G-2 Compliance Report

WASHINGTON G-2 REPORTS

Vol. IX, No. 4, April 2007

For Hospitals, Laboratories and Physician Practices

Government Looks To Increase Oversight Of Laboratory-Developed Tests

In the latest indication that the federal government is moving toward increased oversight and regulation of laboratory-developed tests (LDTs), Sen. Edward Kennedy (D-MA) in March introduced legislation that would designate LDTs as medical devices subject to premarket review and approval by the Food and Drug Administration (FDA).

The Lab Test Improvement Act (S. 736) generally would categorize LDTs (also referred to as home brew or in-house developed tests) as class II devices subject to special controls. LDTs intended to screen donated blood or to diagnose a contagious disease or condition that is highly likely to be fatal would be assigned to class III.

Continued on p. 2

Lab Industry Requests Delay On NPI Compliance

Concerned about the impact on clinical laboratories, groups representing labs are pressuring the Centers for Medicare & Medicaid Services (CMS) to delay the deadline for compliance with the National Provider Identifier (NPI) requirement.

Currently, the compliance deadline is May 23. Thereafter, only NPIs will be recognized; legacy identifier numbers will be rejected (small health plans have an additional year to comply).

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) mandated adoption of a standard unique health identifier for healthcare providers. The Department of Health and Human Services (HHS) on Jan. 23, 2004, published a final rule establishing the NPI as this identifier.

All HIPAA-covered healthcare providers, whether they are individuals or organizations, must obtain an NPI, which is a 10-digit numeric identifier that does not expire or change.

The American Clinical Laboratory Association (ACLA), citing potential disruptions in claim processing due to a lack of NPI readiness throughout the healthcare industry, has requested a one-year extension beyond the NPI deadline, during which legacy identifier numbers could continue to be used in both electronic standard and paper transactions until NPI compliance is achieved. This would avoid serious disruptions to claims processing and the potential loss of millions of dollars in reimbursement, says ACLA.

Continued on p. 9

Kimberly Scott, Senior Editor,
Kimscott@yahoo.com

Inside this issue


Paul Radensky, Esq.

Laboratory-Developed Tests, *from page 1*

The Health and Human Services Secretary would have discretion to assign an LDT to class I (general controls only) if certain safety and effectiveness requirements are met.

The bill would require the secretary to issue guidance on the special controls to which all LDTs or subcategories of these will be subject. Also, labs that make class II LDTs would generally be exempt from biennial FDA inspections.

S. 736 would require labeling to indicate intended use and regulatory status, registration of manufacturers and a list of LDT tests, and reporting of adverse events. The bill also calls for a rulemaking to establish a specialty area for LDTs, with standards for proficiency testing, plus "a mechanism for enhanced reimbursement under federal programs for in vitro diagnostics and LDTs."

> ***"This is too complex an area and there are just too many detailed, technical issues to examine that it shouldn't be rushed through. —Paul Radensky, Esq.***

The FDA already plans to require premarket review for a specific category of lab-developed tests that the agency calls in vitro diagnostic multivariate index assays (IVDMIAs), which use an assay and an algorithm to generate a patient-specific result. Examples include proprietary tests to diagnose and guide treatment for breast and other cancers, cardiovascular disease, and Alzheimer's disease (*GCR, March 2007, p. 1*).

Tighter controls are needed for IVDMIAs, the FDA says, because of their novel technologies and the potentially lethal risks. Of particular concern is the fact that the algorithm used to derive a test result is proprietary, making it hard for physicians to know how to interpret the result.

Go Slow, Say Groups

Concerned that lawmakers may attach S. 736 to FDA user fee reauthorization bills under consideration this spring, industry groups are urging lawmakers to provide additional time for more careful analysis and discussion of the Lab Test Improvement Act.

In a March 16 letter to Kennedy, a number of groups and laboratories said the issues raised by S. 736 deserve their own legislative hearing and stakeholder input. "The organizations that have signed this letter have varying views on the need for additional oversight of laboratory developed tests," they wrote. "However, we are fully united in our request for more time to provide feedback and discuss pathways that will not have unintended consequences on laboratory services.

