G-2 Compliance Report

WASHINGTON G-2 REPORTS

Vol. IX, No. 5, May 2007

For Hospitals, Laboratories and Physician Practices

CMS Implements Contingency Plan For NPI Compliance

Healthcare entities unable to meet the May 23, 2007, deadline for compliance with the National Provider Identifier (NPI) regulations under the Health Insurance Portability and Accountability Act (HIPAA) will have an additional year to come into compliance, according to the Centers for Medicare and Medicaid Services (CMS).

CMS announced an NPI contingency plan on April 3. While the NPI compliance date remains May 23 of this year, CMS will not impose penalties on noncompliant entities if they make reasonable efforts to become compliant. The grace period will last until May 23, 2008.

Good Faith Efforts

HIPAA, which became law in 1996, required the Department of Health and Human Services (HHS) to adopt national standards for electronic healthcare transactions and code sets and identifiers to be used in those transactions. The final rule adopted the NPI as the standard unique health identifier for healthcare *Cont. on p. 2*

CMS Offers Guidance On Employee Education About False Claims Recovery

The Centers for Medicare and Medicaid Services (CMS) has offered additional guidance on requirements for employee education about false claims recovery, mandated by the Deficit Reduction Act of 2005 (DRA).

Section 6032 of DRA requires entities that make or receive annual Medicaid payments of $5 million or more in any state to establish and disseminate certain written policies applicable to their employees, certain contractors, and agents and to include information about the policies in employee handbooks, effective Jan. 1, 2007. The required policies must provide detailed information about applicable state and federal false claims laws and the entities' policies and procedures for preventing fraud, waste, and abuse.

In "Frequently Asked Questions" posted to its Web site in late March, CMS addresses a number of key issues, including which entities and contractors are covered by Section 6032, how the $5 million threshold should be measured, how entities should disseminate the mandated policies, and enforcement by state Medicaid agencies, according to an e-alert from the law firm of Foley & Lardner. *Cont. on p. 8*

Kimberly Scott, Senior Editor,
Kimscott@yahoo.com

Inside this issue

NPI Compliance, *from page 1*

providers was published on Jan. 23, 2004, and became effective on May 23, 2005. Under the rule, all covered entities must be in compliance with the NPI provisions by May 23, 2007, except for small health plans, which must be in compliance by May 23, 2008.

Compliance means, in part, that the NPI must be used by covered entities to identify providers on all HIPAA-covered transactions that call for healthcare provider identifiers. Covered transactions that require a healthcare provider's identifier that are transmitted containing only legacy identifiers (those currently in use) or containing both legacy identifiers and NPIs would be noncompliant.

According to the agency's contingency plan announcement, CMS recognizes that transactions often require the participation of two covered entities, each of whom is required to comply with HIPAA, and that noncompliance by one covered entity may put the second covered entity in a difficult position.

"CMS also understands that if one of the covered entities is a small health plan, which has a May 23, 2008, compliance date, compliance by the covered trading partner may be especially challenging," says the announcement. "Therefore, during the 12-month period immediately following the May 23, 2007, compliance date for all covered entities other than small health plans, CMS intends to look at both covered entities' good faith efforts to come into compliance with the NPI standards in determining, on a case-by-case basis, whether reasonable cause for the noncompliance exists and, if so, the extent to which the time for curing the noncompliance should be extended."

Organizations that have exercised good faith efforts to correct problems and implement the changes required to comply with HIPAA should document such efforts in the event of a complaint being filed, says CMS.

For the 12-month period after the compliance date (through May 23, 2008), CMS will not impose penalties on covered entities that deploy contingency plans if they have made reasonable and diligent efforts to become compliant and, in the case of health plans (that are not small health plans), to facilitate the compliance of their trading partners, says CMS.

Specifically, as long as a health plan can demonstrate to CMS its active outreach/testing efforts, it can continue processing payments to providers. In determining

whether a good faith effort has been made, CMS will place a strong emphasis on sustained actions and demonstrable progress. It will also limit the period during which covered entities may deploy contingency plans to allow additional time to carry out needed testing and other activities without payment disruption, while providing a clear ending date for those activities.

A covered entity may end its contingency plan at any time prior to May 23, 2008, but cannot continue it after that date.

