G-2 Compliance Report

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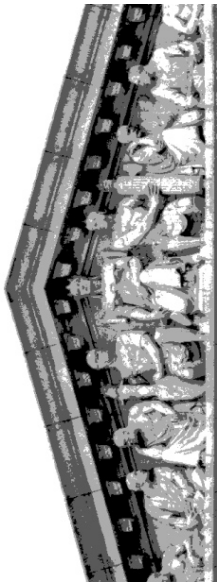

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OIG Withdraws 'Substantially In Excess' Proposal

In what is welcome news to many in the healthcare industry, the Health and Human Services Office of Inspector General (OIG) announced June 18 that it is withdrawing its 2003 proposed rule in which it attempts to define what constitutes excessive charges to Medicare and Medicaid.

The proposed rule, issued on Sept. 15, 2003, attempted to define the terms "substantially in excess" and "usual charges" for purposes of determining when providers had overcharged Medicare and Medicaid.

Under the proposal, the OIG would have defined "substantially in excess" as any charge that is more than 120% of the usual charge for an item or service. "Usual charges" would have been based on either a provider's average charge or median charge and would have included amounts billed to cash-paying patients and patients covered by indemnity insurers with which the provider has no contractual arrangement.

Significantly, "usual charges" would also have included any fee-for-service rates that a provider agrees to accept from any payor, including any discounted fee-for-service rates negotiated with managed care plans. The OIG had stated that since negotiated rates make up a large part of provider revenues, those discounts effectively are their charges. *Cont. on p. 2*

Medical Device Industry May Get More Attention From DOJ

While the medical device industry is accustomed to regulatory scrutiny from the Food and Drug Administration (FDA) and, more recently, from the Department of Health and Human Services (HHS), the "new reality" will be greater enforcement activity from the Department of Justice (DOJ), an official from the U.S. attorney's office in Philadelphia said May 24 during an audio conference sponsored by the Bureau of National Affairs (BNA), the parent company of IOMA/Washington G-2 Reports.

Virginia A. Gibson, chief of the Civil Division of the U.S. Attorney's Office for the Eastern District of Pennsylvania, said manufacturers need to be aware of the requirements for reporting safety risks and adverse events associated with their devices. Ensuring quality of care is an "overriding issue" *Cont. on p. 8*

Ron Wisor, Esq.

OIG Withdraws Proposal, *from page 1*

The 2003 proposal was the third time since 1990 that the OIG had attempted to more narrowly define the terms "substantially in excess," "usual charges," and "good cause" that appear in the section of the Social Security Act that gives the OIG the ability to exclude healthcare providers from the Medicare and Medicaid programs for overcharging federal or state governments for items or services.

Many in the healthcare industry worried that, if finalized, the proposal could have limited the ability of providers—including clinical laboratories—to negotiate discounted contracts with physicians or managed care plans for Medicare and Medicaid services.

For more on lab pricing issues, be sure to register for our July 24 audio conference: "Putting Lab Pricing Under the Microscope: It's Not Business As Usual in Dealing with Medicare & Managed Care." *The program features David Nichols, president and founder of NMG; Michael Snyder, principal, Clinical Laboratory Solutions; and W. Bradley Tully, partner, Hooper, Lundy & Bookman. Details are available on our Web site at www.g2reports.com.*

Single Benchmark "Unadvisable"

In a notice published in the June 18 *Federal Register*, the OIG says it has concluded that it does not have sufficient information at this time to establish a single, fixed numerical benchmark for "substantially in excess" that could be applied equitably across healthcare sectors and across items and services as originally proposed.

"Our intent in proposing the 120% benchmark was to create a bright-line standard by which all providers could evaluate their usual charges," the OIG wrote. "Upon reviewing the comments, we believe that a single benchmark for 'substantially in excess' is unadvisable at this time."

The OIG, however, noted that it remains concerned about disparities in the amounts charged to Medicare and Medicaid when compared to private payors and retains the right to evaluate and address instances where it believes the federal programs are being overcharged.

"We will continue to evaluate billing patterns of individuals and entities on a case-by-case basis and to use all tools available to OIG to address instances where Medicare or Medicaid are charged substantially more than other payors, without good cause," the OIG wrote in the June 18 notice.

No Surprise

Ron Wisor, a partner with Hogan & Hartson (Washington, DC), says he is not surprised the OIG decided to withdraw the proposal.

