CCH Health Care Compliance LETTER

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Proper safeguards key to cost sharing programs

by Susan A. Marks, Esq., Contributing Editor

The Office of the Inspector General (OIG) would not impose penalties or violations on a cost sharing program in which the hospital would share, with five cardiology physician groups, a percentage of the hospital's actual cost savings based on the cardiologists' implementation of certain cost saving measures, even though the program would implicate civil monetary penalties and violate the anti-kickback statute, because the program has proper safeguards in place.

Product standardization. In general, the cost savings would be generated from changes in how the cardiovascular groups currently work in the catheterization laboratory. The arrangement includes protocols to curb inappropriate use and waste, but the bulk of program savings would come from product standardization. The cardiology groups would be asked to standardize the types of cardiac catheterization devices they use, such as stents, balloons, interventional guidewires and catheters, vascular closure devices, diagnostic devices, pacemakers and defibrillators. They would also be required to limit the use of certain vascular closure devices to an "as needed" basis. Of importance to the OIG was the fact that the individual cardiologists would determine the most appropriate device on a patient-by-patient basis and that the availability of devices would not be compromised by standardization. Of equal importance was that the economies gained through the program were not from restricting devices.

The hospital hired a program administrator to oversee the program and study the cardiology groups, and make recommendations on cost savings that could be achieved. The hospital would pay the program administrator a monthly fixed fee that was certified to be the fair market value, in an arm's-length transaction, for services provided. The fee would not be tied to the cost savings or the cardiology groups' compensation under the program. When the arrangement begins, the hospital would enter into a separate contract with each group. The contract would specify the historic costs, base year costs and projected cost savings opportunities. The hospital would pay each group 50 percent of the cost savings realized, subject to several limitations.

Problems with cost sharing programs. Properly structured, cost sharing arrangements can serve legitimate business needs and medical purposes. They can also reduce waste and enhance efficiency, resulting in increased profitability for the hospital. However, such arrangements often influence physician judgment to the detriment of patient care, resulting in stinting on patient care, "cherry picking"the healthy patients and steering sicker patients to hospitals without cost sharing programs, payments in exchange for referrals and unfair competition among hospitals.

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Letters to the Editor

The CCH Health Care Compliance team welcomes comments or questions regarding articles published in the CCH Health Care Compliance Letter. Send comments to Sharon Sofinski, Coordinating Editor, at sofinsks@cch.com. For more information about the CCH Health Care Compliance Portfolio visit our online store at http://health.cch.com.

Civil monetary penalties. The Social Security Act, §§ 1128A(b)(1)-(2), establishes a civil monetary penalty (CMP) against any hospital that knowingly makes a payment directly or indirectly to a physician (and any physician who receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians who receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments. The OIG reviewed the eighteen recommendations for cost savings and found that they implicated the CMP. The recommendations regarding standardization of devices and limitations on the use of vascular closure devices constituted an inducement to reduce or limit the current medical practice at the hospital and therefore a CMP would apply to the program.

Safeguards. However, the OIG would not seek sanctions under this program because the program has several features that provided sufficient safeguards. Specifically, the program provided that:

(1) there would be identification of the specific cost-saving actions and the resulting savings. This would allow for public scrutiny and individual physician accountability for any adverse effects of the arrangement.

(2) the recommendations would not adversely affect patient care because there was credible medical support for implementation.

(3) payments under the arrangement would be based on procedures and not the patient's insurance coverage, and all payments would be subject to the cap on federal health care programs.

(4) there would be protections against inappropriate reductions in service because the arrangement utilized objective historical and clinical measures to establish baseline thresholds for payment.

(5) the product standardization portion of the arrangement protected against inappropriate reductions in services because it ensured that individual physicians would have available the same selection of devices as before the arrangement.

(6) the hospital and the cardiology groups would provide patients with written disclosures of the hospital's and physician's involvement in the program and would provide patients an opportunity to review the cost savings recommendations before their admissions.

(7) financial incentives are limited in duration and amount.

(8) the cardiology group profits are distributed on a per member, per capita basis and therefore any incentive for an individual cardiologist to generate disproportionate cost savings was mitigated.