According to CMS, indications of good faith might include such factors as:

- ❑ Increased external testing with trading partners;
- ❑ Lack of availability of, or refusal by, the trading partner to test the transaction with the covered entity whose compliance is at issue (prior to May 23, 2007);
- ❑ In the case of such a health plan, concerted efforts both before and after the compliance deadline to conduct outreach and make testing opportunities available to its provider community; and
- ❑ For a healthcare provider, having obtained an NPI and having the ability to use it on HIPAA transactions.

Organizations that have exercised good faith efforts to correct problems and implement the changes required to comply with HIPAA should document such efforts in the event of a complaint being filed, says CMS. This flexibility will permit health plans to mitigate unintended adverse effects on covered entities' cash flow and business operations during the 12-month transition to NPI standards, as well as on the availability and quality of patient care.

A critical aspect of implementing the NPI, the agency notes, is the ability for covered entities to match a provider's NPI with the many legacy provider identifiers that have been used to process administrative transactions. CMS says it plans to make data available from the National Plan/Provider Enumerations System (NPPES) that will assist covered entities in developing these "crosswalks."

CMS encourages healthcare providers that have not yet obtained NPIs to do so immediately and to use their NPIs in HIPAA transactions as soon as possible. NPIs may be obtained through the NPPES Web site at *https://nppes.cms.hhs.gov/*.

Resource

- ❖ CMS NPI contingency guidance: *www.cms.hhs.gov/NationalProvIdentStand/Downloads/NPI_Contingency.pdf*

Company's Rx Help For Part D Enrollees Raises Kickback Concerns, But No Sanctions

A pharmaceutical company's proposal to provide free drugs to needy Medicare Part D drug benefit enrollees could violate the anti-kickback law, but the Department of Health and Human Services Office of Inspector General (HHS OIG) says in a new advisory opinion that it would not impose sanctions.

In Advisory Opinion No. 07-04, the HHS OIG told a company that manufactures and markets prescription drugs that its proposal to expand its patient assistance programs (PAPs) to include needy Medicare Part D beneficiaries contains sufficient safeguards to reduce the risk of sanctions. The safeguards will ensure the PAPs will operate entirely outside the Part D benefit, the OIG concluded, and thus there is a minimal risk of fraud and abuse under the Part D program.

For several years, the pharmaceutical company has provided some drugs for free to qualifying financially needy patients. Under the proposed arrangement

to expand the eligibility for its PAPs to include financially needy Medicare beneficiaries enrolled in a Part D plan, PAP applicants must use one or more of the PAPs' covered drugs and demonstrate financial need.

The pharmaceutical company has certified that it will coordinate data with the Centers for Medicare and Medicaid Services at HHS to ensure neither Medicare nor any Part D plan will pay for the free drugs.

The safeguards will ensure the PAPs will operate entirely outside the Part D benefit, the OIG concluded, and thus there is a minimal risk of fraud and abuse under the Part D program.

Financial Need

The PAPs will notify the enrollees' plans that the free drugs are provided outside the Part D benefit and no claims for payment of the drugs will be filed with a Part D plan. In addition, the assistance will not count toward the enrollee's true-out-of-pocket (TrOOP) spending under the Part D program. Eligibility for the PAPs' assistance will be determined based solely on patients' financial need, which will be determined in a reasonable way without regard to providers or the Part D plans, the OIG determined.

According to the advisory opinion, once an enrollee begins receiving a drug for free from the PAPs, the assistance will continue for the remainder of that year. An enrollee's eligibility for assistance in subsequent years will be reassessed each year, and the assistance will not begin until the enrollee has met the eligibility criteria in that year, the OIG said.

The PAPs also will provide the patients with written certification that will notify them of their eligibility to receive the free drug for the remainder of the coverage year. The certification also will require the patient's agreement that no attempt will be made to submit claims for the drug received and acknowledge that the drugs will not count toward the enrollee's TrOOP.

The safeguards substantially mitigate the risk that the PAPs' drugs will be used to tie Medicare beneficiaries to particular outpatient prescription drugs payable by the Medicare Part D program. Further, the OIG determined that the safeguards reduce the risk that the PAPs' drugs will be used to increase costs to the Medicare Part D program.

The OIG determined that the proposed arrangement could generate prohibited payment under the anti-kickback statute if the requisite intent to induce or reward referrals of federal healthcare program business were present. However, the OIG concluded it would not impose administrative sanctions on the pharmaceutical company under sections 1128(b)(7) or 1128A(a)(7) of the Social Security Act in connection with the proposed arrangement.