"We are further united in the opinion that any new legislative initiative in this area should be carefully crafted to focus on the areas of concern and not be so broad as to encompass laboratory tests that are clinically established or that are serving a valuable purpose for rare disease groups and public health needs," the letter continued. Among those signing the letter are the American Association for Clinical Chemistry, the American Clinical Laboratory Association, the American Society for Clinical Laboratory Science, the Clinical Laboratory Management Association, and the Coalition for 21st Century Medicine. A number of independent laboratories also signed the letter.

Paul Radensky, an attorney in the Miami office of McDermott Will Emery and counsel to the Coalition for 21st Century Medicine, tells *GCR* that Kennedy and his staff have already addressed some of the concerns raised by early drafts of legislation and that the groups now need additional time to analyze the current bill.

"This is too complex an area and there are just too many detailed, technical issues to examine that it shouldn't be rushed through," he says.

CMS Extends Deadline For Using Old Version Of Provider Claims Form

The Centers for Medicare & Medicaid Services (CMS) is allowing certain providers to keep using a Medicare claim form past the intended April 1 expiration date due to problems with the new version of the CMS-1500 form.

Specifically, CMS has extended the time for accepting Form CMS-1500 (12-90) until further notice because of problems with the newer version Form CMS-1500 (08-05) released in July 2006. CMS said the delay is the result of some print vendors, primarily the Government Printing Office, selling incorrectly formatted versions of the new form.

Form CMS-1500 is the standard Medicare claim form used by noninstitutional providers and suppliers that qualify for a waiver of the requirement that claims be electronically submitted. Some Medicaid agencies also use the form. The new form was revised by the National Uniform Claim Committee to accommodate the National Provider Identifier. On January 1, CMS began accepting the new version as providers phased out the old versions. Providers were to discontinue using the old version on March 31.

However, CMS said in a March 9 notice to providers that Medicare payment contractors had been directed to continue accepting the older version of the form until further notice, and that it was targeting June 1 as the end date for those forms. Payment contractors also have been told to return to providers any new versions of the claim form that are not properly formatted, CMS said.

The old version of the form reads "OMB-0938-0008 FORM CMS-1500 (12-90)" at the bottom. The revised version reads "OMB-0938-0999 FORM CMS-1500 (08-05).

Resource

CMS notice to providers: *www.cms.hhs.gov/ElectronicBillingEDITrans/Downloads/1500%20problems.pdf.*

Phase III Self-Referral Rule May Be Delayed

The third phase of the final rule implementing the Stark II prohibitions on physician self-referral may be delayed until March 2008, according to the Centers for Medicare and Medicaid Services (CMS).

Under a previously established three-year timeline, CMS was required to respond to public comments on the Phase II interim final rule from the March 26, 2004, *Federal Register* and publish the Phase III final rule no later than March 26 of this year. However, CMS says it will extend the deadline for publication of Phase III through March 26, 2008, and allow the Phase II regulations to remain in effect until the final rule is published.

The Phase II interim final rule, which went into effect July 24, 2004, set forth the physician self-referral prohibition and applicable definitions, interpreted various statutory exceptions to the prohibition, and created additional regulatory exceptions for arrangements that do not pose a risk of program or patient abuse. The Phase II regulations also addressed issues that remained open after the Phase I rulemaking, published in the Jan. 4, 2001, *Federal Register*, and responded to comments on that earlier rule.

CMS says it is not able to meet the three-year timeline for publication because it has received extensive public comments requesting clarification of and revisions to the physician self-referral regulations. In addition, because the rules are jointly enforced by CMS, the Health and Human Services Office of Inspector General, and the Department of Justice, substantial interagency coordination has been necessary, the agency says.