The anti-kickback statute. The anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a federal health care program. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. The OIG has been concerned that the compensation arrangement would be used to disguise remuneration from the hospital to reward or induce referrals. Since the cardiologists would receive not only their Medicare Part B professional fee, but also, indirectly, a share of the hospital's payment, and because there is no applicable safe harbor, the program would be subject to the statute's applicability.

Safeguards. However, the OIG would not impose sanctions because the arrangement contains specific safeguards and was deemed to pose a low risk of fraud or abuse under the anti-kickback statute. Specifically, the program provided that

(1) the circumstances and safeguards of the arrangement would reduce the likelihood that it would be used to attract referring physicians or to increase referrals from existing physicians.

(2) the structure of the arrangement would eliminate the risk it would be used to reward surgeons or other physicians who refer patients.

(3) the arrangement sets forth with specificity the particular actions that would generate the cost savings on which the payments would be based.

The OIG reiterated its concern that many cost sharing programs between hospitals and physicians would be subject to both CMPs and violations of the anti-kickback statute. Any arrangement that has been used to disguise payments for referrals or poses a heightened potential for patient steering or unfair competition would be suspect. The OIG clearly stated that its opinion was predicated on this arrangement only and was limited to this arrangement. And then it cautioned that even if a new arrangement was similar to this one, it could raise different concerns that could lead to very different results than seen here. ■

OIG Advisory Opinion 05-02, February 10, 2005,¶500,124

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No sanctions imposed on proposed cardiac surgery cost savings arrangement

by Anuradha Gupta, JD, Contributing Editor

The Office of Inspector General (OIG) determined that a proposed cost savings arrangement between an acute care hospital and a professional cardiac surgery group could potentially result in improper payment implicating the civil money penalty (CMP) and the anti-kickback statute under the Social Security Act (the Act).

Under the arrangement, the hospital would pay the surgeon group 50 percent of the first year cost savings directly attributable to specific changes in the surgeon group's operating room practices. The measurement of cost savings would be based on the surgeons' use of specific supplies during designated cardiac surgery procedures. According to the program administrator, twenty-nine specific cost savings opportunities were identified that were roughly grouped into the following four categories: (1) opening packaged items only as needed during a procedure; (2) performing blood cross-matching only as needed; (3) substituting, in whole or part, of less costly items for the items currently being used by the surgeons; and (5) product standardization of certain cardiac heart valves where medically appropriate.

Although nearly all of these cost savings opportunities implicate the CMP section of the Act by constituting an inducement to reduce or limit the current medical practice at the hospital, there are several features that provide sufficient safeguards so that the OIG would not seek sanctions under the Act. These features include: (1) the transparency of incentives allowing for public scrutiny and accountability through the medical-legal professional liability system, (2) medical support that patient care should not be adversely affected, (3) payments being based on all surgeries, regardless of patients' insurance coverage, and (4) product standardization ensuring the same selection of devices. In addition, these safeguards reduce the likelihood that the arrangement will be used to attract referring physicians or to increase referrals from existing physicians.

Accordingly, the OIG concluded that (1) sanctions would not be imposed on the requesters in connection with the proposed arrangement even though it would constitue an improper payment to induce reduction or limitation of services; and (2) the proposed arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of federal health care program business were present, but sanctions would not be imposed in the particular cirumstances presented in this case. ■

OIG Advisory Opinion No. 05-03, February 10, 2005,¶500,125

Legal and structuring considerations of hospital-physician joint ventures

by Catherine Hubbard, MA, Contributing Editor

Before entering a joint venture, hospitals and physicians should keep several strategic considerations in mind, such as how the deal will be financed, reimbursed and managed, according to Roger Strode, a partner with Quarles & Brady, Milwaukee, Wisconsin. "Planning and deal execution are key to developing a sustainable partnership," he said during a February 3 Health Financial Management Association conference on hospital-physician joint ventures.

Strode recommended physicians consider how the joint venture would impact physicians who aren't involved in the deal and their relationship with them. "That's something you really have to consider," he said.

Other considerations include what percent of the service line market the hospital currently controls and whether it can increase its market share with a joint venture. He also emphasized the importance of developing an exit strategy when forming a joint venture.