"It would have been such a difficult rule to administer the way it was proposed," he tells *GCR*. "I think the OIG tried to make it work, but just couldn't."

While providers should be pleased that the proposal has been withdrawn, Wisor offers a word of caution, noting that the OIG still left the issue of "substantially in excess" somewhat open ended.

"They seem to imply that this notion of negotiated discounts will count as part of your usual charge—which historically has not been how usual charges have been interpreted—and will be part of their analysis of cases," he says. "But I think they'll have a hard time enforcing it at this point, having three times tried to get a rule and withdrawing it every time."

Discounts For Uninsured Patients

In a related notice issued June 18, the OIG modified its Feb. 2, 2004, guidance on hospital discounts to patients who cannot afford to pay their hospital bills. That guidance stated that free or substantially reduced charges to uninsured persons would not affect the calculation of a provider's or supplier's "usual charges."

In the June 18 notice, the OIG notes that even though it will not promulgate a final rule on excessive charges, "it remains the OIG's enforcement policy that, when calculating their 'usual charges' for purposes of section 1128(b)(6)(A), individuals and entities do not need to consider free or substantially reduced charges to uninsured or underinsured patients who are self-paying patients for the items or services furnished."

The June 18 notice is available at *www.oig.hhs.gov*. Click on "What's New."

OIG Prototype To Test Functionality Of Practitioner Data Bank Alert System

The Department of Health and Human Services Office of Inspector General (OIG) is testing a new alert system that will allow users of two practitioner data banks to receive alerts when information on their enrolled providers is added to either system.

In a June 11 *Federal Register* notice, the OIG said it had extended the Proactive Disclosure Service (PDS) prototype to include users of the Healthcare Integrity and Protection Data Bank (HIPDB). In April, the OIG announced the prototype, which at the time only included users of the National Practitioner Data Bank (NPDB).

The PDS prototype allows HIPDB and NPDB users to receive alerts from the OIG when information on any of their enrolled providers is added to the data banks, rather than requiring users to request such information periodically.

According to NPDB, the purpose of the data bank is "to improve the quality of health care by encouraging State licensing boards, hospitals, and other healthcare entities, and professional societies to identify and discipline those who engage in unprofessional behavior; and to restrict the ability of incompetent physicians, dentists, and other health care practitioners to move from state to state without disclosure or discovery of previous medical malpractice payment and adverse action history."

Currently, HIPDB and NPDB users are required to submit and pay for individual queries, seeking information on providers. The prototype is an alternative to the traditional query system, the OIG explained on the HIPDB/NPDB Web site, by allowing users to pay an annual subscription fee of $3.25 per practitioner entered into the system, then be alerted when any record is added to the data banks pertaining to an individual provider.

All NPDB and HIPDB users are invited to participate in the prototype; however, the OIG said in the *Federal Register* it would close participation when a predetermined number of participants had enrolled. That number was not specified.

The prototype is expected to run at least 18 months before it is opened to all data bank users, the OIG said in the notice.

Additional information about the PDS prototype is available at *www.npdb-hipdb.hrsa.gov/pds.html*.

CMS Seeks More Input On New ABN

A second round of public comment is under way until June 24 on a revised draft of a new single-page Advance Beneficiary Notice (ABN; CMS-R-131). In a *Federal Register* notice on May 25, the Centers for Medicare & Medicaid Services (CMS) invited additional input on changes made to the original proposed version after the first round of public comment earlier this year.

Currently, CMS maintains two versions of the ABN, one general and the other specific to laboratory testing. They are due to expire soon, and CMS is proposing to combine the two into a single notice (with an identical OMB form number) that the agency says will meet both needs.

The ABN is used to inform beneficiaries of potential financial liability, except for certain institutional benefits such as home health services and inpatient hospital services. Physicians, practitioners, providers, and suppliers that are required to use ABNs should continue using the currently approved forms until further notice, CMS says.

The revised ABN draft makes several changes of note to clinical laboratories:

- The term "items/services" was removed from the header and replaced with a blank that users can customize to their business. Labs, for example, can use "laboratory tests" in the space.
- In addition to the above generic version, there are two other versions of the single-page ABN available. One specifies "laboratory tests" in the header. Preprinting of lab-specific information and denial reasons used on the current ABN-L is still permitted, CMS notes.
- More space is allowed for customization. The ABN may be on either letter- or legal-size paper.
- The option box for beneficiaries was rewritten to make the language less formal and bureaucratic. The first option makes beneficiaries aware of their right to receive services and appeal to Medicare should the services be denied.