Two Versions Of ABN May Be Combined Into One

Under a recent proposal by the Centers for Medicare & Medicaid Services (CMS), the two versions of the current Advance Beneficiary Notice (ABN) would be replaced by a new single version that clinical laboratories and other Medicare providers would be required to use.

The ABN is used when there is genuine doubt that Medicare will pay for an otherwise covered service due to lack of medical necessity or other limits. The ABN alerts beneficiaries that they are potentially liable to pay for a denied item or service claim. Before the beneficiary can be billed, the provider must obtain a valid ABN signed by the beneficiary (or representative) prior to furnishing the service. (In emergency or urgent care cases, CMS says, ABNs are never required.)

ABNs are usually given as a hard copy, CMS notes. There is no provision for alternative uses of information technology to deliver ABNs; however, those required to deliver them may store the signed copies electronically.

Until the ABN change is finalized and approved, CMS says, Medicare providers and suppliers must continue to use currently approved versions—CMS-R-131-G for general use or CMS-R-131-L, which is specific to physician-ordered lab tests. (For lab tests, either form may be used.) CMS has required use of these single-page, standardized ABNs since 2003.

The proposed new ABN is written in more beneficiary-friendly language, CMS says, and meets both general and lab-specific needs. The main changes include:

- A more precise title: "Advance Beneficiary Notice of Noncoverage";
- A new grid to identify the item/service, the reason Medicare payment denial is likely, and the estimated cost to help the beneficiary decide whether or not to receive the item/service;
- Addition of the 1-800-MEDICARE number and information about the beneficiary's right to demand that Medicare be billed for a coverage decision;
- Increasing the number of beneficiary choices from two to three to allow them to pay out-of-pocket when they desire;
- Allowing a place for other insurance information to be recorded; and
- Describing the significance of the signature, which indicates that the beneficiary has received the ABN, understands its contents, and freely assumes financial responsibility.

Of special note for labs, the reasons for likely denial preprinted on the current lab-specific ABN are still appropriate for use in the grid on the proposed new ABN. These reasons include:

- "Medicare does not pay for these tests for your condition."
- "Medicare does not pay for these tests as often as this (denied as too frequent)."
- "Medicare does not pay for experimental or research use tests."

ABNs are usually given as a hard copy, CMS notes. There is no provision for alternative uses of information technology to deliver ABNs; however, those required to deliver them may store the signed copies electronically.

The draft ABN proposal is posted at *www.cms.hhs.gov/PaperworkReductionActof1995*. At the menu on the left, click "PRA" listing," then scroll down or search for "CMS-R-131." Comments are due April 24.

COMPLIANCE PERSPECTIVES

What's Next With Pod Laboratories?

This is part one of two parts. See the May issue of G2 Compliance Report for a continuation of this discussion.

Peter Kazon, Esq., is a senior counsel with Alston Bird (Washington, DC). He also serves as a legal advisor to the American Clinical Laboratory Association.

Last year, when it issued the Proposed Physician Fee Schedule (PFS) rule, the Centers for Medicare and Medicaid Services (CMS) introduced a new concept of particular importance to laboratories—the "pod" or "condo" laboratory. No one seems to quite know where the term originated, but its inclusion in the proposed PFS rule was a recognition by CMS of what many in the industry had long been saying: New ventures were increasingly being developed that allowed physicians to share in the revenues earned on their referrals for different types of diagnostic services.

Of course, physicians have long owned clinical laboratories or furnished such services in their offices. What was different about pods is that they represented a movement into the area of anatomic pathology services, which are not only more costly than most clinical laboratory services, but also actually have to be performed and supervised by a pathologist.

The proposed PFS rule included numerous different proposals aimed at curbing the growth of pods, including changes to the Stark self-referral requirements and Medicare's prohibition on reassignment. However, when the final PFS rule came out in December, CMS announced that it needed more time to study the matter. According to the final rule, CMS remained committed to addressing "revenue-driven arrangements that may be facilitating overutilization of diagnostic services," but it wanted to ensure that it did not adversely affect other legitimate arrangements.