Preparation for these deals should encompass assessment of physician objectives, said Strode, who represents hospitals, physician groups and specialty hospitals. "Often hospitals will want to jump into a deal with doctors without fully thinking through what the physicians want," he said. "It's as simple as sitting the physicians down and ... asking them what it is they want to accomplish rather than assuming what they want, you have to ask them," he said.

If the needs of the hospital and physicians mesh, Strode said, then the lawyer can build a legal case around

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On The Front Lines

Inpatient psychiatric facilities prospective payment system

by Patricia L. Brent, J.D, M.P.H.

In this On The Front Lines article, Patricia Brent discusses the development and implementation of a prospective payment system (PPS) for psychiatric facilities.

In 1983, when Congress initially directed implementation of a prospective payment system (PPS) for inpatient acute care hospital services, certain types of specialty hospitals were excluded from the PPS and were allowed to continue being paid on a reasonable cost-based payment system.[1] This included psychiatric hospitals and psychiatric units in acute care hospitals, long-term care hospitals (LTCH), children's hospitals and rehabilitation hospitals and rehabilitation units in acute care hospitals. Cancer hospitals were later added to this list of excluded hospitals.[2]

Since then, Congress has enacted various PPS-type reimbursement systems for certain previously excluded hospitals, including inpatient rehabilitation facilities and rehabilitation units in general hospitals and long-term care hospitals and long-term care units within general hospitals.[3]

In 1999, Congress mandated that a PPS reimbursement system be developed for psychiatric hospitals and psychiatric units in general hospitals (IPF-PPS), to be implemented beginning in October 2002.[4] However, due to development problems, implementation of the IPF-PPS was delayed, thus not becoming effective until cost-reporting periods beginning on January 1, 2005. This article discusses the development and implementation of a prospective payment system for psychiatric facilities and units.

Development Problems from the Beginning

Although the PPS for inpatient psychiatric hospital services and psychiatric units began on January 1, 2005, its development was slow from the beginning. Generally, the creation of a whole new PPS requires an extraordinary amount of lead time in order to conduct the research necessary to accurately develop a new system, including creating data files, testing differing proposed models of reimbursement, and reviewing in-depth cost reports and analyses of system variables.

Complicating the developmental timeline was the enactment of the Medicare Modernization Act, Section 902, which required that the timeliness for regulations to be issued not exceed three years after publication of the preceding proposed or interim final regulations, except under exceptional circumstances.[5] Thus, while the statutory requirements fixed an October 1, 2002 deadline for implementation, the creation process required a maximum length of time to get the system in "running condition." The Proposed Final Rule for the IPF-PPS was issued on November 28, 2003,[6] with the Final Rule being issued on November 15, 2004.[7]

IPFs Affected by IPF-PPS

Inpatient psychiatric facilities (IPFs) are certified under Medicare as inpatient psychiatric hospitals or designated psychiatric units within a general hospital, primarily providing psychiatric services for the diagnosis and treatment of mental illness. An IPF must maintain the clinical records necessary to determine the degree and intensity of the treatment provided to the mentally ill patient and meet staffing requirements sufficient to implement an active treatment program.

Applicability of the IPF-PPS

The new IPF-PPS applies to approximately 1,800 facilities, including freestanding psychiatric hospitals, certified distinct part psychiatric units in general hospitals, and distinct part psychiatric units in critical access hospitals (CAHs), and psychiatric units covered under Sections 412.22, 412.23, 412.25 and 412.27.[8]

Specifically excluded from the IPF-PPS are the following:

- Veterans' Administration hospitals;
- Hospitals reimbursed under state cost control systems approved under 42 CFR part 403;
- Hospitals in Maryland;
- Non-Medicare participating hospitals; and
- Hospitals reimbursed under special demonstration projects funded by the federal government.