Resource

- Advisory Opinion 07-04: *www.oig.hhs.gov/fraud/docs/advisoryopinions/2007/AdvOpn07-04.pdf.*

Cell Therapeutics To Pay $10.5 Million To Resolve Illegal Drug Marketing Charges

Cell Therapeutics Inc. (CTI) agreed to pay the United States $10.5 million to resolve allegations that it illegally marketed anti-cancer drug Trisenox, the Department of Justice (DOJ) announced April 17.

According to the complaint, Seattle-based CTI promoted the drug for various uses that were not approved by the Food and Drug Administration (FDA). The alleged "off-label" uses caused physicians to prescribe Trisenox to treat various forms of cancer for which the drug was neither approved by the FDA nor proven to be either safe or effective, a DOJ press release said.

The complaint, a whistleblower action filed under the False Claims Act, alleged that because of the company's actions, physicians who prescribed Trisenox off-label unwittingly submitted false claims for reimbursement to the Medicare program from 2001 until 2005. In 2005, CTI sold Trisenox to another company, and the drug's new owner halted the off-label promotion campaign, the government said in the statement. Cephalon Inc. now markets Trisenox.

COMPLIANCE PERSPECTIVES

What's Next With Pod Laboratories?

***This is the second of two parts. The first part was published in the April issue of* G2 Compliance Report.**

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

In last month's issue we talked about the definition of pod labs, why the lab and pathology industry are concerned, and the legal issues that pod labs create (such as potential kickbacks). The Health and Human Services Office of Inspector General (OIG), which enforces the anti-kickback law, has often expressed concern about arrangements that are comparable to pods. The OIG issued an advisory opinion in 2004 (No. 04-17) that seemed to call into question the very structure of many pod arrangements and raised significant questions about them.

Kickbacks are just one of the legal issues raised by pods. Other legal issues raised by these arrangements are discussed below.

Self-Referral Issues

The Stark self-referral law prohibits physicians from referring Medicare and Medicaid work to entities with which they have a financial relationship. Unlike the anti-kickback law, there is no "intent" requirement under the Stark law. That is, one does not have to have a bad intent or the intent to induce referrals to violate the law. If the requirements of the Stark law are not met, it is violated regardless of the intention.

The Stark law can be implicated by pod arrangements because they involve referrals from a physician to another entity (the pod laboratory) with which the physician has a contract, which creates a compensation arrangement with the pod. As a result, a referral to the pod could be prohibited unless there is an exception that applies.

To comply with the Stark law, most pods reportedly try to fit within one of two different exceptions in the law, the "In-Office Ancillary Services Exception" or the "Physician Services Exception." Each provision is fairly complex, and there are numerous issues involved with complying with each. In the proposed physician fee schedule rule (PFS) last year, CMS sought to clarify some of the provisions under each to prevent abuse.

The in-office ancillary services exception is designed to permit members of a group practice to refer to each other, without violating the Stark self-referral prohibition. However, to qualify, the entity must meet certain requirements that are designed to ensure that it is operating as a part of the group practice and not simply as an outside supplier of services. One provision requires that the space where the services are performed meet the requirements of a "centralized building," where the group provides these services to its patients.

Pod organizers take the position that the space dedicated to the individual group practice meets the definition of a centralized building for Stark purposes. This is why the personnel rotate among the various cubicles, to ensure that the services are being furnished in the group's "centralized building." In Advisory Opinion 04-17, the OIG raised some concerns about whether it was really possible to rotate personnel among these various

sites as required. It noted that it would be "virtually impossible to monitor" the arrangement, especially in an off-site facility and therefore there was a possibility of abuse, including overutilization and improper claims.

One of the proposals made by the Centers for Medicare & Medicaid Services (CMS) last year was designed to ensure that the space used as the "centralized building" met certain requirements. It proposed a requirement that the space had to be at least 350 square feet, although the limitation would only have applied if there were four or more group practices providing services in the same building. In addition, CMS also proposed that the space had to include all of the equipment necessary to furnish substantially all of the diagnostic services; that is, the equipment couldn't be moved from one site to another.

It does seem likely that if CMS decides to act to limit pods, it will again focus on the "centralized building" requirement as a way to limit them.