Now, CMS is reportedly considering reissuing some of its proposals when the new proposed PFS rule is issued later this year. And numerous organizations representing laboratories, including the American Society of Clinical Pathology and the American Clinical Laboratory Association, have expressed concerns about the rapid growth of pods. (In the interests of full disclosure, I should point out that I act as counsel to ACLA on these and other issues.) As a result, this seems like a useful time to review the issues related to pods and see where CMS may decide to go next.

What Is A Pod, Exactly?

The first step in this analysis is to define what we are talking about when we discuss pods. That is not an easy task as the arrangements can take a variety of different forms. There does not appear to be a single type of pod and no single definition. The term is used to denote a variety of different business structures that permit a referring physician, who frequently orders anatomical or pathology services, to share in the revenues earned on those referrals, even though the referring physician does not actually perform or supervise the services. Recently, particular attention has been focused on arrangements involving urologists and gastroenterologists, both of whom frequently order anatomic pathology services on biopsies.

In the proposed PFS rule issued last summer, CMS described a typical pod arrangement. In such an arrangement, according to CMS, an entity leases space in a medical building and then subdivides the space into separate cubicles or pods, each of which is equipped with microscopes and other laboratory equipment. Each pod is then subleased to a physician group practice, which may be located miles away from the pod laboratory and may even be in a different state. A histotechnologist, hired by the pod organizer, does the technical component (TC) of the laboratory service, and a pathologist, who is also recruited by the pod organizer, performs the professional component (PC) and supervises the histotech. Each separate cubicle or pod is subleased to a different group practice.

There is ample evidence to support the view that when physicians have an ownership interest in an outside venture, the physician's utilization of these services is likely to increase.

In order to meet regulatory requirements under the Stark self-referral law and the reassignment rules, which are discussed further below, the pathologist and the histotech have to move from pod to pod as they perform their services. For example, when they are looking at slides referred from Group A, they have to be physically present in Group A's pod. When they look at slides from Group B, they have to move to Group B's pod, and so forth, for all of the cubicles on the floor. According to CMS, the group usually pays the manager of the pod a set fee to cover the costs of the histotechnologist and the rent of the pod, and then works out a per-case or other fee with the pathologist. The group practice then bills Medicare for the pathology services furnished in its pod.

Not surprisingly, the basic structure has reportedly evolved over time, and so the structure described above is probably not the only one. According to CMS, sometimes the lab entity bills the TC, and the group bills the PC. Recently, the Maryland State Board of Physicians looked at a situation where a group of urologists set up a histology laboratory in their office, but then contracted with an independent laboratory to staff it with the laboratory's employees and perform the services.

In another scenario described in the same opinion, a urology group referred the TC of a service to an independent laboratory, which the laboratory billed directly, but then returned the prepared slide to the group. The group then contracted with a pathologist at a set fee to perform the PC, which the group then billed to payers and patients. (Incidentally, the board found that both arrangements may have violated the state's self-referral law.)

What Are The Concerns?

Pods raise many of the same concerns that have been raised by other scenarios where physicians are in a position to profit from their referrals. In this instance, the physician is able to bill for (and profit from) the referrals that he makes for anatomic pathology services. As with other physician investments, the issue raised is whether or not the ability to profit affects the physician's clinical decision making.

For example, there is ample evidence to support the view that when physicians have an ownership interest in an outside venture, the physician's utilization of these services is likely to increase. For example, the impetus for the Physician Self-Referral Act—commonly referred to as the "Stark Law," after its chief proponent, Congressman Pete Stark—was a 1989 study that found that patients of referring physicians who owned or invested in laboratories received more services than Medicare patients in general, at a significant increased cost to Medicare.

A later study by the General Accounting Office (GAO) came to a similar conclusion, finding that "physician owners tended to order more and more costly laboratory services." A recent study by McKinsey & Company, a well-known consulting and economics firm, found that one of the contributing factors to higher healthcare costs in the United States generally was physicians' ownership of facilities, which gave them a strong incentive to self-refer cases, thereby driving up utilization and costs.