Implementation Dates

While the implementation date is effective for a cost-reporting period beginning on or after January 1, 2005, actual claims processing won't begin until April 4, 2005, in order to complete the necessary changes in the computer systems. CMS plans to reconcile the payments after April 1, 2005, with a mass adjustment occurring by July 1, 2005. Thus, for cost reporting periods beginning on or after January 1, 2005, but before April 1, 2005, TEFRA payment amounts will be issued, with a blended TEFRA/PPS payment issued later, after reconciliation is completed.[9]

Phase-in (Transition) Period of the IPF-PPS

There is a three-year "phase-in" (transition) period that incorporates a blending of TEFRA (reasonable cost-based payments with cost limits) and IPF-PPS payments. Over the transition period, there will be a decreasing percentage of the total payment coming from TEFRA limits and, at the same time, the IPF-PPS fraction of the total payment will increase (see the Table below). The transition payments will made only to existing providers. Newly established IPFs will be paid the full PPS federal per diem amount (100 percent IPF-PPS).[10]

Transition Year	Cost Report Period Beginning on or After	TEFRA Percent	IPF-PPS Percent
1	January 1, 2005	75%	25%
2	January 1, 2006	50%	50%
3	January 1, 2007	25%	75%
	January 1, 2008	0%	100%

The Basis of the IPF-PPS Payment Structure

The IPF-PPS is structured in a similar manner to other prospective payments systems currently in use, such as with inpatient rehabilitation facilities (IRF-PPS) and long-term care hospitals (LTC-PPS). The initial BBRA required that a budget-neutral, per diem prospective payment be established and that it include an adequate patient classification system that reflected the differences in patient resource use and costs amount psychiatric hospitals and psychiatric units. Budget neutrality requires that the payments for these services must not total more than they would have under the previous TEFRA payment system.

There is a federal payment for each patient day in an IPF. This payment amount is derived from the national average daily routine operating, ancillary and capital costs in IPFs.[11] The per diem rate covers nearly all the labor and non-labor cost of providing patient care but excludes bad debts and other costs specifically separated from the base per diem rate. Included in the federal base payment rate are:

- Operating costs;
- Ancillary costs; and
- Capital costs.

Durable medical equipment costs and physician and professional costs are not included in the base per diem rate. The federal per diem base rate is $575.95, with a labor share (0.7258) of $417.73 and a non-labor share (0.27472) of $158.22.[12]

This per diem rate is then adjusted by factors that account for differences in patient and facility characteristics that might cause variations in patient resource utilization.

Payment Adjustments

In addition to the federal base per diem rate payment, there are certain payments, called adjustments, which are added on to the federal base payment amount. These adjustments are characterized as "facility-related adjustments" or "patient-related adjustments."

Facility-related adjustments are defined as additional payments made to the base rate that account for special circumstances experienced by some facilities.[13] Among these, where applicable, are:

- Wage index adjustment—CMS is using the unadjusted FY 2005 pre-reclassified IPPS wage index.
- Rural location adjustment—CMS is allowing for a 17 percent adjustment for hospitals that are located in CMS-defined rural areas.[14]
- Teaching facility status adjustment—the adjustment parallels the IME adjustment for IPPS hospitals, using a ratio of interns and residents to the average daily census, plus 1, raised to the power of 0.5150.[15]
- COLA adjustment for IPFs in Hawaii and Alaska;[16] and
- Emergency Department adjustment—for IPFs that maintain a full service emergency department, CMS will provide an adjustment factor of 1.31, added to each case's base payment rate for the first day of admission. In order to qualify, the Emergency Department must be a dedicated ER, have provider-based status, be licensed by the state, advertised to the public and have one third of all its outpatients seeking urgent treatment for emergency conditions (i.e., not having made a previously scheduled appointment).[17]

Patient-related adjustments, where applicable, account for individual patient circumstances that are unique to each case. They include:

- DRG adjustment—CMS is providing for all DRGs that contain a psychiatric ICD-9-CM code, with a principal diagnosis included in Chapter Five of the ICD-9-CM or the DSM-IV-TR. These will be classified based on 3M's Grouper 32. If a code does not group to one of the 15 DRGs, then a DRG adjustment will not be paid, although the base IPF-PPS payment rate will apply.[18]
- Co-morbidities—CMS will provide an additional payment amount to a case with a designated co-morbidity, as listed in the Final Rule. The co-morbidity adjustment will be applied to each day of the stay. There is also a co-morbidity adjustment for developmentally-disabled patients in order to reflect their higher per diem costs.[19]
- Patient age—CMS also provides an additional adjustment factor for patients with ages greater than 45, calculated us-

ing five year increments. Patients under 45 years of age will receive the base payment rate.[20]