Finally, CMS also asked for comments on whether there should be a requirement to have a full-time nonphysician employee on site, which again was designed to ensure that the space truly was used by the group on some significant basis. It also requested comments on whether there should be limits on locating the centralized building in states other than the one where the group was located, or beyond a certain distance from the group's offices. It is not known what CMS will do this year, and whether it will reissue these same restrictions. It does seem likely, however, that if CMS decides to act to limit pods, it will again focus on the "centralized building" requirement as a way to limit them.

The other exception that is sometimes utilized by pods is the physician services exception. Under this exception, a group member is permitted to make a referral to another group practice physician for physician services, such as pathology services, if the services are supervised by the other group practice physician. The physician performing or supervising the services does not have to be an employee or shareholder of the group; rather, he only has to qualify as a "physician in the group" (i.e., a physician who has a contract with the group to perform the services at issue). Thus, this exception could also apply to a referral from a group to a pod laboratory, in which case it could cover the pathology services furnished by the physician in the group.

However, the definition of a physician in the group, like the in-office ancillary services exception, contains limits on where the services can be performed. Although it does not use the term "centralized building," it does require that the physician in the group furnish the services in the "group's facilities." Thus, in order to qualify for this exception, the cubicle or pod where the group's testing is performed must be considered the group's facilities.

In the PFS rule, CMS proposed that the same limitations for the centralized building would also apply to the term "group facilities." Thus, they would also have to meet the 350 square feet requirement along with the other requirements. Again, if CMS acts this year to further define what constitutes a "centralized building," it is also likely to impose similar limitations on where other outside contractor physicians can perform those services.

Reassignment Provision

Another issue raised by pods is the "prohibition on reassignment." As discussed above, as a general rule, Medicare will only pay the physician or supplier that actually performs work. However, there are exceptions to this requirement that permit Medicare to pay other persons or

entities, even though they did not actually provide the service. Again, these requirements are important here, because without the exception, the group practice might have difficulty billing for the work done at the pod laboratory.

There have always been specific requirements that limit when a physician can bill for diagnostic tests, like pathology services, that he has purchased from another physician. According to current requirements, if a physician purchased the technical component of a service, then he could not charge Medicare more than he paid for the service and would have to perform the professional component (PC) himself. If a physician bought the PC, then similarly, he had to perform the technical component (TC), but in addition, the requirements stated that the physician purchasing the service could not also be the one who triggered the referral.

These provisions could have limited the ability of many pods to operate, because in many instances, the group practice could be viewed as simply purchasing the TC and/or the PC of the service. However, in the Medicare Modernization Act of 2003 (MMA), Congress enacted a new exception to the reassignment rules, which was read by some to avoid these long-standing restrictions on purchased diagnostic services. Under the new MMA requirement, a physician could bill for services furnished by another entity so long as the physician had a contractual arrangement with the supplier of the services.

In the PFS proposed rule, however, CMS acted to ensure that the limitations on the purchase of diagnostic tests should still apply even to those entities acting pursuant to a contractual arrangement. As a result, CMS proposed to make explicit that the rules limiting the purchase of the PC or TC would still generally apply even if the purchaser had a contractual arrangement with the physician who furnished the service. CMS also stated that it was reviewing whether the anti-markup provision that applies to the TC should be extended to apply to both the TC and the PC. Finally, it also would have made explicit the requirement that to purchase one service, the other component had to be performed by the group itself.

It is not clear what action CMS may take in this area, but it seems likely that it may again act to ensure that the current requirements on purchased diagnostic services are applied even to those situations where the supplier, like the pod laboratory, has a contract with the referring physicians.

These changes also would have implications for the Stark law as well, because its provisions require that to qualify as a "physician in the group," the physician must also comply with the reassignment requirements, which now would explicitly include the limitations on purchased testing discussed above.

Again, it is not clear what action CMS may take in this area, but it seems likely that it may again act to ensure that the current requirements on purchased diagnostic services are applied even to those situations where the supplier, like the pod laboratory, has a contract with the referring physicians.

In sum, it is unclear what action, if any, CMS will take with regard to pods in the coming year. However, if the agency follows up on actions from last year, it may impose new limitations on these arrangements, which may limit how the deals operate and how they have to be structured. This is an issue that clearly will require further scrutiny as the year progresses.

Peter Kazon, Esq., can be reached at Alston & Bird, the Atlantic Building, 950 F St., NW, Washington, D.C., 20004-1404. Phone: 202-756-3334. E-mail: peter.kazon@alston.com.