Although there is no research on the impact of pods, per se, these studies raise the possibility that if a physician is able to earn a profit on referrals, then that may affect decisions about when to order tests and how many tests to order. As a result, the physician may be more likely to order testing, and may order more tests, than would one without such incentives. In pathology, because every specimen examined represents a separate billable event, it is fairly easy for a referring physician to increase the number of biopsies and thus increase the billings.

Pods represent a "perfect storm" under Medicare regulations, because they bring together anti-kickback, self-referral, reassignment, and billing issues all in one entity.

Clearly, CMS has recognized this possibility because it noted in the proposed PFS rule that it was "concerned that allowing physician group practices or other suppliers to purchase or otherwise contract for the provision of diagnostic tests and then to realize a profit when billing Medicare may lead to patient and program abuse in the form of overutilization of services and result in higher costs to the Medicare Program." Similarly, the Medicare Payment Advisory Commission, which advises Congress on Medicare payment policy, noted in its comments to CMS on the PFS rule that it would support policies that would limit financial incentives for inappropriate use of services.

A related issue raised by pod arrangements concerns Medicare's long-standing policy that limits when physicians or other suppliers can purchase services from others and then bill them to the Medicare program. In general, Medicare tries to restrict these arrangements and imposes specific requirements that they must meet.

For example, Medicare has also limited the ability of physicians to purchase diagnostic tests and then bill the program for them as their own. While a physician can purchase the technical component of a diagnostic test and bill for it, the physician is not permitted to mark up the cost of the TC above the acquisition cost and must also usually perform the professional component. Other restrictions apply to the purchase of the professional component. In short, Medicare's long-standing policy is to pay the person who did the service, and it has enumerated specific requirements where it deviates from this policy.

What Legal Issues Are Created?

Regardless of the policy issues, the real issue for pods is, of course, whether they comply with various laws governing Medicare billing and referrals. And that is a difficult determination. Pods represent a "perfect storm" under Medicare regulations, because they bring together anti-kickback, self-referral, reassignment, and billing issues all in one entity. Thus, the lawfulness of any particular arrangement requires a review of numerous complex rules and requirements. Some of these issues were discussed by CMS last year in the proposed PFS rule, and it seems likely that it will address many of these same issues again if it revisits the matter, as expected, later this year. In addition,

the Health and Human Services Office of Inspector General (OIG) has also looked at some of these issues, so it is important to also review its position as well.

Anti-Kickback Issues

Under the anti-kickback law, it is unlawful to offer or pay "remuneration" to induce referrals reimbursed by Medicare. It is also unlawful to solicit or accept such remuneration, in connection with the referral of Medicare, Medicaid, or other services reimbursed by federal healthcare programs. The OIG, which enforces the anti-kickback law, has often expressed concern about arrangements that are comparable to pods, and the issues they may raise under the anti-kickback law.

In 2003, the OIG issued a Special Fraud Alert on what it referred to as "Contractual Joint Ventures," which it described as situations where a referring physician enters into an agreement with an outside entity to provide the resources needed to operate a business to which the physician then refers. According to the OIG, in these situations, the physician is the nominal owner of the venture, but he neither operates the new business nor commits substantial financial, capital, or human resources to the venture. Instead, the business contracts out substantially all the operations of the new business. A manager or supplier, comparable to the organizer of a pod, typically agrees to provide not only management services, but also a range of other services, to run the business. According to the OIG, the practical effect of the arrangement, viewed in its entirety, is to provide the physician-owner the opportunity to bill insurers and patients for business otherwise provided by the manager or supplier.

Subsequently, the OIG actually applied this analysis to a pod situation in an advisory opinion. In Opinion 04-17, it reviewed a situation where a pathology laboratory entered into a series of contracts with physician group practices to operate pathology laboratories for the groups in an off-site location. The organizer of the lab would obtain the space and the technical and professional services, but they would all be billed by the group practice. The pathologist and histotechnoloist would rotate among the various spaces subleased by each practice, just as in the example described above.

