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FY 2007 OIG Work Plan
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John asks the leadership your questions

Editors note: John Falcetano is Chief Audit/Compliance Officer for University Health Systems of Eastern Carolina and a long-time member of HCCA. This column has been created to give members the opportunity to submit their questions by e-mail to Jfalcetano@cox.net and have John contact members of HCCA leadership for their response.

Question: Our facility only provides a business associate with limited data set personal health information (PHI). Do we need to have a “data use agreement”?

The answer is provided by Marti Arvin, JD, CHC, CCEP, CIPP/G CPC. Marti is the Privacy Officer at the University of Louisville.

It depends. If the business associate is the ultimate recipient of the limited data set, then yes, your organization will need a “data use agreement” as well as a “business associate agreement.”

If the business associate’s function is to create a limited data set on your organization’s behalf and then provide that to the final recipient, the “data use agreement” would need to be with the ultimate recipient of the limited data set and your organization.

If the business associate is creating the limited data set on behalf of your organization and is the ultimate recipient, then your organization will need both agreements with the business associate.

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Inserted in this issue of Compliance Today is a quiz related to an article: “Compliance officers in the line of fire?” by Ronald H. Levine, on page 4.

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Compliance officers in the line of fire? Document considerations and obstruction of justice

By Ronald H. Levine

Editor’s note: Ronald H. Levine is a partner at the law firm of Post & Schell, PC in Philadelphia. Mr. Levine was previously Chief of the Criminal Division of the U.S. Attorney’s Office for the Eastern District of Pennsylvania. He can be reached by e-mail at rlevine@postschell.com.

In some organizations, both large and small, compliance officers wear several hats. For better or worse, sometimes their duties include collecting or overseeing the collection of documents integral to an internal investigation, and/or responding to government subpoenas and the like. If so, the compliance officer likely will be in communication with the company’s in-house or outside counsel about this process. At the very least, the compliance officer may possess non-privileged documents that are requested during an internal inquiry or demanded by the government.

In this environment, compliance officers should be aware of the reach of federal obstruction of justice and spoliation exposures, the limits of the attorney-client privilege, and the government’s recent aggressive use of the crime-fraud exception to pierce otherwise privileged communications about document production.

Obstruction of justice exposures
If there were any doubts that the federal government could reach almost any act arguably constituting obstruction of justice, the doubts were resolved by a Sarbanes-Oxley Act (SOX) addition to the Federal Criminal Code. That SOX amendment (18 U.S.C. § 1519) provides that:

Whoever knowingly alters, destroys…conceals…any…document…with the intent to impede…the investigation or proper administration of any matter within the jurisdiction of any department or agency of the United States,…or in relation to or contemplation of any such matter…(emphasis added).

Obstruction is serious stuff. Section 1519 provides for a maximum penalty of 20 years in jail, and the advisory Federal Sentencing Guidelines call for a “base offense level” sentence of 15 to 21 months imprisonment.

Note the sweeping embrace of Section 1519. It does not require that a federal investigation actually be pending, known about, or even expected at the time of the alleged obstruction. The “administration of a matter” before a federal agency can occur long before a civil or criminal investigation commences. Moreover, even if the “administration” of the matter has not commenced, obstruction may still lie under this statute if the alleged misconduct occurred “in contemplation” of the matter.

Thus, under this statute, the government may view the destruction of documents to be obstruction of justice, if, at the time of destruction, the entity had reasonable grounds to think that a government inquiry would be commenced or to believe that the government would make inquiry if it knew of the facts which the corporation has learned. While one would hope that the exercise of prosecutorial discretion would confine the enforcement of this broad statute to “clear” cases of obstruction, it is, as yet, relatively untested.

Spoliation and other exposures related to document destruction

Even short of criminal obstruction of justice charges, prejudice to the organization can arise from careless handling of documents either related to an internal investigation or likely subject to subpoena or discovery requests. Thus, in civil litigation, the destruction of documents after the organization is on notice of a threatened civil lawsuit can result in findings of “spoliation” of evidence, adverse evidentiary inferences drawn against the organization, and substantial financial sanctions.

The now famous Zubulake case (Zubulake v. UBS Warburg LLC, 229 Federal Research Division 422 [S.D.N.Y. 2004]) illustrates exactly these dangers. In that employment litigation, the employer’s alleged failure to retain and readily produce backup tapes containing relevant e-mails ultimately led to a U.S. District Court finding that the employer had willfully deleted relevant e-mails. The employee’s motion for sanctions was granted, the employer was ordered to pay costs, and the jury was instructed that it could draw an inference adverse to the employer from the fact of the missing documents.

Finally, even short of an outright criminal obstruction of justice prosecution or civil spoliation claim, the perception that a company
The privilege generally does not embrace providing legal advice (8 Wigmore, Evidence § 2292, at 554 (McNaughton Rev. 1961)). The privilege generally does not embrace communications between corporate counsel and a third party, because the presence of the third party destroys the confidentiality of the communication.

However, the courts have acknowledged the complexities of the modern corporation and the underlying misconduct being investigated. On the criminal side, it could tip the scales between a corporation being charged with the underlying crime or not. It could also mean the difference between simple disgorgement and double or triple damages under the False Claims Act. Finally, it could provide a basis for civil liability of upper management or board members.

In short, document integrity policies – as part of a larger compliance program – can have a far reaching impact on whether the company and its representatives are perceived as a good corporate citizen or the reverse by the government and potential civil litigants. To the extent the compliance officers are a part of the document retrieval process, the compliance officers – in consultation with organization counsel – should document their efforts in this regard. This might entail a memorandum-to-file detailing the persons contacted regarding the document collection effort, locations from which documents were retrieved, and assurances from persons contacted that a good faith search was made for responsive documents.

The attorney-client privilege and the crime-fraud exception

Compliance officers often talk with company counsel about document collection. Are those conversations privileged? It depends. The attorney-client privilege applies to: (a) all communications between client and counsel; (b) intended to be, and in fact, kept confidential; (c) made for the purpose of obtaining or providing legal advice (8 Wigmore, Evidence § 2292, at 554 (McNaughton Rev. 1961)). The privilege generally does not embrace

The corporate manager (i.e., the compliance officer) to communicate the fact of the subpoena and provide legal advice about which documents were sought by the government. The manager subsequently failed to direct that
e-mail deletions must cease, including e-mails embraced by the subpoena. The manager was targeted for obstruction of justice.