False Claims Guidance, *from page 1*

For example, the FAQs note that for purposes of section 6032, an individual could be considered an entity as long as that person receives or makes payments totaling at least $5 million annually under the state Medicaid plan. Several of the FAQs address questions relating to what constitutes an "entity" when an organization consists of multiple parts (e.g., a parent corporation with multiple subsidiaries). The FAQs repeatedly indicate that "[f]or purposes of section 6032 compliance, the entity is the largest separate organizational unit that furnishes Medicaid healthcare items or services and includes all sub-units of that organizational unit that furnish [such] items or services, even if the components are separately incorporated or located in different states." An entity can potentially include a number of organizations, with multiple subsidiaries, locations, tax identifier numbers, and provider numbers.

$5 Million Threshold

CMS indicates that for purposes of determining whether an entity meets the $5 million threshold for any given year, the relevant time period is the immediately preceding federal fiscal year. For example, in determining whether an entity must comply for calendar year 2007, the organization would determine whether it has received or made payments totaling $5 million during the period Oct. 1, 2005, to Sept. 30, 2006.

Entities that receive payments both from a state Medicaid agency and from Medicaid managed care organizations (MCOs) are only required to count the funds received from the Medicaid agency, and need not count amounts received from Medicaid MCOs. Similarly, patient cost-sharing amounts need not be included.

When an entity receives payments from multiple states, those payments are not aggregated in determining whether the threshold is met. However, once an organization meeting the definition of an "entity" satisfies the $5 million annual threshold in one state, the entity must comply with section 6032 with respect to its employees in all the states in which it operates.

When a corporate parent has several components operating in the same state, the amounts received or paid by its various subsidiaries must be aggregated if the parent itself: 1) is either a health system, or 2) itself provides Medicaid healthcare items or services, in which case the parent would constitute the "entity" under the guidelines described above.

Application To Contractors

A number of the FAQs address the applicability of Section 6032 to contractors of entities. CMS has previously indicated that covered contractors include those which, on behalf of the entity, furnish or otherwise authorize the furnishing of Medicaid healthcare items or services, or are involved in monitoring healthcare provided by the entity. CMS indicates that this includes supply vendors that provide products used in the furnishing of Medicaid healthcare services. It also includes contractors, such as contract therapists, physicians (including but not limited to, house staff, hospitalists, and independent contractors), and pharmacies.

Providers have previously expressed concern that requiring contractors to adopt the policies of multiple entities would be unworkable and would subject the contractors to a multiplicity of potentially conflicting obligations. The FAQs continue to require that entities disseminate their policies to their contractors and that the contractors adopt them. However, CMS clarifies that a contractor is only required to abide by the policies of each entity in connection with the work the contractor performs for that entity.

Resource

- Employee Education About False Claims Recovery—Frequently Asked Questions: *www.cms.hhs.gov/smdl/downloads/SMD032207Att1.pdf*

Qui Tam Cases Falling, Could Be Good Sign

The number of healthcare-related qui tam whistleblower cases filed nationally under the False Claims Act dropped by more than half from 2005 to 2006, signaling the possibility that hospitals and providers have adopted effective compliance programs, according to Amy Berne, chief of the civil division in the U.S. Attorney's Office for the Northern District of Georgia.

In 2005, there were 268 healthcare qui tam cases filed around the country, but in 2006 the number of cases filed was only 110. Also, non-qui tam cases filed under the False Claims Act have dropped by more than half, from 34 in 2005 to 16 in 2006, she said. Berne spoke March 19 at a health law and policy forum sponsored by the law firm of King & Spalding (Atlanta).

While the qui tam caseload has dropped by more than half, the amount of money recovered has doubled, from $1.1 billion in 2005 to almost $2.3 billion in 2006.

Berne said the statistics "show that, hopefully, things are getting better out there, so that we're not getting as many cases." Although she was not sure what caused the decrease, Berne speculated that "more and more hospitals and physicians and medical providers have established comprehensive and effective compliance programs, so therefore there's less fraud for us to pursue."

Interestingly, she said, while the qui tam caseload has dropped by more than half, the amount of money recovered has doubled, from $1.1 billion in 2005 to almost $2.3 billion in 2006.

In almost every case she has handled over 10 years, the relators in the qui tam cases came to federal prosecutors only after first going to the provider to complain about a problem. "They were somewhat stonewalled or they were ignored and they then came" to federal prosecutors for help, she said.