- Variable per diem adjustment—CMS included a payment adjustment that accounts for differing lengths of stays and is intended to reflect the higher costs associated with the early part of an inpatient stay.[21]

Other IPF-PPS Adjustments

There are other adjustments that may be made to the IPF base payment rate, depending on the circumstances, including the following:

- Electroconvulsive therapy treatments (ECT)—CMS provides a payment adjustment of $247.96 as an add-on to the federal base payment rate to account for the high cost of providing ECT treatments. To receive this payment IPFs must include Revenue Code 0901 on their claim form and the procedure code 94.27, as well as indicate the number of treatment units provided to the patient.[22]
- Outlier payments—as in other PPS systems, CMS provides an outlier adjustment to providers for cases that are extraordinarily costly. Outlier payments are considered to be a risk-sharing mechanism between the provider and CMS. For IPFs, the most costly cases usually are those with the longer lengths of stay. Outlier payments are made on a per-case basis, with a PPS payment plus a fixed dollar loss amount of $5700. The threshold is adjusted for wage area, teaching, rural location, and COLA.[23]
- Stop-loss payments—CMS has also adopted a "stop-loss" payment policy in order to target IPFs that may experience the greatest negative impact relative to current payments and to limit the size of the reductions to the federal per diem in order to maintain budget neutrality. The stop-loss payment will be equal to 70 percent, i.e., the new IPF payment would be equal to no less than a minimum of 70 percent of the expected TEFRA payment during the three-year transition period. This stop-loss provides an additional risk-sharing arrangement (to the outlier payment).[24]
- Periodic Interim Payments—are available for providers already receiving PIPs.
- Interrupted Stays—this policy is similar to interrupted stay policies used in PPS reimbursement systems for Inpatient Rehabilitation Facilities and Long-Term Care Hospitals. If a patient is discharged from an IPF and admitted to any IPF within three consecutive days of the discharge from the original stay, the stay would be treated as continuous for the purposes of the variables.[25]

Future Updates and Anticipated Refinements

The first update of the IPF-PPS is expected to be on July 1, 2006. The annual updates will cycle in 12-month intervals and will include capital market basket updates, updates to the hospital wage index, fixed dollar loss threshold amount relating to the outlier payments and any update related to ECT adjustments. The first payment update will be effective for July 1, 2008.

Because of the implementation timeline requirements enacted in the MMA (see explanation above), at least one component of the IPF-PPS still remains under development and is currently undergoing OMB review and feasibility testing for potential use. This is known as the Case Mix Assessment Tool (CMAT), developed by the University of Michigan. When the results of the CMAT feasibility test become available, CMS will make them public. Also, there is additional research currently being conducted to help provide information on staffing resources needed to provide quality inpatient psychiatric care. Furthermore, CMS expects that, in the coming months, more information on differences between IPFs, unit characteristics, patient characteristics, discharge and transfer criteria and economic incentives will become available.

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1 Social Security Act, §1886 (d)(1)(B).
2 Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, §6004(a).
3 See Balanced Budget Act of 1997 (BBA), Pub. L. No. 105-33; The Medicare, Medicaid & SCHIP Balance Budget Refinement Act of 1999 (BBRA), Pub. L. No. 103-113; and The Medicare, Medicaid & SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Pub. L. No. 106-554.
4 The Medicare, Medicaid & SCHIP Balanced Budget Refinement Act of 1999 (BBRA), §124, Pub. L. No. 103-113.
5 The Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA), §902, Pub. L. No. 108-173.
6 Proposed rule, 68 FR 66920, November 28, 2003.
7 Final rule, 69 FR 66922, November 15, 2004.
8 Id. at 66972.
9 Id. at 66924.
10 Id. at 66964.
11 Id. at 66930.
12 Id. at 66982
13 Id. at 66952.
14 Id. at 66954.
15 Id.
16 Id. at 66057.
17 Id. at 66959.
18 Id. at 66936.
19 Id. at 66938.
20 Id. at 66946.
21 Id. at 66947.
22 Id. at 66951.
23 Id. at 66960.
24 Id. at 66964.
25 Id. at 66962.

the Stark II rule and establish that the joint venture makes good business sense and that it's not a structure designed to induce physician referrals. "The worst case scenario is sitting down with the business people and physicians constructing a deal that has pieces of it that are illegal," he said. "You need to understand up front what your legal constraints are," he said.