Compliance Programs Remain Robust In Health Sector

Compliance programs continue to be robust components of healthcare entities, with 90% of respondents to a recent survey saying compliance programs were mandatory for their entire organizations.

A majority of respondents to the Health Care Compliance Association (HCCA) Ninth Annual Survey *2007 Profile of Health Care Compliance Officers* also said compliance training was mandatory for employees in their organizations. HCCA released the survey at its annual compliance conference in Chicago in April.

The survey found that the three most common areas of compliance specialization for organizations were privacy and information security, conflict of interest, and coding and billing.

Other top areas of coverage for compliance departments included physician self-referral and anti-kickback laws, excluded persons, contract managements, Emergency Medical Treatment and Labor Act, employment issues, quality of care, and cost reporting. Over the next three years, respondents said, compliance departments will be focused on monitoring/auditing, education/training, and new/revised policies and procedures.

Computer-based and Web-based training continue to be growing methods of delivering compliance awareness training, with more than 70% of respondents saying their organizations use such methods. Nevertheless, training led by compliance officers also remains a key training delivery method, with 68% saying such classroom-based compliance training is still conducted in their organizations.

Video training is used by 32% of the respondents, and 34% reported using a "self-study module" for compliance awareness training.

For topic-specific training, most respondents indicated they used computer-based/Web-based training, instructor-led classroom training with instructors other than the compliance officer, and instructor-led classroom training with the compliance officer as the instructor. Only 27% said they used video training for topic-specific training.

Compliance budgets appear to be about the same as they have been the past two years, with a majority of respondents saying their budgets are less than $300,000. More than 8% had budgets greater than $1 million. Salaries comprise the greatest share of compliance budgets, and one-third of compliance officers said training was a line item in their annual compliance budget, while others reported that compliance training was absorbed by other departments' budgets.

The survey is available at *www.hcca-info.org/Content/NavigationMenu/ComplianceResources/Surveys/survey9.pdf*.

COMPLIANCE PERSPECTIVES

IRS Issues Memorandum On Health IT Subsidies

Deborah Ashford and Robert Leibenluft are partners with Hogan & Hartson (Washington, DC)

On May 11, 2007, the Internal Revenue Service (IRS) issued a memorandum reassuring tax-exempt hospitals and healthcare organizations that—provided they structure health information technology subsidy arrangements with staff physicians properly within certain Department of Health and Human Services (HHS) regulations and operate in accordance with certain guidelines—they will not run afoul of the proscriptions against impermissible private benefit or inurement under section 501(c)(3).

This guidance comes in response to HHS regulations issued on Aug. 8, 2006, which provide an exception to the physician self-referral statute and a safe harbor under the anti-kickback statute for subsidizing the costs of certain health information technology (IT) items and services toward the adoption of electronic health records and e-prescribing.

The HHS regulations specifically require that physicians share the costs of purchasing and using the health IT items received. Physicians may pay at least 15% of the costs of certain identified health IT items and services before the physician receives any of the items or services. Furthermore, the regulations do not permit hospitals or related parties to finance, including through loans to the physician, any portion of a physician's share of the costs.

Under the HHS regulations, permissible subsidized health IT items and services include software, interfaces, connectivity services, training, and help-desk and other types of maintenance and support services. Hospitals are not permitted to donate or subsidize the costs of hardware or staffing for physician's offices. Subsidized health IT items and services cannot duplicate what the physician already has and must contain electronic prescribing capability, either through a direct prescribing component or an electronic interface with the physician's existing prescribing system.

The HHS regulations explicitly require that subsidized health IT items and services be "necessary and used predominantly to create, maintain, transmit, or receive electronic health records"; therefore, such items and services may not be used "primarily to conduct personal business or business unrelated to the physician's medical practice."

In addition to directing that benefits fall within the range of health IT items and services that are permissible under the HHS regulations, in its memorandum the IRS also directs hospitals to operate in accordance with certain guidelines in providing such benefits. To that end, the IRS set forth the following guidelines:

1 **Health IT subsidy arrangements.** Hospitals enter into health IT subsidy agreements with medical staff physicians for the provision of health IT items and services at a discount (health IT subsidy arrangements).