The Court ruled that the crime-fraud exception applied and that the corporate counsel could be compelled to testify about his communications with the manager and also to produce his notes regarding those communications. The Court found that the government’s ex parte submission (i.e., a communication directly with the judge about the issues in the case without the other parties’ knowledge), an FBI agent’s affidavit, was sufficient to support the finding that the manager “could be found to have engaged in the ongoing crime of obstruction of justice.” (In Re Grand Jury Investigation, 445 F.3d at 275-76). Yet, the Court appeared to stretch the crime-fraud exception.

The Court found it of no moment that the attorney, and not the manager, initiated the telephone call. It then devoted its analysis to supporting the proposition that if the manager had knowledge from the corporate attorney of the government’s interest in retrieving certain e-mails, but then failed to direct that e-mail deletions cease, she could be viewed as furthering an obstruction for purposes of the crime-fraud exception to the privilege (In Re Grand Jury Investigation, 445 F.3d at 275).

The Court implied that the crime-fraud exception would apply even without a showing that, at the time of the legal advice, the manager intended to commit a crime. Such an open-ended application of the crime-fraud exception is of great concern. How far the

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courts will go in permitting the government to invade the attorney-client privilege by using the crime-fraud exception is an unfolding story. Yet the potential for aggressive government action mandates that compliance officers speak with corporate counsel about ways to ensure that their communications about document production are afforded the protection of the privilege and that compliance officers adhere to the letter of counsel’s directives regarding document “holds” and document collection.

Conclusions and tips
Whether compliance officers should be involved in document retrieval and collection is a matter for reasonable debate. To the extent that compliance officers do become involved in document retrieval and collection during an internal investigation, or in response to government inquiries, it is important to be aware of these potential exposures, both personal and corporate.

Practically, compliance officers involved in the document production process should consider the following tips:

□ Understand that document destruction is not a crime when it is part of an ongoing, legitimate document retention/destruction policy, but that:
  □ Documents must never be destroyed for purpose of having them unavailable for a government inquiry; and
  □ Documents must be preserved when there exist reasonable grounds to believe that a government or civil inquiry about matters relating to those documents will be coming or you learn of facts, which if known to the government, would reasonably lead to government inquiry.

□ Speak with corporate counsel directing the responsive document retrieval process so that you understand both what is expected of you and in what way the process is to be documented.

□ Speak with corporate counsel about ways to ensure that your communications about document production are afforded the protection of the privilege.

□ Adhere to the letter of counsel’s directives regarding document “holds” and document collection.

□ With corporate counsel’s knowledge and approval:
  □ Document all instructions and directives from company counsel regarding your duties and responsibilities in the document collection process; and
  □ To the extent you have responsibility for actually making inquiry of others in the organization about their possession of responsive documents, document with whom you speak, their response, and what they produce.

□ Make sure that you are thinking about electronic as well as hard copy documents, and on-site as well as off-site locations, in the retrieval process.

To earn one CEU for this article, take the quiz inserted in the envelope with this issue of Compliance Today.
Editor’s note: The following articles will review hospital, physician, home care/LTC/hospice, and pharmaceutical issues outlined in the U.S. Department of Health and Human Services Office of Inspector General Work Plan Fiscal Year 2007. We thank the authors for their contributions to this Compliance Today Feature Focus. If you have questions you may contact the authors by telephone:

■ Carel Hedlund, a principal in the Baltimore Office of Ober, Kaler, Grimes & Shriver, may be reached at 410/347-7366.
■ Asha B. Scielzo, an Associate in the Washington, D.C. office of Jones Day, may be reached at 202/879-5449.
■ Lisa M. Silveria, the Home Care Compliance Officer for Catholic Healthcare West, may be reached at 209/956-2608.
■ Sarah Giesting, a consultant with Polaris Management Partners, may be reached at 212/502-1870.

Hospital issues

By Carel T. Hedlund


The portion of the Work Plan relating to the programs administered by The Centers for Medicare and Medicaid (CMS) is an essential resource for hospital compliance programs. It identifies those Medicare and Medicaid areas where the government believes it may be vulnerable to overpayments caused, at best, by inaccuracies in billing, cost reporting, and system weaknesses, and, at worst, by intentional efforts to defraud the programs. It thus provides a “head’s up” for potential investigations and enforcement actions by the government, giving hospitals an opportunity to review and revise their operations, if necessary, to ensure compliance.

Hospitals are well advised to review the Work Plan carefully. This, of course, includes a close review of the sections specifically labeled as “hospital” issues. Hospitals should also do at least a passing review of other sections of the plan, such as physician issues, that may affect those sectors of the healthcare system in which hospitals regularly interact, because the issues identified for those components could cause changes in behavior or operations that could affect hospitals as well.

Hospitals may want to send copies of the physician section of the Work Plan to their medical staffs, as well.

Compliance committees should review the Work Plan to identify any new issues, not previously reviewed by the committee, that may present particular areas of risk, given their operations, services and structure, and document this review in their minutes. For issues that are determined to be potential risk areas, they should convene the appropriate internal staff to review the systems and procedures in place, and consider an internal or external audit of given issue. This rigorous review process provides the opportunity to identify any training that might be needed in a specific area, as well as changes in policies or procedures that might be necessary to ensure the identified requirements are met and that billing to governmental programs is accurate.

The following identifies the Medicare and Medicaid issues for hospitals that will be the subject of OIG’s focus in the coming year. It also highlights other areas that may be of interest to hospitals. My comments are in italics.

New Medicare hospital initiatives

The Work Plan identifies the following eleven items as “new starts.”

1. Hospital capital payments. In the course of examining the accuracy and appropriateness of the method used to update the inpatient capital rates, OIG will also determine whether hospitals have used capital payments for their intended purposes. This may involve a review of whether hospitals are appropriately classifying costs as capital or operating costs.

2. Medicare-dependent hospital (MDH) program. OIG will examine the appropriateness of Fiscal Year (FY) 2002 base-year costs for MDHs, which are used to determine MDH payments beginning October 1, 2006, if they result in higher payments than the inpatient prospective payment system (IPPS). Base-year costs under the various prospective payment method-
ologies [this is not about IPPS] are always a target for government scrutiny, because they can determine payment for years to come. MDHs may want to review their FY 2002 cost reports to determine whether there are any corrections that should be reported to the Intermediary.