Nursing Home Investigations

Speaking at the same conference, Scott Smeal, an assistant attorney general who leads Georgia's State Healthcare Fraud Control Unit, said his investigators are looking at "insurance expense issues" at nursing homes "that are being passed through the cost reports."

In a separate nursing home case, he said, the unit is investigating allegations "of acuity inflation."

The state's Department of Community Health, he explained, pays nursing homes on a cost-based methodology, but for the past several years, nursing homes reimbursed by Medicaid have been allowed an add-on cost of up to 4%, depending on the acuity level, or severity of the case. Smeal said the allegation is that the nursing home has committed "deliberate acuity inflation to trigger the add-on 4%."

If the case "pans out," Smeal said he might look for similar cases on the "Medicare side" under Part A and Part B. Smeal said he could not discuss specific information about either case because the investigations are continuing.

He said healthcare fraud investigators today are better able to handle complex investigations than they were a decade or more ago. Because of that, his office has hired more auditors and recently hired several nursing home investigators to help read patient charts and give auditors a "preliminary assessment" of potential fraud, he said.

Tenet To Pay $10 Million In SEC Settlement

Tenet Healthcare Corp. (Dallas) has agreed to pay a civil penalty of $10 million to settle charges brought by the Securities and Exchange Commission (SEC) concerning Medicare outlier payments prior to November 2002.

The civil settlement, filed April 2 in U.S. District Court in Los Angeles, arises from a civil complaint filed simultaneously by the SEC against Tenet and four former officers of the company alleging violation of certain anti-fraud and disclosure provisions of U.S. securities laws. The settlement, in which Tenet neither admitted nor denied the allegations, will resolve the SEC complaint against the company.

As part of the settlement, the SEC said it will seek to deposit the $10 million civil penalty paid by Tenet into a "fair fund" to be distributed to eligible individuals and entities that demonstrate losses related to the value of their Tenet shares purchased or sold between April 12 and Nov. 7, 2002.

The SEC alleged that between 1999 and 2002 Tenet engaged in an unsustainable strategy to reach its earnings targets by deliberately exploiting the Medicare reimbursement system. Tenet's scheme allegedly involved outlier payments, which are designed to compensate hospitals for caring for extraordinarily sick Medicare patients.

According to the SEC, Tenet's management realized the company could inflate its revenue from outlier payment by simply increasing the gross charges set by its hospitals. From 1999 to 2002, Tenet's outlier revenue more than tripled and Tenet's earnings goals were surpassed year after year. Tenet's outlier growth from fiscal 1999 to fiscal 2002 accounted for more than 54% of its cumulative growth in earnings per share from operations, the SEC said. Similarly, by fiscal 2002, Tenet's outlier revenue comprised more than 40% of its earnings per share.

"By exploiting a loophole in Medicare regulations, Tenet embarked on an unsustainable strategy to turbocharge its earnings," said Randall Lee, director of SEC's Los Angeles regional office. "Yet even as Tenet's strategy produced nearly half of its earnings per share, Tenet's management kept investors in the dark about the central business strategy underlying its earnings growth."

Dramatic Changes

Since new management and a virtually new board assumed control of Tenet in 2003, the company has undertaken dramatic changes in its operations, financial safeguards, governance, and compliance, according to Tenet officials.

"With this SEC settlement, we have now concluded all the investigations and litigation that arose after the outlier and other matters first surfaced in late October 2002," said Peter Urbanowicz, Tenet's general counsel. "Tenet today is virtually a new company. We are proud of the progress we have made in our commitment to quality care for our patients and transparency in all our operations.

The settlement also concluded a separate SEC investigation into Tenet's accounting treatment of certain managed care contractual reserves taken at three hospitals in California before 2003. In January 2006, the company concluded its own special internal investigation of these contractual reserves by restating certain of its financial results for prior fiscal year.

As part of the settlement, the SEC said it will seek to deposit the $10 million civil penalty paid by Tenet into a "fair fund" to be distributed to eligible individuals and entities that demonstrate losses related to the value of their Tenet shares purchased or sold between April 12 and Nov. 7, 2002.

OIG Signs Off On Credit Rewards To Nursing Home

A proposed arrangement to use rewards from credit cards to buy goods and services for a nursing home would not violate the anti-kickback statute, according to the Department of Health and Human Services Office of Inspector General (OIG).