2 **Compliance with HHS regulations.** Health IT subsidy arrangements require both the hospital and the participating physicians to comply with the HHS regulations on a continuing basis.

3 **Hospitals' access to records.** Health IT subsidy arrangements provide that, to the extent permitted by law, the hospital may access all of the electronic medical records created by a physician using the

health IT items and services subsidized by the hospital.

4 Physician participation. Hospitals ensure that health IT items and services are available to all of its medical staff physicians. Clearly, the schedule for physician participation would be determined by the hospital according to healthcare needs of the community.

5 Uniform agreements among physicians. Hospitals provide the same level of subsidy to all of its medical staff physicians or vary the level of subsidy by applying criteria related to meeting the healthcare needs of the community.

The directive should allay any concerns that hospitals may have in implementing health IT arrangements with physicians. In implementing a health IT system, hospitals will want to structure health IT subsidy arrangements with physicians in accordance with the guidelines the IRS has set forth in the memorandum.

Deborah Ashford and Robert Leibenluft can be reached at Hogan & Hartson LLP, Columbia Square, 555 13th St., NW, Washington D.C. 20004. Phone: 202-637-5600.

HHS Safe Harbor

The Department of Health and Human Services (HHS) on Aug. 8, 2006, issued a final rule establishing a new safe harbor under the federal anti-kickback statute for certain arrangements involving the provision of electronic prescribing technology. In addition, the rule created a separate new safe harbor for certain arrangements involving the provision of nonmonetary remuneration in the form of electronic health records (EHR) software or information technology and training services.

Exception For Electronic Prescribing Arrangements

To qualify for the physician self-referral exception regarding donations of electronic prescribing technology and training services, the following criteria must be satisfied:

- The items and services must consist of hardware, software, or information technology and training services that are necessary and used solely to receive and transmit electronic prescription information;
- The items and services must be provided by a hospital to a physician who is a member of its medical staff, by a group practice to a physician who is a member of the group, or by a prescription drug plan sponsor or Medicare Advantage organization to a prescribing physician;
- The items and services are provided as part of, or are used to access, an electronic prescription drug program that meets applicable standards under Medicare Part D at the time the items and services are provided;
- The donor (or any person on the donor's behalf) does not take any action to limit or restrict the use or compatibility of the items or services with other electronic prescribing or electronic health records systems;
- For items or services that are of the type that can be used for any patient without regard to payer status, the donor does not restrict, or take any action to limit, the physician's right or ability to use the items or services for any patient;
- Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor;
- Neither the eligibility of a physician for the items and services nor the amount or nature of the items or services is determined in a manner that takes into account the volume or value of referrals or other business generated between the parties;
- The arrangement is in writing, is signed by the parties, specifies the items and services being provided, identifies the cost to the donor of items and services, and covers all of the electronic prescribing items and services to be provided by the donor. This requirement will be met if all separate agreements between the donor and the physician (and the donor and any family members of the physician) incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by the secretary upon request; and

- The donor does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the fact that the physician possesses or has obtained items or services equivalent to those provided by the donor.

Exception For EHR Arrangements

To qualify for the physician self-referral exception regarding donations of electronic health records software or information technology and training services, the arrangement is required to satisfy the following criteria:

- The software and training services must be necessary and used predominantly to create, maintain, transmit, or receive electronic health records;
- The items and services are provided to a physician by a hospital or other entity that furnishes designated healthcare services;
- The software is interoperable (as defined at §411.351) at the time it is provided to the physician. For purposes of the exception, "interoperable" means that the software is able to (1) communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings, and (2) exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered. Software is deemed to be interoperable if a certifying body recognized by the secretary has certified the software no more than 12 months prior to the date it is provided to the physician;
- The donor (or any person on the donor's behalf) does not take any action to limit or restrict the use, compatibility, or interoperability of the items or services with other electronic prescribing or electronic health records systems;
- Before receipt of the items and services, the physician pays 15% of the donor's cost for the items and services. The donor (or any party related to the donor) does not finance the physician's payment or loan funds to be used by the physician to pay for the items and services;
- Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor;
- Neither the eligibility of a physician for the items and services, nor the amount or nature of the items and services, is determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties;
- The arrangement is in writing; is signed by the parties; specifies the items and services being provided, the cost to the donor of the items and services, and the amount of the physician's contribution; and covers all of the electronic health records items and services to be provided by the donor. This requirement will be met if all separate agreements between the donor and the physician (and the donor and any family members of the physician) incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by the secretary upon request. The master list should be maintained in a manner that preserves the historical record of agreements;
- The donor does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the fact that the physician possesses or has obtained items or services equivalent to those provided by the donor;
- For items or services that are of a type that can be used for any patient without regard to payer status, the donor does not restrict, or take any action to limit, the physician's right or ability to use the items or services for any patient;
- The items and services do not include staffing of physician offices and are not used primarily to conduct personal business or business unrelated to the physician's medical practice;
- The electronic health records software contains electronic prescribing capability, either through an electronic prescribing component or the ability to interface with the physician's existing electronic prescribing system, that meets the applicable standards under Medicare Part D at the time the items and services are provided;
- The arrangement does not violate the anti-kickback statute or any federal or state law or regulation governing billing or claims submission; and
- The transfer of the items or services occurs on or before Dec. 31, 2013.

Medical Device Industry, *from page 1*

that has a significant impact on where the government focuses its resources, she said.

Other "hot issues" include kickbacks involving financial relationships between manufacturers and providers and off-label marketing or misbranding of products, Gibson said.

> ***"It is helpful [when under investigation] to have a robust compliance program, with written evidence of training" to demonstrate good compliance and that the issue is taken seriously.***
>
> ***— Laura Laemmle-Weidenfeld***

Laura Laemmle-Weidenfeld, an attorney at Patton Boggs LLP, Washington, agreed that many in the medical device industry traditionally focused on FDA requirements, but added that device manufacturers now are "solidly on the government's radar."

Although federal officials say device investigations will be based on the same template as earlier investigations of the pharmaceutical industry, Laemmle-Weidenfeld said it would be a "mistake" to say that the pharmaceutical model translates exactly to the device industry.

Quality, Kickbacks

According to Laemmle-Weidenfeld, government investigations of the pharmaceutical industry generally look at four areas: quality-of-care or regulatory violations, financial relationships with providers (kickbacks), off-label promotion, and pricing or reimbursement issues.

For the device industry, however, potential violations are more likely in the areas of quality-of-care issues or kickbacks, Laemmle-Weidenfeld said.

The physician is much more involved in the use of the device than with other products subject to enforcement action, she said. That means the manufacturer has a greater duty to educate and train the physician. "Poor technique or poor patient choice [in use of a device also] could lead to bad results even where the product itself is perfect," she noted.

Physician consultants also tend to play a much more active role in the development of medical device products than they do in the pharmaceutical industry, Laemmle-Weidenfeld said. With drugs, physicians are used primarily for marketing and research after the product comes to market. In the device arena, physicians often work with the company to develop new products and to train other physicians to use the devices.

Device companies should focus on what they are paying their physician consultants, the current fair market value for a doctor's services, and should document everything, she said. Paying significant sums or sponsoring expensive vacations for consulting doctors, even if it is justified, can draw the attention of federal regulators and enforcement agencies, as well as whistleblowers inside the company, Laemmle-Weidenfeld said.

Reporting Requirements

On the issue of safety, Gibson said the failure to report adverse events can come into play in Department of Justice investigations and serve as the underlying violation in many fraud prosecutions. Moreover, serious violations could lead to criminal prosecutions, not just civil enforcement, Gibson said.

In one example, Gibson said, Guidant Corp. pleaded guilty in a 2003 criminal action in which the company failed to report significant malfunctions of its heart rhythm devices, some resulting in patient deaths, and where the sales force actively participated in the cover-up. The factors in that case tended to show that the state of mind of Guidant's officers, in the government's view, was sufficient to show criminal intent, Gibson said.

Gibson also cautioned against improper off-label promotion.

Medical device manufacturers "really believe in their products," Gibson said. But it is important that the manufacturer does not attempt to substitute its judgment on safety and efficacy for that of the FDA, she said.

One federal court has concluded that a company's promotion of off-label use, even if truthful, can "severely frustrate the FDA's ability to evaluate" off-label uses, Gibson said, citing *United States v. Caputo* (N.D. Ill, 10/16/06).