The OIG noted that the lab could provide services in its own right and in its own name, but had chosen instead to enter into an agreement with a referring group. The payment to the manager of the laboratory varied with the volume of referrals from the physicians, and the benefit to the physicians would also vary based on its referrals. As a result, the OIG found that the relationship could raise issues under the anti-kickback law. It noted that "we are unable to exclude the possibility that the parties' contractual relationship is designed to permit the [laboratory organizer] to do indirectly what it cannot do directly; that is, pay the Physician Groups a share of the profits from their laboratory referrals."

The OIG went on to note that this could constitute "impermissible remuneration" because it gave the group "the opportunity to obtain the difference between the reimbursement received by the Physician Groups from the federal healthcare programs and the fees paid by the Physician Groups to the [laboratory organizer] (i.e., the profit from pathology services ordered by the Physician Groups)." In short, this opinion seems to call into question the very structure of many pod arrangements, and raises significant questions about them.

See the next issue of GCR for additional discussion of the legal issues raised by pod labs, including concerns about self-referral and reassignment.

Peter Kazon, Esq., can be reached at Alston & Bird, the Atlantic Building, 950 F St., NW, Washington, D.C., 2004-1404. Phone: 202-756-3334. E-mail: peter.kazon@alston.com.

NPI Compliance, *from page 1*

Separately, the National Committee on Vital and Health Statistics (NCVHS) has called for a six-month contingency plan, depending on when HHS releases a key NPI dissemination notice. The NPI data cannot be released until HHS publishes this notice in the *Federal Register*.

Both ACLA and the NCVHS warn that HHS delay on the NPI dissemination is hampering the ability of trading partners to exchange NPI data and allow sufficient time to test the software among themselves. Many health plans need the data to crosswalk legacy numbers to NPIs, the NCVHS noted, and providers need to obtain the NPIs of other providers, since claims require the number of both the primary billing provider and the ordering or referring provider.

In addition, full compliance is not feasible by May 23, the groups say, because many providers still do not have an NPI. More than 1.7 million NPIs have been issued, the NCVHS noted, but many providers have yet to sign up, including many who don't yet realize they must.

A new ACLA white paper (posted online at www.clinical-labs.org) examines the impact of the NPI on the independent lab industry. In particular, the paper looks at issues involving administration, implementation, and technical details and offers recommendations for labs and CMS.

Granting a contingency period for NPI compliance is not unprecedented. CMS did so when implementing standards for electronic transaction/code sets and remittance notices, giving most providers up to two years to become compliant.

For more NPI information, go to *www.cms.hhs.gov/NationalProviderStand*. Providers can apply for an NPI online at *https://nppes.cms.hhs.gov* or by calling the NPI enumerator at 800-465-3202.

Illinois Court Upholds PC Billing By Pathologists

An Illinois court on March 6, 2007, dismissed a class action suit by a group of pathologists and others that alleged the practice of professional component billing to be unlawful, according to the College of American Pathologists (CAP).

In the case, *Martis v. Pekin Memorial Hospital, et al.*, the Tazewell County Circuit Court upheld the practice of professional component billing, noting the precedent created in *Central States Health & Welfare Fund v. Pathology Lab of Arkansas* (71 F.3d 1251 (7th Circuit 1995)). In the Central States case, the court found that professional clinical pathology services provided "value to all patients" and concluded that, in the absence of a state law or health plan contract to the contrary, pathologists had the right to bill plans and/or patients for these services.

Medicaid HMO Hit With Additional $190 Million Penalty

A federal judge March 13 imposed civil penalties of more than $190 million against Amerigroup Illinois and Amerigroup Corp., raising the company's total liability following its healthcare fraud conviction last fall to a record $334 million (*United States ex rel. Tyson v. Amerigroup Illinois Inc.*, N.D. Ill, No. 92C6074, 3/13/07).