In response to a request by the operator of a nursing home, the OIG in Advisory Opinion No. 07-3 concluded that the portion of the proposed arrangement involving rewards given by the operator to its employees comes within the statutory exception and regulatory safe harbor for employee compensation.

The OIG emphasized that only the requestor's bona fide employees would be eligible to receive the credit card rewards under the program. The risk of fraud and abuse is typically reduced with bona fide employer-employee relationships, in part because the employer is generally fully liable for the actions of its employees and is thus more motivated to supervise and control them, the OIG said.

The nursing home operator proposed to use credit cards issued in its name to buy goods and services for the nursing home and said it might seek reimbursement from Medicare and Medicaid for the costs associated with its credit card purchases. The credit card issuers provide rewards for the use of the credit cards, which will be used to purchase additional goods and services for the nursing home or given to the requestor's employees as performance-based compensation.

No Referrals Expected

The OIG noted that based on the facts presented in the request, there will be no referrals between the credit card issuers and the operator of the nursing home. Therefore, neither the transfer of rewards to the requestor nor the subsequent use of some rewards to buy items or services for the nursing home would give rise to sanctions under the Social Security Act.

The risk of fraud and abuse is typically reduced with bona fide employer-employee relationships, in part because the employer is generally fully liable for the actions of its employees and is thus more motivated to supervise and control them, the OIG said.

Neither the issuers nor their sponsors will be healthcare entities or affiliated with the healthcare industry, the OIG said. They will not be in a position to receive or influence referrals of items or services covered under a federal healthcare program.

The requestor and the nursing home certified that they will appropriately reflect items and services obtained through the rewards on cost reports and claims submitted to a federal healthcare program to avoid grounds for the imposition of sanctions, the opinion said. The rewards to employees will be granted only to the requestor's employees for furnishing items or services for which payment may be made in whole or in part under Medicare, Medicaid, or other federal healthcare programs as performance-based compensation for fulfilling the job duties, the OIG said.

Further, the OIG said, the requestor certified that the rewards would be characterized as part of an employee's compensation for income tax purposes. The advisory opinion concluded that the proposed arrangement would not generate prohibited remunerations under the anti-kickback statute and, accordingly, the OIG would not impose administrative sanctions on the operator in connection with the proposed arrangement.

Resource

❖ Advisory opinion No. 07-03, available at *www.oig.hhs.gov/fraud/docs/advisoryopinions/2007/AdvOpn07-03.pdf*.

Marketing Settlement: Two subsidiaries of Pfizer Inc. have agreed to pay $34.7 million to resolve criminal allegations relating to the marketing and promotion of the human growth hormone product Genotropin, according to U.S. Attorney for the District of Massachusetts Michael Sullivan. One unit, Pharmacia & Upjohn Co. Inc., agreed to plead guilty to one count of offering a kickback to a pharmacy benefit manager, to pay a fine of $19.68 million, and to be excluded permanently from participation in federal health programs. Another part, Pharmacia & Upjohn Co. LLC, entered into a separate deferred prosecution agreement to resolve charges it promoted Genotropin for "off-label" use and agreed to pay $15 million.

DME Suppliers Noncompliant: A new report from the Health and Human Services Office of Inspector General (OIG) has found that 45% of durable medical equipment companies in South Florida failed to comply with Medicare supplier standards. Based on the findings, the OIG report recommended the Centers for Medicare and Medicaid Services strengthen its enrollment process in a number of ways for durable medical equipment, prosthetics, orthotics, and supply (DMEPOS) companies. The tougher process should come in 11 areas, the report said, including conducting more surprise site visits, performing more rigorous background checks of applicants, and requiring suppliers to post a surety bond. The report is available at *www.oig.hhs.gov/oei/reports/oei-03-07-00150.pdf*.

Preventable Deaths: Among the 40 million Medicare hospitalizations, about 1.2 million experienced preventable medical errors, amounting to a nearly 3% incident rate from 2003 to 2005, according to a study issued April 2 by HealthGrades, an independent healthcare ratings organization. Nearly 250,000 Medicare patient deaths involving medical errors could have been prevented during the three-year time period, according to the fourth annual HealthGrades Patient Safety in American Hospitals Study. The study is available at *www.healthgrades.com/media/dms/pdf/PatientSafetyInAmericanHospitalsStudy2007.pdf*.

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.