Good Practices Tips

Device companies need to "win back the trust of customers," Gibson said. Companies should not wait for DOJ or other entities to contact them about potential problems, she advised. Companies should update their compliance efforts, match incentives to good compliance, and review their sales and marketing procedures.

Laemmle-Weidenfeld offered her own suggestions for best practices.

"It is helpful [when under investigation] to have a robust compliance program, with written evidence of training" to demonstrate good compliance and that the issue is taken seriously, she said. In potential kickback relationships, she said, companies should document the fair market value of their consultant's services.

In addition, the "advice of counsel defense" also can be "very powerful" if a company receives legal advice that is on point, she said.

Gibson's presentation is available at *http://op.bna.com/hl.nsf/r?Open=thyd-73htch*. Laemmle-Weidenfeld's presentation is available at *http://op.bna.com/hl.nsf/r?Open=thyd-73htcu*.

CMS Proposes Measures Against Fraud In Medicare Advantage, Part D Drug Plans

The Centers for Medicare & Medicaid Services (CMS) on May 21 proposed more stringent oversight requirements and streamlined arrangements for fraud penalties in an effort to combat scams in Medicare Advantage plans and Part D prescription drug plans.

The agency is under pressure to improve its enforcement after reports of widespread complaints involving the sale and marketing of MA plans, which are being aggressively promoted in various states.

The CMS proposal would clarify provisions relating to contract determinations, including new steps to help expose potential fraud or misconduct through mandatory self-reporting, changes to streamline the process relating to intermediate sanctions and contract determinations (including nonrenewals), and clearer rules for imposing civil money penalties, the agency said.

"While the majority of Medicare Advantage (MA) and Medicare prescription drug plans that offer important benefits to beneficiaries are conducting themselves professionally, it is important for CMS to be able to take swift action to safeguard beneficiaries from unlawful or questionable business practices," acting CMS Administrator Leslie Norwalk said in a statement.

"We want to have every enforcement tool available to ensure that Medicare beneficiaries are protected," she said.

Agency Under Pressure

The agency is under pressure to improve its enforcement after reports of wide-

spread complaints involving the sale and marketing of MA plans, which are being aggressively promoted in various states.

Abby Block, director of CMS's Center for Beneficiary Choices, believes the proposal will speed up compliance actions. Currently, attempts to terminate contracts, for example, can take a long time, she said.

Comments on the proposed rule, which was published in the May 25 *Federal Register*, will be accepted until July 24. A final rule is expected to be released later this year.

CMS also released another proposal that makes technical changes to the regulations implementing the Part D prescription drug benefit.

The proposal, also published May 25, makes certain technical corrections and clarifications to the Jan. 28, 2005, final rule. Areas addressed in the regulation include inhaled insulin, coordination of benefits, and the retiree drug subsidy, among others. CMS also proposed, effective in 2009, to refine certain rules relating to the determination and reporting of prescription drug costs. CMS also is proposing to update the requirements of Part D sponsors to ensure adequate access to home infusion pharmacies.

Physical Therapy Clinic Owner Draws 54 Months In Prison For Medicare Fraud

A federal court in New Jersey June 11 sentenced the owner of two physical therapy clinics to 54 months in federal prison for defrauding Medicare of about $3.79 million, U.S. Attorney for the District of New Jersey Christopher J. Christie said in a news release (*United States v. Ikeh*,).

Judge Garrett E. Brown Jr. of the U.S. District Court for the District of New Jersey also ordered Chidi Ikeh, who owned and operated Vital Health Care Services (Ewing, NJ) and U.S. Vital Health Care Services (Cherry Hill, NJ), to pay $3.79 million in restitution and to serve three years of supervised release at the conclusion of his prison term.

False Claims Admission

Ikeh pleaded guilty March 5 to one count of healthcare fraud and one count of wire fraud in connection with Medicare billings submitted from February 2002 until August 2005.

At the plea hearing, Ikeh admitted that he billed Medicare for false claims totaling $6.7 million, for which he received $3.7 million, for physical therapy services, evaluations, and re-evaluations allegedly provided to patients.