3. Inpatient rehabilitation facility (IRF) classification criteria. OIG will review the extent to which admissions to IRFs meet specific regulatory requirements and whether the IRFs billed for services in compliance with Medicare regulations. The Medicare program has been concerned for years with whether IRFs are meeting the criteria for admitting a threshold percentage of patients with specific diagnoses in order to be excluded from IPPS.1 IRFs already should have in place a rigorous monitoring process to ensure they continue to meet these criteria. Although OIG termed this a “new start,” this issue also appeared in prior Work Plans.

4. Inpatient rehabilitation payments - late assessments. OIG will examine the accuracy of Medicare payments for inpatient rehabilitation stays when the patient admission and discharge assessments are entered late, and will determine how Intermediaries make these adjustments and confirm that payments are accurate. Although called a “new start,” this item also appeared in the FY 2006 Work Plan. While this review focuses on Intermediary processes, it will likely be accomplished by reviewing payments to individual IRFs. IRFs should review the timelines of their transmissions of admission and discharge assessments, and whether their payments have been properly reduced by 25 percent when the assessments have been submitted late. IRFs should report any errors in payment to the Intermediary.

5. Long-term care hospital (LTCHs) admissions. OIG will scrutinize the extent to which LTCHs are receiving most of their patients from a single acute care hospital, thus effectively functioning as units of those hospitals. This OIG evaluation could result in recommendations to CMS to re-evaluate the LTCH status of certain hospitals or to change the criteria for qualifying as an LTCH.

6. Long-term care hospital classification. OIG will also evaluate whether hospitals currently reimbursed as LTCHs are in compliance with the average length of stay (ALOS) criteria. In general, to qualify as a long-term care hospital, a hospital must have an ALOS greater than 25 days for Medicare inpatients. While this is a new study item for OIG, LTCHs should already have in place a rigorous monitoring program to ensure they comply with the ALOS threshold.

7. Unbundling of hospital outpatient services. OIG will review the extent to which hospitals and other providers have been submitting claims for services that should be bundled into outpatient services. Although the FY 2007 Work Plan indicates this is a “new start,” it appears to be a repeat from the FY 2006 Work Plan.

8. “Inpatient only” services performed in an outpatient setting. OIG will assess whether Medicare payments are appropriately denied for “inpatient only” and related services performed in an outpatient setting and the extent to which Medicare beneficiaries are held liable for denied inpatient claims for these services. This is another “new start” that appears to be a repeat from the FY 2006 Work Plan.

9. Medical appropriateness and coding of diagnosis-related group (DRG) services. OIG will scrutinize inpatient claims to identify providers who exhibit high or unusual patterns for selected DRGs, and then will determine the medical necessity, the appropriate level of coding, and reimbursement for a sample of services billed by these providers. This evaluation could be setting the stage for a new round of “upcoding” reviews, following numerous investigations of upcoding involving pneumonia and septicemia.

10. Medicare Rural Hospital Flexibility Program (RHFP). OIG will examine the extent to which hospitals in the RHFP serve beneficiaries from rural areas, and examine CMS oversight. In addition, OIG will review a sample of RHFP facilities, including critical access hospitals (CAHs), to determine whether the number of beds and distance between facilities meets minimum requirements. This is another evaluation that could result in recommendations to change the RHFP. CAHs should confirm they continue to meet the relevant criteria.

11. Inappropriate payments for interpretation of diagnostic x-rays in hospital emergency departments.2 OIG will determine the extent of inappropriate payments for the interpretation of diagnostic x-rays performed in emergency departments (EDs). Contractors are to pay for only one interpretation of an x-ray procedure furnished to an ED patient. They pay for a second interpretation, identified through the use of modifier 77, only under unusual circumstances. OIG will review to determine whether the services were medically necessary and if the tests were interpreted contemporaneously with the patient’s treatment. One issue here may be whether bills submitted for a “second read” are medically necessary rather than being performed for quality control purposes.

On-going Medicare hospital studies

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OIG is continuing the following audits and evaluations begun in prior years. Even though hospitals may have already reviewed these items to determine whether they were risk areas in the past, they should be considered again to determine whether anything has changed since they were last reviewed:

1. **Adjustments for graduate medical education payments.** OIG will determine whether audit adjustments for direct and indirect graduate medical education that fiscal intermediaries make while settling Medicare cost reports were properly reflected in the revised Medicare reimbursement.

2. **Payments for observation services versus inpatient admission for dialysis services.** OIG is continuing its examination of whether payments were made for inpatient admissions for dialysis services when the physicians’ orders stated the level of care as admission to observation status.

3. **Nursing and allied health education payments.** OIG will review the appropriateness of payments for provider-operated nursing and allied health education programs.

4. **IPPS wage indices.** OIG is appraising whether hospital and Medicare controls are adequate to ensure the accuracy of the hospital wage data used for calculating wage indices for the IPPS, and the effect of inaccurate wage data on DRG reimbursement.

5. **IRF compliance with Medicare requirements.** OIG continues to scrutinize the extent to which admissions to IRFs meet Medicare requirements, whether a claim paid as a discharge should have been paid as a transfer, and IRF outlier claims.

6. **Organ procurement organizations (OPOs).** OIG is looking at payments made to OPOs and will identify and review controls and cost containment practices used by OPOs to acquire organs for transplant.

7. **Inpatient hospital payments for new technologies.** OIG will examine the costs associated with the new devices and technologies to determine whether the reimbursement is appropriate.

8. **Inpatient psychiatric facilities.** OIG will review payments to psychiatric facilities under the inpatient psychiatric facility PPS, focusing on outlier payments as well as payments for interrupted stays.

9. **Long-term care hospital payments.** OIG will continue its review of the appropriateness of early discharges to home and interrupted stays.

10. **Critical access hospitals (CAHs).** OIG is scrutinizing the administrative and other costs incurred by CAHs for inpatient and outpatient services before and after their conversion to CAH status.

11. **Rebates paid to hospitals.** This ongoing review assesses whether hospitals are properly identifying purchase credits rebates as a separate line item in their Medicare cost reports. OIG is comparing the amount of rebates paid to hospitals by several large vendors in a given year with a sample of Medicare hospital cost reports to determine whether the rebates were properly credited on the Medicare cost reports.

12. **Outpatient outlier and other charge-related issues.** The issue of outliers continues to be a focus for OIG.

