in any real way," she added.

Asked what the Secretary's panel could do to help, beyond the two letters of support it has written and the priority given to the matter by placing it first on the meeting agenda, Boughman said, "We are using every avenue we know to use. I don't know of any specific actions that you could do at this point." Even so, the committee agreed to help by adding to the agenda of its October meeting an opportunity for individuals who complain of genetic discrimination to speak out publicly and possibly galvanize support for legislative action.

The Secretary's advisory committee also discussed a draft resolution on genetics education and training of health professionals developed by the panel's education task force, chaired by Joan Reede, MD, MPH, MS. Its main thrust is to promote the dissemination of genetic and genomic understanding among a wide range of these professionals, so it becomes an integral part of clinical medicine and public health.

CMS Mulls Pathology Referral Issue

Lab sources contacted by NIR *view the pathology and laboratory referral issues as linked. But CMS is inclined to see pathology referrals as a separate matter, an agency official told* NIR

Officials at the Centers for Medicare & Medicaid Services are engaged in internal discussions, *NIR* has learned, about their approach to paying for pathology interpretations that clinical laboratories in one carrier jurisdiction refer to entities in another carrier jurisdiction.

Under current policy, Medicare reimburses these services at the Part B physician fee schedule rate applicable to the locality where the interpretation is rendered. As a result, to bill for the services, the provider will have to enroll with the carrier having jurisdiction over that locality. In contrast, starting this July 1, clinical laboratories that bill for lab tests referred elsewhere will be paid by the carrier with jurisdiction over their location, even if the tests were referred out and performed in another state.

This payment approach is possible for clinical lab services because CMS has provided each carrier with the lab fee schedules of all other carriers, along with new software to apply the correct payment amounts. Thus, each carrier should be able to pay a lab claim at the correct amount, regardless of where the testing was done. As a result, labs in one state that refer testing to a lab in another state will no longer have to enroll with the out-of-state carrier in order to bill for the referred work.

But as noted, CMS is applying this approach only to clinical laboratory services, and not to physician pathology services. One possible reason is that lab fees under Medicare Part B can vary by carrier jurisdiction, which in most cases is statewide, and are capped by national limitation amounts. But Part B fees for pathology, like all physician services, vary by Medicare-set localities, adjusted for local economic factors. Thus, pathology fees within a state can actually vary based on the zip code where the service was performed. Applying the lab referral solution to pathology work would be more complex, observers note.

IT Czar Promotes Electronic Healthcare Data Sharing

Electronic medical records are seen as a way to improve coordinated care through secure exchange of up-to-the-minute information among hospitals, labs, physicians and other providers

The head of the Bush Administration's initiative to promote adoption of electronic health records over the next decade has called for use of health information exchanges to share laboratory and other important clinical data. At a June 17 hearing of the House Ways & Means health subcommittee, David Brailer, MD, PhD, who holds the new high-level position of National Health Information Technology Coordinator within the U.S. Department of Health & Human Services, said, "My goal in the next year is to focus on a well-developed plan and coordinated actions to accelerate widespread adoption of electronic health records and e-prescribing."

Indiana University professor Marc Overhage, MD, PhD, described to the committee one such exchange model, the Indiana Network for Patient Care, formed in 1997 by five hospital systems and two large primary care groups in Indianapolis with support from the National Library of Medicine and the HHS Agency for Healthcare Research & Quality. The aim is to avoid data for research. The network allows providers to share lab data, demographics and encounter data for 95% of all beds and emergency department visits in the metropolitan area. It includes real-time lab test results for active surveillance of reportable conditions.

OIG Seeks To Calm Hospitals' Anxiety Over Discounts

The move was designed to elaborate on the Medicare policy affirmed earlier this year by Health & Human Services Secretary Tommy Thompson, in response to concerns raised by the American Hospital Association (NIR, 25, 10/ Mar. 8, '04, p. 6)

A top official with the HHS Office of Inspector General has assured hospitals and other healthcare providers that they don't risk kickback allegations or Medicare exclusion by not charging full price to patients who can't afford to pay for their care, if certain conditions are met.

"Nothing in the OIG rules or regulations prohibits hospitals or other providers or suppliers from offering discounts to [these] patients," said Vicki Robinson, chief of the OIG's industry guidance branch, during a June 1 open-door forum. "The OIG fully supports efforts to lower healthcare costs for those unable to afford care."

She drew a distinction between discounts for the uninsured, where "our legal authorities are extremely limited," and discounts for federal health program beneficiaries, where "our laws and regulations clearly enable hospitals and other healthcare providers to help patients experiencing financial hardships."

Robinson acknowledged worries by some providers that offering discounts could implicate the federal anti-kickback statute, but noted that the statute bans or restricts discounts only if they are tied directly or indirectly to referrals of Medicare and other federal health program business. She also pointed out that the "OIG has never excluded or attempted to exclude providers for offering discounts to the uninsured." And most recently, she added, the OIG's proposed rule on discriminatory billing specifies that services to uninsured patients at no charge or at substantially reduced rates are excluded from the calculation of "substantially in excess" of "usual charges" (*NIR, 24, 22/Sept. 29, '03, pp. 1-2*).

Cost-Sharing Waivers

While the law generally bans routine waivers of beneficiary co-insurance, there is an exception for "financial need," but only if it is not routine, is not promoted in advertising, and the provider has made a case-by-case determination "in good faith that the individual was in financial need and that reasonable collection efforts have failed." Financial need is not limited to indigence, but can encompass any reasonable measures of financial hardship.