In October 2006, a federal jury found that the Medicaid health maintenance organization Amerigroup Corp. and its Illinois subsidiary, Amerigroup Illinois Inc., violated the False Claims Act by avoiding signing up pregnant women or sick people as a way to keep costs down, fining the insurance company $48 million—a penalty tripled under federal guidelines to $144 million.

The total damages of $334 million are the largest ever awarded in a federal healthcare fraud case in the Northern District of Illinois, according to the office of Patrick Fitzgerald, U.S. attorney for the district. Senior U.S. District Judge Harry Leinenweber based the penalties on a finding of 18,130 false claims and assessed a penalty of $10,500 on each false claim, totaling just over $190 million.

From 2000 to 2004, Amerigroup was paid $243 million to set up a Medicaid managed care health plan in Illinois. Part of the payments was intended to help low-income pregnant women who had inadequate prenatal care to navigate the complicated healthcare system, but the company ultimately spent less than half the state and federal funds it received on providing healthcare, according to prosecutors.

In accordance with federal law and its contract with the state, Amerigroup was required to market to all eligible Medicaid beneficiaries and was prohibited from discriminating on the basis of health status or need for health services, according to prosecutors. Yet, the jury found that Amerigroup illegally avoided signing up pregnant women and other people with expensive health conditions while it continued receiving state and federal dollars that were paid with the understanding the company was not engaging in health status discrimination. As a result of Amerigroup's discrimination, the federal and state governments overpaid Amerigroup by millions of dollars, according to prosecutors.

The verdict followed a three-week trial after nearly four years of litigation originally filed by Amerigroup Illinois's former head of government relations, Cleveland Tyson, under the False Claims Act and the Illinois Whistleblower Reward and Protection Act, under which Tyson is eligible to receive between 15% and 25% of the total damages awarded in the case.

Amerigroup Vows Appeals

Amerigroup Corp., in a March 13 statement, said it had already begun the appeal process and will ask the U.S. Court of Appeals for the Seventh Circuit to review the decision.

"Amerigroup strong disagrees with this decision and will aggressively pursue an appeal. We believe our Illinois subsidiary acted at the direction and with the knowledge of the Illinois Department of Public Aid (IDPA)," said Amerigroup's chairman and chief executive officer Jeffrey McWaters. "During the period covered by this litigation, our Illinois subsidiary repeatedly disclosed its marketing training programs to IDPA and they agreed with those programs."

Amerigroup attorney Theodore Olson said March 13 that the company has very strong arguments as to liability and damages, given the "significant errors" that occurred at trial.

"The size of this judgment alone raises serious Constitutional questions, in that the $334 million judgment is approximately 28 times Amerigroup Illinois Inc.'s cumulative earnings over 11 years of operations," Olson said. "Amerigroup is an ethical company, and we look forward to the opportunity to present our arguments to an appellate panel."

Proposal To Subsidize Ambulance Costs Could Violate Kickback Rules, OIG Says

A hospital's proposed arrangement to subsidize ambulance transportation costs for out-of-area patients could likely run afoul of the anti-kickback statute and violate the civil monetary penalties provisions, the Department of Health and Human Services Office of Inspector General (OIG) said in a March 14 advisory opinion (07-02).

The hospital, which is known as a leader in cardiac care services and is a subsidiary of a large nonprofit healthcare system, said it wanted to contract with various air and group ambulance providers to transport patients from outside the hospital's local area for a negotiated rate, then bill third-party payers, including Medicare and Medicaid, for the services. As part of the proposal, the hospital would absorb any charges not covered by insurers, according to the OIG's opinion.

In the request for the opinion, the hospital told the OIG that patients are occasionally transferred to the facility from outside the local area and that, historically, claims for transportation services have been paid by the local Medicare carrier.

However, the opinion stated, the carrier had started refusing the full claim amounts, saying Medicare only provided for local ambulance transport except in cases where nonlocal transportation was required to take patients to the nearest hospital with appropriate facilities.