13. **Outpatient department payments.** In its ongoing review of payments to hospital outpatient departments, OIG will review the appropriateness of payments made for multiple procedures, repeat procedures, and global surgeries.

14. **Oversight of specialty hospitals.** OIG is evaluating CMS’s oversight of physician-owned specialty hospitals to ensure patient safety and quality of care at these hospitals, including policies related to staffing requirements at these hospitals.

### Medicaid Hospital Issues

In addition to the Medicare issues outlined above, there are also Medicaid issues that need to be reviewed:

1. **Hospital outlier payments.** OIG is looking at whether Medicaid state agencies’ methods of computing payments for inpatient hospital cost outliers result in reasonable payments.

2. **Medicaid disproportionate share hospital (DSH) payments.** OIG will be reviewing several states’ disproportionate share hospital (DSH) payments to selected hospitals to verify that the states calculated the payments according to their approved state plans and that the payments to individual hospitals did not exceed the hospital’s uncompensated care costs. OIG will also be assessing whether states have implemented the statutory requirement that DSH claims be audited annually.

3. **Hospital eligibility for DSH payments.** Similarly, OIG is reviewing whether states are appropriately determining hospitals’ eligibility for Medicaid DSH payments.

4. **Billing for Medicaid nursing home patients transferred to hospitals.** OIG is scrutinizing states’ Medicaid claims data to determine whether Medicaid made duplicate payments to nursing facilities and hospitals for the same patients and whether hospitals are receiving payments for Medicaid patients who have been discharged.

### Non-hospital Items that hospitals should review

As indicated above, hospitals should also review non-hospital items in the Work Plan. Some of the items that hospitals should be aware of include:

1. **Place of Service Errors.** This review will determine whether physicians properly coded the place of service on claims for services provided in ambulatory surgical centers and hospital outpatient departments.

   *Hospitals may wish to consider periodically informing the medical staff of all current provider-based outpatient departments, to*

   *Continued on page 13*
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2. Psychiatric services provided in an inpatient setting. OIG will determine whether physician psychiatric services provided in an inpatient setting are being properly billed to Medicare. Because a group therapy session is reimbursed at a lower rate than an individual session, physicians may have an incentive to bill Medicare for an individual session to receive a higher reimbursement when a group therapy session was actually provided.

3. Laboratory services rendered during an inpatient stay. OIG indicates it is reviewing the extent to which laboratory services rendered during an inpatient stay are unallowable. It is unclear from the description exactly what this review is aimed at. It could be assessing the medical necessity of inpatient tests, or looking at whether, when lab tests for inpatients are sent to an outside lab, that lab is improperly billing Medicare directly, instead of billing the hospital "under arrangements."

Conclusion

The OIG Work Plan provides hospitals with an opportunity to realign their auditing and monitoring activities and to refresh their training programs to target areas of governmental scrutiny. The “effectiveness” of a hospital compliance plan could be questioned if a hospital fails to review and respond to this important tool.

Implications for physicians

By Asha B. Scielzo, Esq.

In September 2006, the Office of Inspector General of the Department of Health and Human Services (OIG) released its Work Plan Fiscal Year 2007 (the 2007 Work Plan). The 2007 Work Plan is intended to reflect what OIG believes “best identifies vulnerabilities of Department of Health and Human Services programs and activities,” including Medicare and Medicaid. The 2007 Work Plan serves as an important compliance tool for physicians, hospitals, and other healthcare providers, because it offers a “behind the scenes” look at areas of critical focus for OIG in the coming year. Issues relating to medical necessity, billing and coding compliance, and improper incentives are recurring themes.

The 2007 Work Plan as it relates to physicians includes many of the same action items from the 2006 Work Plan, but also incorporates nine new focus areas. A common element of these new areas is OIG’s targeting of physicians’ attempts to “game the system” to gain increased Medicare reimbursement. The new action items also reflect OIG’s scrutiny of services that show sharp increases in use in recent years, such as advanced imaging services and polysomnography.

New Action Items Identified in the 2007 Work Plan

- OIG will evaluate the appropriateness of services billed “incident to” physician services. Specifically, OIG will focus on the extent to which the services met Medicare standards for medical necessity, documentation, and quality of care. The “incident to” rules are confusing, so physicians should take extra care to ensure all “incident to” billing requirements are met before submitting any such claims.
- OIG will determine whether Medicare payments for ophthalmology services related to cataract and LASIK eye surgery were appropriately billed, and evaluate whether carriers have adequate claims processing controls in this area.
- OIG will examine the extent to which physicians received separate payments for evaluation and management (E&M) services provided during the global surgery period and whether the rate of E&M services has changed since introduction of the global surgery fee concept. E&M services provided during the global surgery period should not be billed and paid separately by Medicare.
- OIG will determine whether physicians are properly billing Medicare for inpatient psychiatric services. Because individual therapy sessions are reimbursed at a higher rate than group sessions, OIG recognizes

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that there may be an incentive for physicians to bill a group session as an individual session.

- OIG will examine the factors contributing to the rise in Medicare reimbursement for polysomnography and the appropriateness of services billed to Medicare. According to OIG, Medicare reimbursement for these services increased nearly 175 percent in 4 years. Polysomnography is a diagnostic tool used in sleep studies.

- OIG will determine if Medicare Part B “long-distance” physician services are being appropriately billed for home health and skilled nursing facility services.

**Areas of focus continued from 2006**

- OIG will review the types of arrangements physicians have with billing companies and determine the impact of these arrangements on physicians’ claims.

- OIG will assess whether physician billings for pathology services performed in physicians’ offices comply with Medicare Part B requirements.

- OIG will review the appropriateness of professional and technical component billing for cardiology and echocardiography services.

- OIG will review medical necessity, adequate documentation and physician certification statements for physician and occupational therapy services.

- OIG will examine the appropriateness of payments to providers for initial preventive physician examinations and whether physicians may have the opportunity to claim a higher payment for services that may already have been performed in a previous E&M visit.

- OIG will evaluate medical necessity and billing compliance for Part B mental health services provided in physician offices.

- OIG will assess medical necessity and billing compliance for wound care services billed by physicians.

- OIG will assess whether CMS’s systems are able to identify and prevent payment for duplicate claims for physical therapy.