Anti-referral statutes. Both the anti-kickback statute and Stark II have to be analyzed whenever you do this deal. "There needs to be a rational justification for doing these deals," Strode emphasized.

These closely related laws are aimed at certain designated health services reimbursed under Medicare, including imaging and inpatient/outpatient hospital services. "Most physician/hospital deals will implicate Stark II and will need to be structured to comply with a specific Stark II exception," Strode said.

Stark II is a civil, strict liability statute, said Strode, adding that the deal structure must meet the exact terms of a safe harbor. "Your structure needs to fit within the four corners of an appropriate exception, or you can't do the deal," he said.

Strode also advised that physicians should take an active role in the operations of the venture. "The deals need to be real deals," he said.

The anti-kickback statute is a broad criminal statute that makes it illegal to pay or receive any remuneration in exchange for referring or accepting referrals of Medicare or Medicaid reimbursable items or services. The safe harbors are similar to the Stark II exceptions that say that if the arrangement is not within a safe harbor, the remuneration will not be deemed remuneration for purposes of the statute, said Strode. "If you can't structure within the confines of a safe harbor," he said, "the OIG [Office of Inspector General] can look at your deal," he said. "You need to assess [whether] what you're doing is in fact an inducement for a referral."

Strode noted that most physician/hospital deals can be structured to comply with applicable safe harbors. However, he said, the OIG is saying that physicians are setting up a captive patient base, are contributing very little financial risk and reaping the benefits off the business. He noted there is significant OIG guidance under the anti-kickback statute, showing it is concerned.

Tax status. Tax-exempt hospitals will need to be mindful of inurement and private benefit concerns, Strode said. He noted that certain ventures may throw off taxable income to the hospital in the form of unrelated business taxable income. "Taxes may need to be factored into any pro-forma financial projections," he said. "Protect exempt status of what you're borrowing and the hospital," he advised.

Regarding financing, Strode said that while hospitals are used to borrowing on a tax-exempt basis, when structuring a joint venture, that's not likely to happen. "If you do a deal with physicians, likely you are not going to be able to borrow money on a tax-exempt basis," he said. "Therefore, the cost of capital in the deal is going to be higher," which will require higher margins, he added.

Strode also warned that most joint ventures become reimbursement plays, advising, "Never go into a joint venture with physicians without determining how the services involved will be reimbursed." ■

CCH Washington Bureau, February 25, 2005

OIG addresses proposed cost sharing arrangement with cardiology groups

by Gené Stephens, JD, Contributing Editor

A proposed arrangement in which a hospital would share a percentage of its cost savings with eight cardiology groups to assist with the implementation of cost reduction measures would implicate both the antikickback statute and physician self-referral laws, as well as the civil monetary penalty provisions for reduction of direct patient care services provided to federal health care program beneficiaries. However, the proposed arrangement had several features that, in combination, provided sufficient safeguards to avoid the imposition of sanctions and civil monetary penalties by the OIG.

Under the proposed arrangement, the hospital would pay each of the cardiology groups a share of the first year's cost savings directly attributable to specific changes in each of the cardiology group's cardiac catheterization laboratory practices. The results of the cost savings would be summarized in a Practice Patterns Report with seventeen recommendations addressing ways to reduce the inappropriate use or waste of medical supplies in three categories. Compensation, under the proposed arrangement, would be paid to each cardiology group for services performed under individual contracts and would constitute 50 percent of the difference between the individual cardiologist group's adjusted current year costs and base year costs. While the proposed arrangement, if properly structured, would serve legitimate business and medical purposes, each of the seventeen recommendations regarding the standardization of devices and limitations on the use of vascular closure devices and products substitution would constitute an inducement to reduce or limit the hospital's medical practice. The OIG, however, refused to impose administrative sanctions because the proposed arrangement contained clear quality of care measurements and limitations on physician referrals.