The requestor said that patients had begun complaining that they were receiving bills from their ambulance suppliers for the uncovered portion of nonlocal ambulance trips and that physicians had become less inclined to order or recommend transfers to the hospital when they knew patients might incur excess mileage charges.

For those reasons, the hospital proposed subsidizing nonlocal transportation costs. However, the OIG said that the proposal could generate prohibited remuneration and trigger CMP penalties.

The OIG said that the proposal likely would violate the anti-kickback statute and civil monetary penalty provision because the payment or subsidy of transportation expenses would amount to remuneration to a patient because those costs typically would be borne by the individual. In addition, the arrangement likely would influence patients' initial and subsequent choice of the hospital to receive items or services reimbursable by Medicare or Medicaid.

The OIG said that the proposal likely would violate the anti-kickback statute and civil monetary penalty provision because the payment or subsidy of transportation expenses would amount to remuneration to a patient because those costs typically would be borne by the individual.

"For example, many of the patients who benefit from the proposed arrangement will be cardiac patients, who are likely to develop ongoing relationships with a hospital provider," the opinion stated.

Furthermore, the OIG said, the arrangement could influence patients to choose the hospital's ambulance suppliers over other suppliers. Although the hospital said it would not advertise the subsidy directly to patients, the OIG said that was an insufficient safeguard because physicians could be influenced in their referral decisions because of the program.

Resource

Advisory opinion 07-02: available at *www.oig.hhs.gov.fraud/docs.advisoryopinions/2007/AdvOpn07-02E.pdf*

FCA Settlement: Raritan Bay Medical Center in New Jersey has agreed to pay the United States $7.5 million to resolve charges, made in three separate False Claims Act whistleblower actions, that the hospital defrauded Medicare, the Department of Justice announced March 15. The government said Raritan Bay deliberately inflated charges for inpatient and outpatient care, from January 1998 through August 2003, to make the cases appear more costly than they actually were and thus received Medicare outlier payments that it was not entitled to receive. Raritan Bay has denied the allegations by the government and whistleblowers.

J&J Issued Subpoenas: Johnson & Johnson said March 12 that it had received subpoenas from three U.S. attorneys seeking information related to the sales and marketing of three drugs manufactured by its subsidiaries. The company said the subpoenas relate to previously disclosed investigations concerning its drugs Risperdal, manufactured by Janssen LP; Topamax, manufactured by Ortho-McNeil Neurologics Inc.; and Natrecor, manufactured by Scios Inc. "The subpoenas request information regarding Johnson & Johnson's corporate supervision and oversight of these three subsidiaries, including their sales and marketing of these drugs," the company said.

Hospital Chain Served With Search Warrant: Universal Health Services Inc. said recently that its South Texas Health Systems affiliates were served with a search warrant in connection with a criminal investigation. The company in its announcement also cited an earlier subpoena from the Department of Health and Human Services. In 2005, the HHS Office of Inspector General served South Texas Systems with a subpoena that was thought to be part of an investigation of compliance with Medicare and Medicaid rules and regulations under the False Claims Act. At the time, the Civil Division of the U.S. attorney's office in Houston said the investigation pertained to the employment of physicians and the solicitation of patient referrals from doctors beginning in January 1999 to the date of the subpoena, the company said.

G-2 Compliance Report (ISSN 1524-0304) is published by Washington G-2 Reports, 3 Park Avenue, 30th Floor, New York, NY 10016-5902. Tel: 212-244-0360. Fax: 212-564-0465. Order line: 212-629-3679. Web site: www.g2reports.com.

Kimberly Scott, Senior Editor; Dennis Weissman, Executive Editor; Janice Prescott, Sr. Production Editor; Perry Patterson, Vice President and Publisher; Joe Bremner, President.

Receiving duplicate issues? Have a billing question? Need to have your renewal dates coordinated? We'd be glad to help you. Call customer service at 212-244-0360, ext. 2.