In addition to the focus areas specifically identified in the “Medicare Physicians and Other Health Professionals” chapter of the 2007 Work Plan, physicians should be aware of a few other sections of the 2007 Work Plan that may be relevant to their practices. For example, OIG will also look at quality of care at physician-owned specialty hospitals. In addition, OIG will continue to assess providers’ compliance with the terms of corporate integrity agreements. OIG will also evaluate improper claims for physician assistant reimbursement. Further, OIG will evaluate contractual arrangements in which a supplier, such as a laboratory or DME company, agrees to operate a service on behalf of a physician’s practice.

In conclusion, it is advisable that all providers examine their compliance practices and procedures, with particular emphasis on those areas identified by OIG in its 2007 Work Plan.
Home Health, Skilled Nursing, and Hospice issues

By Lisa M. Silveria RN, BSN

The U.S. Department of Health and Human Services Office of Inspector General, on schedule, released its Work Plan Fiscal Year 2007. I was asked to provide a summary outlining the government’s focus on skilled nursing and long-term care facilities (SNF/LTC), home health care (HHC), and hospice issues. As part of the Catholic Health West Compliance team, these areas fall under the auspice of my oversight and monitoring.

Skilled nursing/Long-term care

I was not surprised by the fair number of focus areas in skilled nursing and long-term care settings. As our population continues to grow and age at much greater numbers than our current healthcare system can sustain and families are more diverse in location, the demand for institutional settings is also growing. The focus areas for this setting are:

1) The Office of Audit Services will look at payments made to facilities with the inpatient prospective payment system (IPPS), in accordance with Medicare rules related to early discharges and interrupted stays, to see if charges are being properly determined and coded.

2) The Office of Evaluation and Inspections will look at this same category in assessing their relationship(s) with one or two key single acute hospitals. Long-term care hospitals (LTCH) have grown at a much more rapid pace than expected, and there are growing concerns about proper level of care for beneficiaries, especially in light of the greater base-rate payment than an acute care setting. In conjunction, the Office of Audit Services will also be looking at average length of stays (ALOS). To qualify for the LTCH licensure, the average Medicare inpatient stay needs to be greater than 25 days.

3) The Office of Audit Services will be focusing on Medicare skilled facilities in 3 distinct areas:
   a) Proper utilization and medical necessity for rehabilitation and infusion services
   b) Payment issues surrounding day of discharge, which is not a billable service
   c) Duplicate billing for Part B services – this is an ongoing focus area for OIG and has yielded significant refunds to Medicare in past years

4) The Office of Evaluation and Inspections has several more areas they will be directing their attention towards in the upcoming year:
   a) SNF stay beneficiaries also involved with inpatient acute care consecutive stays
   b) Continued work with SNF compliance with state and federal enforcement action as a result of survey findings and whether or not the Fiscal Intermediary and CMS have proper safeguards in place for payment denials for noncompliant facilities
   c) Accuracy of medical decision support assessments and care planning appropriateness and survey findings
   d) Ongoing review of medical necessity for both imaging and laboratory services

5) Additionally, the Office of Audit Services will be reviewing for potential duplicative Medicaid payments to both the acute inpatient and skilled settings for already discharged patients.

Home Health Care

There are neither surprises nor new areas of focus for OIG in this setting. Both the Office of Audit Services (OAS) and the Office of Evaluation and Inspection (OEI) will continue efforts in the following areas:

1) Determine if outlier payments to agencies were in compliance with Medicare rules, explore frequency of such payments by specific agency and clustering of home health resource groupings (HHRG) and/or geographic areas (OAS)

2) Continue review that therapy services provided were medically necessary, provided by appropriately licensed staff, and met Medicare regulations for the amount of therapy rendered (OAS and OEI)

3) Examine trends and patterns detected during survey and address quality of care issues, looking for cyclical noncompliance and CMS action in terms of sanctions when these patterns are noted (OEI)

4) Determine to the extent possible the accuracy and completeness of agency information and quality data submission on the CMS Home Care Compare Web site

5) Review agency’s accurate coding of the Outcome and Assessment...
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 Feature focus: 2007 Work Plan
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Information Set that establishes the HHRG payment method for home health setting and possible improper payments (OEI)
6) Indirectly related to HHC, OAS will review records related to durable medical equipment items and supplies while a beneficiary is receiving home health services to assure reasonableness and necessity and to avoid duplicative payments when such items may fall under the auspice of the home health episode payment

Hospice
This continues to be an area where CMS is widening it’s focus and taking a more in depth approach. In fact, after 20+ years, CMS has introduced a new set of “proposed” conditions of participation (CoPs) with significant impact to this industry. Not surprisingly, most of the focus will fall under the Office of Evaluation and Inspection. These areas are:
1) Review and determine whether hospice payments for services of dually eligible beneficiaries/residents were accurately rendered; determine overlap and/or underutilization of services in accordance with regulatory requirements
2) Accuracy of assessments and if complete plans of care truly reflect the services the beneficiary is receiving
3) Medical review of accuracy of level of care billed and what services the beneficiary did indeed receive
4) For dually eligible beneficiaries, the Office of Audit Services will review the determination of propriety of drug claims for beneficiaries who elected the Hospice benefit under Medicare Part A and drug coverage under Medicare Part D to assure no duplication of payment for those medications that the hospice is responsible for, as related to the terminal illness under Medicare Part A

As the “baby boomer” generation quickly nears retirement, and the shortage of healthcare professionals and settings is on the rise, it is even more imperative that we assure the proper resource allocation to these unique settings. A commitment from leadership that will filter down to assure proper education and monitoring practices is essential to the success of any compliance plan and the operations of the facility/agency.

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Editor's note: This interview was conducted by Dan Roach, HCCA President, in late November 2006 with Larry Goldberg, Principal Deputy Inspector General, U.S. Department of Health and Human Services Office of Inspector General.

DR: Please tell our readers a little about your background prior to your appointment as Principal Deputy Inspector General.

LG: I had been a branch chief and then the Assistant Inspector General for Legal Affairs in the Office of Counsel to the Inspector General. My primary responsibilities were overseeing the Office of Inspector General’s (OIG) enforcement of fraud and abuse laws and leading the OIG’s efforts to ensure compliance in the health care industry. Prior to my time in OIG, I worked for the Maryland Attorney General’s Office, the Civil Rights Division of the Department of Justice, and the National Center for Law and Deafness, where I focused on the legal rights of people with disabilities.

DR: What specific experiences in your long public career do you feel helped prepare you for your current role?