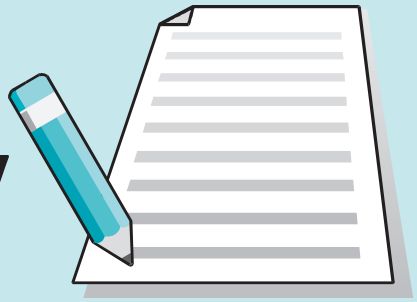
Ikeh admitted billing Medicare for physical therapy services as if they had been provided by or under the supervision of a licensed physician, although the services were never performed, were not supervised by a physician, or were provided by people with no physical therapy qualifications, licensing, or certification.

Ikeh admitted that he did not have a licensed physician on site at all times when physical therapy was being performed at his clinics and that he instructed "therapists" to indicate in the medical records that they had performed certain procedures on patients, although the services had not been performed.

He also admitted that he provided patients with money, food, and raffle prizes to induce them to continue with therapy at his clinics.

Ikeh has been held without bail since federal agents arrested him in September 2006 when he returned from Nigeria to his home in Houston.

For the R·e·c·o·r·d



Implementation Of Carrier Jurisdictional Pricing Rules For All Purchased Diagnostic Service Claims

The Centers for Medicare and Medicaid Services (CMS) is replacing temporary physician billing instructions specified in CR 3630 (Transmittal 415, issued on Dec. 23, 2004) with new billing procedures to allow all physicians and suppliers to receive the correct payment amount for purchased diagnostic services, based on the ZIP code of the location where the service was rendered.

Under current rules, physicians who purchase out-of-jurisdiction diagnostic tests/interpretations are allowed to bill their local carrier for these services and receive the local rate. CR 5543 (Transmittal 1250, issued May 25, 2007) changes that policy.

Effective for claims with dates of service on or after Oct. 1, 2007, carriers/MACs shall use the national abstract file for purchased diagnostic tests/interpretations to price all claims for purchased diagnostic services based on the ZIP code of the location where the service was rendered, in accordance with the carrier jurisdictional pricing rules specified in Chapter 1 of the Medicare Claims Processing Manual.

Physicians and suppliers should begin reporting the rendering physician's/supplier's information and location where the service was rendered on all claims for purchased tests/interpretations with dates of services on or after Oct. 1, 2007, including those for tests/interpretations performed outside of the local carrier jurisdiction.

Physicians and suppliers should not report the National Provider Identifier (NPI)/Provider Identification Number (PIN) of the out-of-jurisdiction performing physician/supplier when submitting a claim for a diagnostic service purchased outside of their local carrier's/MAC's jurisdiction. Physicians and suppliers should maintain this information on file and provide it, upon request, to their local carrier/MAC.

CR 5543 (Transmittal 1250) is available online at *www.cms.hhs.gov/transmittals/*.

Fraud Arrests: Florida Attorney General Bill McCollum recently announced the arrest of 11 South Florida residents for their alleged role in a multi-county healthcare fraud scheme that also involved criminal racketeering, money laundering, and grand theft. According to McCollum's office, the 11 were involved in fraudulent Medicare and Medicaid billing by Belle Glade Family Health Group Inc., a Belle Glade clinic located in Palm Beach County. The group fraudulently billed Medicare for more than $6 million, according to a probable cause affidavit.

Lost Opportunities? The Centers for Medicare and Medicaid Services (CMS) could have saved at least $6.3 million if it had implemented a number of priority recommendations that the Department of Health and Human Services Office of Inspector General (OIG) made in recent years, the OIG says in a new report. The Compendium of Unimplemented Office of Inspector General Recommendations lists eight new cost-savings recommendations for the Medicare and Medicaid programs since the last such listing in 2006. The OIG included 29 previous recommendations that have never been implemented. The report is available at *www.oig.hhs.gov/publications/docs/compendium/Compendium2007.PDF*.

Medicare Overpayments: Medicare overpaid $64 million in 2004 for surgical debridement services that did not meet program requirements, the Department of Health and Human Services Office of Inspector General (OIG) said in a June 6 report. The OIG said that 64% of surgical debridement services provided during the year in review failed to meet at least one Medicare requirement for reimbursement and that the highest cost services were the most likely to be claimed inappropriately. Nearly 40% of all debridement services (the removal of dead or unhealthy tissue from a wound using a sharp instrument) in 2004 were incorrectly coded, and nearly 30% were not properly documented, the OIG said in *Medicare Payments for Surgical Debridement Services in 2004*. The report is available at *www.oig.hhs.gov/oei/reports/oei-02-05-00390.pdf*.

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