Hospitals and other providers have the flexibility to design their own financial need program, "as long as it is reasonable, with objective criteria that can be verified, and uniformly applied to all patients." It would be prudent to document financial need decisions, Robinson added. But using cost-sharing waivers to influence a beneficiary's choice of provider is prohibited, she warned. The idea behind this ban, required under HIPAA (the Health Insurance Portability & Accountability Act of 1996), is "to stamp out schemes luring beneficiaries to unnecessary, overpriced or substandard services." She urged providers that have questions about discounts to call the industry guidance branch at 202-619-0335.

Also on hand at the June 1 forum were officials from the Centers for Medicare & Medicaid Services. They clarified that recent agency guidance allowing hospitals to provide discounts to the uninsured and underinsured, including cost-sharing waivers, applies to other healthcare providers too, such as those that file Medicare cost reports and are eligible to claim bad debt payments from Medicare. This would include, for example, nursing homes and end-stage renal disease (ESRD) facilities, but not physicians or independent laboratories, healthcare lawyers told *NIR*.

INFOBYTES

FDA Wraps Up Ethics Review

In a fast-track review, a Food & Drug Administration management team has concluded that, except for one case, none of the agency's higher-level staff obtained approval to engage in outside activities that risked a conflict of interest with companies the FDA regulates. The team scrutinized more than 1,800 approval requests and faulted only the one granted to researcher Emanuel Petricoin, PhD, who, while working on ovarian cancer testing with Correlogic Systems under a cooperative research and development agreement, was allowed to have a paid consulting arrangement with a competitor, Biospect, since renamed Predicant Biosciences *(NIR, 25, 15/May 24, '04, p. 8)*.

Despite the clean bill of health, the FDA is imposing additional oversight to prevent any potential conflicts of interest. Among the preventive steps: the director of each product-based FDA center must personally review all requests for outside activities; more staff must disclose their financial holdings, including non-administrative employees at the GS-13 pay grade; and outside activities must be reviewed annually, linking each activity with financial disclosure statements.

Noridian Selected As Contractor For Washington, Alaska

The Centers for Medicare & Medicaid Services announced June 3 that Noridian Mutual Insurance Co. will replace Premera Blue Cross as the Medicare contractor for the states of Washington and Alaska. Noridian will take over Part A claims processing and payment duties held by Premera since 1966. Premera said it wanted to focus on its core business in other areas.

Noridian already handles Part A claims in Minnesota and North Dakota and is the Part B contractor for Alaska and Washington, along with nine other states—Arizona, Colorado, Hawaii, Iowa, Nevada, North and South Dakota, Oregon and Wyoming. The transition from Premera to Noridian is to be completed by Sept. 30 of this year, CMS said.

♦CODING A·D·V·I·S·O·R·Y

In the first step toward establishing Part B fee schedule payments for new CPT lab test codes in 2005, the Centers for Medicare & Medicaid Services will hold a public meeting on July 26 to receive recommendations from interested parties. The codes will be posted at *cms.hhs.gov/paymentsystems* on or after June 28.

After the first round of public input, CMS will consider comments received, propose fees for the new codes, then invite further comment before finalizing payment amounts

CMS is still getting information on the new lab codes from the American Medical Association's CPT Editorial Panel, an agency official tells *NIR*; thus far, it looks like there will be about 10 new ones. Details are unavailable since the CPT panel clamps a tight lid on its deliberations. But other sources have told *NIR* in recent months that CPT has also been working on a new system of numeric-alpha modifiers for genetic tests, modification of flow cytometry and urinalysis codes, cell counts commonly performed in immunocompetency and transplant assessment, and in situ hybridization (*NIR, 25, 11/Mar. 22, '04, p. 2*).

Fees for new lab test codes are typically determined by cross-walking a new code to an existing one that is substantially equivalent or by gap-filling, a method which derives a fee from local pricing patterns.

Registration for the CMS meeting, to be held at agency headquarters in Baltimore, MD, begins June 28 and ends July 22. You may register online at *cms.hhs.gov/paymentsystems* or by fax to Attn: Anita Greenberg, 410-786-0196 (tel: 410-786-4601).

Medicare Alerts Hospitals On Bloodborne Pathogen Standards

In accord with the standards, blood and body fluids are to be considered potentially infectious. To protect workers exposed to them in the course of their duties, employers must make available appropriate safeguards such as gloves, gowns and safety needles and sharps

Most, but not all workers in U.S. hospitals are protected under federal or equivalent state standards against risks of on-the-job exposure to HIV, hepatitis and other bloodborne pathogens. Now, following congressional action, the Centers for Medicare & Medicaid Services is moving to close that gap.

In a May 26 letter, the agency alerted hospital administrators that as of this July 1, all Medicare-participating hospitals must, as part of their Medicare provider agreement, comply with the bloodborne pathogen standards established by the federal Occupational Safety & Health Administration. The change, mandated by Congress in the Medicare Modernization Act of 2003, will affect an estimated 849 non-federal, government-owned hospitals in 26 states, the District of Columbia, the Virgin Islands and Guam.

A hospital's Medicare provider agreement won't be terminated if the hospital is found in violation of the bloodborne pathogen standards, but the hospital could risk civil money penalties for failure to comply, noted CMS official Rachael Weinstein in the letter. Weinstein is director of the clinical standards group within the CMS Office of Clinical Standards & Quality.

OSHA promulgated the standards in 1991. In 2001, in response to the Needlestick Safety & Prevention Act, the standards were revised to require employers to select safer needle devices, involve employees in identifying and choosing these devices and maintain a log of injuries from contaminated sharps (*www.osha.gov/SLTC/bloodbornepathogens*).

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