LG: I’ve had enormous opportunities to effect change, first in the field of disability law, and more recently in the health care enforcement and compliance arenas. Throughout my career, I’ve been in positions where new legislative enactments have provided new challenges—challenges to be creative, to advocate on behalf of vulnerable individuals or programs that serve important public purposes, and to achieve significant results. Serving in management roles in a variety of federal, state, and public interest settings has also helped prepare me to lead a large organization, such as OIG.

DR: What have been the most significant challenges and opportunities since your appointment as Principal Deputy Inspector General?

LG: The most significant challenges have also been the greatest opportunities. Since I came on board as Principal Deputy, OIG has been accorded a number of new authorities and responsibilities, particularly under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and the Deficit Reduction Act of 2005 (DRA). The challenges of creating new work plan proposals, increasing resources to meet these new responsibilities, bringing in staff with new and relevant skills, and internal reorganization to meet these challenges have provided the opportunity to effect significant change regarding the way that the Medicare and Medicaid programs operate and are protected from fraud, waste, and abuse.

DR: What are the primary enforcement issues that you and OIG staff are focused on, currently and in the future?

LG: In some respects, OIG’s enforcement work depends on the types of referrals and complaints received; however, OIG identifies focus areas where it plans to concentrate efforts.

Prescription drugs are one such priority. For several years, OIG has focused significant attention on the Medicaid and Medicare Part B drug benefits, including the resolution of numerous cases involving pharmaceutical manufacturers and pharmacies, and this will continue. More recently, Medicare Part D has become an area where OIG is investing significant resources. The initial Part D-related investigations have involved marketing schemes and enrollment fraud, as well as types of pharmacy fraud, such as billing for a more expensive drug than was dispensed, that OIG has encountered in other health care programs.
OIG also continues to focus on quality-of-care issues for beneficiaries residing in nursing facilities. OIG pursues patterns and egregious instances of abuse or neglect, which may constitute a failure to provide care. OIG is expanding these efforts to other settings, such as residential treatment facilities.

In addition, OIG has launched an initiative to target fraudulent Medicare providers, recover federal funds, and address systemic vulnerabilities in the Medicare provider enrollment process. Initial efforts are focused on south Florida and on durable medical equipment suppliers and providers of infusion services. OIG plans to expand this initiative to other regions and may target other types of providers as well.

Finally, OIG plans to increase the use of its Civil Monetary Penalty authority, particularly in pursuing anti-kickback violations and Stark violations across all health care industry segments.

**DR:** What do you see as the top priorities for OIG in 2007?

**LG:** OIG is charged with protecting the integrity of over 300 Department of Health and Human Services (HHS) programs. Each year, OIG identifies the top management challenges facing HHS, and this list provides a framework for our strategic planning and prioritization of resources. This year’s list includes 10 management challenges. I’d like to highlight four:

- Medicare Part D: In addition to focusing on enforcement, OIG will focus significant attention on Medicare Part D oversight through audits and evaluations. The magnitude of expenditures and impact of this benefit on beneficiaries, from both health and financial perspectives, make it critical that Medicare Part D operate efficiently and effectively and be protected from fraud and abuse.
- Medicaid Integrity: The Federal share of Medicaid outlays is expected to exceed $200 billion in 2007, and the integrity of this critical safety net program is also among OIG’s top priorities. OIG received additional funding under the DRA, which will enhance its oversight of Medicaid integrity.
- Health Information Technology: The promotion of health information technology in a manner that protects the integrity of the federal health care programs is also a top priority for OIG. In addition, OIG is increasing its use of technological tools to fight health care fraud.
- Emergency Preparedness and Response: The events of September 11, 2001, the 2005 Gulf Coast hurricanes, and the potential for future public health emergencies have underscored the importance of having a comprehensive national public health infrastructure that is prepared to rapidly respond to public health emergencies. OIG is continuing its work to ensure that hurricane recovery funds are used appropriately, to examine HHS’s response to the public health challenges resulting from the hurricanes, as well as to ensure preparedness for possible future emergencies.

**DR:** How will the OIG focus on the priorities you just outlined?

**LG:** OIG carries out its mission through a network of audits, evaluations, investigations, and legal services performed by component offices the Office of Audit Services, Office of Evaluation and Inspections, Office of Investigations, and Office of Counsel to the Inspector General. OIG develops and executes a comprehensive and evolving work plan to address priority areas through all component disciplines. For example, regarding Medicare Part D, OIG is investigating allegations of potential fraud and misconduct related to marketing and enrollment practices; providing legal guidance to industry with respect to whether certain arrangements for providing prescription drug assistance to financially needy Part D beneficiaries implicate fraud and abuse laws; auditing Part D payment accuracy and controls; and evaluating Part D safeguards against fraud and abuse, as well as several beneficiary access and protection issues. OIG applies this coordinated and multifaceted approach to all of its priority areas.

**DR:** In this issue we are reviewing OIG’s work plan. Can you provide us with some tips on how compliance officers can benefit from this annual document?

**LG:** Compliance officers can benefit by using OIG’s work plan as a guide to identify areas of potential fraud and abuse vulnerabilities and to target these areas to ensure compliance. OIG’s mission and scope of responsibilities far exceed its resources. To ensure the most efficient and effective use of limited resources, OIG works to identify those areas at greatest risk of fraud, abuse, or waste. To make these assessments, OIG synthesizes information from numerous sources, including deficiencies identified through previous work by OIG and others, input from program administrators and other stakeholders, and tools such as the Office of Management and Budget Program Assessment and Rating Tool. By reviewing the work plan, compliance officers can benefit from OIG’s efforts to identify risk areas, and this may assist them in directing their own activities and resources more effectively.

**DR:** In the past, OIG published an educational resource to assist Boards of Directors in overseeing corporate compliance. Does the OIG plan to develop similar resources in the future?

**LG:** Although OIG does not have immediate plans to publish similar compliance resources for Boards of Directors, both Boards of Directors and senior management within health care organizations may benefit from reviewing OIG’s work plan, semiannual

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reports, and advisory opinions to inform their own compliance efforts. For instance, besides using the tips for compliance officers, a Board can use OIG’s work plan and identification of risk areas as a guide to devise its own process for surveying and reviewing an organization’s compliance with federal health care program requirements.

In addition, the Compliance Program Guidances that OIG has issued for various industry sectors continue to provide direction to Boards and their health care organizations regarding both the implementation of compliance program elements and relevant industry risk areas.