While the proposed arrangement, if properly structured, would serve legitimate business and medical purposes, each of the seventeen recommendations regarding the standardization of devices and limitations on the use of vascular closure devices and products substitution would constitute an inducement to reduce or limit the hospital's medical practice. The OIG, however, refused to impose administrative sanctions because the proposed arrangement contained clear quality of care measurements and limitations on physician referrals. ■

OIG Advisory Opinion No. 05-04, February 10, 2005, ¶500,126

Preventing patient identity theft

by Catherine Hubbard, MA, Contributing Editor

Patients are especially vulnerable to identity theft, but there are several steps providers can take to reduce the chances their patients will become victims and to help those who do become victims to respond in the best possible way.

"Health care organizations are particularly vulnerable to ID theft crime due to the wealth of patient personal, demographic and financial information that we collect, we transmit and we maintain in the course of our daily operations," said Nancy Davis, MS, RHIA, director of privacy and security officer for Ministry Health Care, Milwaukee, Wisconsin, during a February 22 audio seminar sponsored by the American Health Information Management Association.

Organizations fear hacking into databases to steal not only their patients' health information, but also demographic information, including names, addresses, Social Security Numbers and credit card account numbers, Davis said. "We must be aware of the threat that identity theft poses to our organizations and take proactive steps to prevent opportunities for identity theft," she said. If these steps fail, then providers need to have a plan to mitigate damage to victims and to the organization, she emphasized.

One of the main challenges health information managers face is to ensure preventive safeguards to protect the privacy and security of patient information and then to balance the privacy protections and regulations when disclosing information to patients and law enforcement agencies, said Davis. "It is in our best interest to recognize the impact that identity theft has on our organizations [and] how this crime impacts us as HIM professionals," she said. She predicted that the challenges will only continue to grow.

In 2004, there were 9.3 new victims of identity fraud, said Kimberly Roberts, MSA, RHIA, CHP, privacy manager and HIM operation manager for a large teaching hospital in Michigan.

Davis suggested developing guidelines for how victims can respond. Providers also should document any incidents, she said.

In addition, organizations should plan ahead how they will respond to an internal ID theft event, respond to a patient request for an amendment of their PHI (personal health information) due to ID theft and what external guidance they have available, Davis suggested. When developing a plan or policy for dealing with ID theft, she said, the organization should consider their areas of vulnerability.

Responding to incidents. In response to an ID theft event, health care organizations need to determine whether they need to contact the patient. "My guess would be in most cases you would," Davis said. The organizations should describe to the patient what is known about the compromise, explain what the appropriate responses are, provide current resources regarding ID theft and provide contact information for law enforcement officers assigned to the case, she said. They also should determine the need for a media release or response and should consider proactively drafting a media release, she added.

Davis told of a recent incident at a hospital that suspected 85 cases of ID theft, yet the story broke in the news. "Had that organization been [more] prepared, they might have issued a proactive release," she said. "You want to respond if the scope of your identity theft is big enough to make the press," she advised.

If there is an information technology or systems component to the ID theft, the organization should consider activating the IS security incident response team, said Davis. "Most organizations have those in place," she said. In addition, she said, the organizations should identify and sequester pertinent records and suspend billing processes.

The provider also should ask the victim to review their PHI to determine if it's accurate, Davis said. If the victim determines the information is not accurate, she said, the organization should request that the victim's request to amend PHI be in writing. The victim should provide supporting documentation, often in the form of a police report or an affidavit of ID theft. Davis said she would not feel comfortable moving forward if the victim doesn't supply the supporting documents. She noted that her company has policies and procedures in place to deal with amendment requests. "Because of HIPAA, we certainly have a process and a policy in place for amendment requests and we understand that we have the ability to deny that amendment request, knowing that the victim may appeal," she said.

Follow-up and prevention. After the event, the organization should follow up with a "post-mortem" evaluation to review the event, identify risk factors, assess the organization's response and determine the need for added safeguards, Davis suggested.

To help prevent ID theft, hospitals should consider minimizing or eliminating Social Security Numbers as a patient identifier, instituting physical safeguards for electronic and paper PHI, and using appropriate disposal and destruction of PHI, Davis said. "The identity theft events are happening more often because of paper trail information than electronic trail information," she said, referring to recent research. Organizations also should increase staff training, education and awareness, focusing most of the training on how to respond to an ID theft event, Davis said. ■

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