**DR:** How does the OIG promote the role of organizations’ Boards of Directors in its settlements and corporate integrity agreements (CIA)?

**LG:** Promoting compliance from the highest levels of an organization is critical to a successful compliance program. Therefore, Boards of Directors, in addition to senior operations executives, should be required to take an active role in the review and oversight of matters relating to compliance with federal health care program requirements and with CIA obligations.

OIG promotes this active role for Boards of Directors through the requirements that it includes in CIAs. First, OIG strives to ensure communication between Boards of Directors and compliance officers. OIG has consistently required, under its CIAs, that an organization’s compliance officer make periodic reports on compliance matters directly to the Board of Directors and that the compliance officer have unfettered access to report to the organization’s Board of Directors on compliance matters at any time. Second, OIG has begun to incorporate more detailed Board-level requirements into its CIAs. For example, in the recent CIA with Tenet Health care, Inc., OIG has required the Tenet Board to annually (1) evaluate the performance of its chief compliance officer and compliance executives, (2) review the effectiveness of its compliance program, (3) retain an independent compliance expert to assist the Board in reviewing and assessing the compliance program, and (4) submit to OIG its resolution that an effective compliance program meeting both integrity agreement and federal health care program requirements has been implemented.

**DR:** Many organizations inside and outside of health care have begun to add compliance professionals to their Boards or to the audit or compliance committee. Does OIG believe that this approach can improve the governance practices and help organizations create the right culture?

**LG:** As I mentioned, promoting compliance from the highest levels of an organization is critical, and when an organization includes individuals with significant compliance experience on its Board, this communicates that it is serious in its commitment to compliance. In addition, these compliance professionals can also contribute substantially to Boards and audit or compliance committees. Because Boards are ultimately accountable for issues pertaining to corporate governance, individuals with significant compliance experience can provide an important avenue through which to inform the Boards’ decisions regarding compliance matters. The organizations could further benefit if Boards of Directors ensure that either compliance professionals or those with significant compliance experience serve in various functions across their organizations.

**DR:** Will the OIG be developing additional compliance-related resources in the near future?

**LG:** Over the last several years, OIG has issued compliance program guidance for a wide array of health care entities, including durable medical equipment suppliers, pharmaceutical manufacturers, physicians, and hospitals. More recently, OIG issued supplemental compliance program guidance for hospitals.

Although OIG is not currently drafting new compliance-related guidance, I recommend that health care entities review the CIAs that are available on the OIG Web site. These documents provide useful information regarding the types of compliance program elements that OIG has required of entities in various industry segments in connection with settlements of false claims cases. CIAs often contain unique review procedures and training provisions, specific to the conduct at hand in each settlement. Health care entities may wish to review CIAs, along with OIG’s Work Plan and other resources, as they develop audit and educational work plans for their organizations.

**DR:** Will the OIG focus on the new Medicare Part D? And if so, what aspects of it?

**LG:** Yes, oversight of Medicare Part D is an OIG priority, and OIG will devote significant attention to this program. OIG’s comprehensive strategic plan for Medicare Part D oversight includes audits, evaluations, investigations, and legal services. OIG has categorized these activities into the following issue areas:

- **Enforcement and Compliance:** includes most of OIG’s investigative and legal work, as well as evaluations of safeguards to prevent and detect fraud and abuse;
- **Payment Accuracy and Controls:** includes audits of Medicare payments to Part D drug plans, Medicare payments under the Retiree Drug Subsidy, and payments between Medicare and Medicaid on behalf of beneficiaries enrolled in both programs;

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Benjamin Goldberg

Compliance culture and internal controls include, but are not limited to, the following: success with respect to these critical functions is a benchmark of compliance. Benchmarks or indicators of success are developed to ensure the provider has an effective system of quality monitoring, quality assurance, and quality improvement.

There are several sources of OIG’s legal authority to enforce quality-of-care compliance. First, OIG is required by statute to exclude from federal health care programs any person who has been convicted of a criminal offense related to abuse or neglect. Second, OIG has the discretion to exclude any person or entity that has furnished care failing to meet professionally recognized standards. Third, if a provider bills federal health care programs for substandard or medically unnecessary care, such conduct could give rise to liability under the civil False Claims Act for billing of services not rendered.

In appropriate circumstances, OIG is willing to waive its permissive exclusion authority in exchange for a quality-of-care CIA with an organization that has provided poor quality-of-care to its patients. The quality-of-care CIAs are not intended to replace or duplicate the CMS and State survey agency functions in regulating and monitoring the quality of care in long-term care facilities. The CIA focuses on ensuring that the provider has an effective internal system of quality monitoring, quality assurance, and quality improvement.

To achieve this goal, OIG requires (under the CIA) the appointment of an independent monitor whose responsibilities include helping the provider develop necessary internal systems and reporting findings and observations to both the provider and OIG.

**DR:** What message would you want to pass on to the provider community?

**LG:** It has long been the position of OIG and its law enforcement partners that the government alone cannot detect and prevent all instances of health care fraud and abuse. It is essential that OIG rely on the health care industry to establish effective voluntary compliance programs and upon compliance professionals to act as internal watchdogs and to cultivate a culture of compliance within the organization.

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**Continued on page 25**
DOJ Revises Charging Guidelines for Prosecuting Corporate Fraud
On December 12, U.S. Deputy Attorney General Paul J. McNulty announced during a speech at a meeting of the Lawyers for Civil Justice in New York that the Department of Justice is revising its corporate charging guidelines for federal prosecutors throughout the country.

The new guidance revises the Thompson Memorandum, which was issued in January 2003 by then-Deputy Attorney General Larry D. Thompson, and is titled the “Principles of Federal Prosecution of Business Organizations.” The memo provides useful guidance to prosecutors in the field through nine factors to use when deciding whether to charge a corporation with criminal offenses. For more: http://www.usdoj.gov/opa/pr/2006/December/06_odag_828.html

SEC Proposes Revisions to SOX
The December 15 issue of the Boston Globe reported that “Proposed revisions to a landmark 2002 anti-fraud law will include relaxing some rules for small public companies in a bid to curb what they say have been excessive costs related to audits, the Securities and Exchange Commission’s accounting chief said yesterday.” For more: http://www.boston.com/business/globe/articles/2006/12/12/changes_to_sarbanes_oxley_to_ease_costs_for_small_firms/

Guidance Issued for Employee Education About False Claims Recovery
On December 14, the Centers for Medicare & Medicaid Services (CMS) released guidance to State Medicaid agencies on the implementation of Section 6032 of the Deficit Reduction Act of 2005 (P.L. 109-171). Section 6032 of the Deficit Reduction Act establishes section 1902(a)(68) of the Social Security Act, which requires any entity (those that receive or make annual Medicaid payments under the state plan of at least $5 million) to provide Federal False Claims Act education to their employees. This provision must be implemented no later than January 1, 2007, except as provided for in section 6034(e) of the Deficit Reduction Act. To the extent a State determines that it requires legislation to implement this provision and wishes to avail itself of the section 6043(e) delayed effective date, it must request through CMS that the Secretary concur with the determination that legislation is required. For more link to the State Medicaid Director letter:

The State Medicaid Director letter

State Plan Preprint

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Pharmaceutical issues

By Sarah Giesting, Esq.

The Office of the Inspector General (OIG) Work Plan Fiscal Year (FY) 2007 provides a layout for the Department of Health and Human Services’ (DHS) activities and projects for the upcoming year. The 93-page Work Plan released September 25, 2006, reinforces the OIG’s commitment to fighting fraud, waste, and abuse. Speaking to pharmaceutical manufacturers specifically, OIG states that it “will continue to identify and investigate illegal schemes to market, obtain, use, and distribute prescription drugs.” A goal of these investigations is to ensure the integrity of Medicare and Medicaid payments for pharmaceutical drugs.

Following an active year in 2006, in which Schering-Plough agreed to pay a fine of $435 million and to an addendum to its previous Corporate Integrity Agreement (CIA), rigorous enforcement of the pharmaceutical industry will continue in 2007. What does this mean for the pharmaceutical industry? The OIG Work Plan serves as a warning to pharmaceutical manufacturers that OIG will focus its attention and resources on several key areas:

- Federal and state False Claims Act cases
- Oversight of clinical trials and clinical investigators
- Medicare and Medicaid

OIG Work Plan Background

The purpose of the OIG Work Plan is to set forth projects to be addressed during the fiscal year which will be used to identify systemic weaknesses and vulnerabilities in DHS programs and activities. Projects are planned by the Office of Audit Services, the Office of Evaluation and Inspections, the Office of Investigations, and the Office of Counsel to the Inspector General.

The Work Plan outlines the ongoing and proposed work of the following operating divisions of DHS: the Centers for Medicare and Medicaid Services (CMS), the seven major public health agencies, the Administration of Children and Families, and the Administration on Aging. Projects will also cover issues that cut across departmental programs, including state and local government use of federal funds and the functional areas of the Office of the Secretary.

OIG uses program audits, inspections, and investigations to identify areas of weakness. Tools available to correct such weaknesses include promulgating regulations and legislation, use of administrative sanctions and program exclusion, and development and monitoring of corporate integrity agreements. While most projects are planned as new issues arise or new information is learned, other projects in the OIG Work Plan are required by statute.

Enforcement of federal and state False Claims Act

The False Claims Act has been a profitable tool for fighting fraud, especially in FY 2006, which is expected to be a record year for recoveries. FY 2006 saw large settlements in the pharmaceutical arena, including Serono, King Pharmaceuticals, and Schering-Plough. The Office of Counsel to the Inspector General promises to continue developing and pursuing False Claims Act cases against individuals and entities that defraud the government in FY 2007.

At the state level, section 1909 of the Social Security Act, 42 U.S.C. 1396h, requires OIG to determine whether a State that has in effect a law relating to false or fraudulent claims meets certain enumerated requirements. Although states are not required to have a law relating to false or fraudulent claims, the states have been encouraged to do so. Effective January 1, 2007, states that have a law in effect that satisfies the enumerated requirements receive an increased recovery of ten percentage points from legal actions brought pursuant to the law. OIG published guidelines in the Federal Register on August 21, 2006, outlining the requirements for state false claim laws which will satisfy the enumerated requirements. In FY 2007, OIG will begin assessing whether state false claims laws meet these criteria.

The likely result? Pharmaceutical companies can expect another record year for recoveries under federal and state false claims laws. Because pharmaceutical companies may be facing settlement negotiations with the federal government as well as multiple states, they can also expect higher settlement amounts and more rigorous CIA requirements.

OIG’s Regulation of Clinical Trials

Relationships between pharmaceutical manufacturers and clinical investigators were a hot topic in 2006. The National Institute of Health (NIH) came under fire this year when a bipartisan group of congressional legislators asked NIH to disclose the financial relationship between one of its senior researchers and pharmaceutical companies. The adequacy of NIH’s policies and oversight came under fire when it was reported that the senior researcher had accepted fees from two pharmaceutical companies in recent years.

In another incident this year, the Food and Drug Administration (FDA) announced that pharmaceutical drug maker Bayer A.G. had failed to disclose the results of a large clinical trial showing that its
heart-surgery medicine Trasylol might increase the risks of death and stroke. The FDA learned about the study only after a researcher involved in the study notified the FDA, raising questions about the FDA’s oversight abilities for clinical trials.

To address these issues, OIG plans to assess the nature of financial interests disclosed by clinical investigators to the FDA and the extent to which the FDA monitors the financial interests disclosed by clinical investigators. OIG will also investigate the extent to which drug and biologic applicants monitor their clinical investigators for conflicting financial interests.

OIG also recognizes that recent incidents concerning clinical drug trials have raised questions about the FDA’s processes for inspecting clinical trials. Thus, OIG will expand on previous work by examining the extent to which the FDA conducts inspections of clinical trials.

OIG plans to continue evaluating the completeness of records contained in the clinical trials data bank maintained by the Secretary of DHS under the Food and Drug Administration Modernization Act. Guidance issued by the FDA in March 2002 requires drug sponsors to submit clinical trial protocol information to the clinical trials data bank for serious or life-threatening diseases and conditions. OIG notes in the Work Plan that the number of submissions has been less than expected, and it plans to identify and assess reasons for the low number.

The FDA is enduring substantial pressure in this area, and will look for ways to improve its perception with congressional leaders, the public, and the industry. In FY 2007, the pharmaceutical industry can expect more FDA pressure. Wise compliance officers and legal counsel will ensure that opportunities for investigator fraud within their organization are minimized through early detection and prevention.

**Oversight of Medicare and Medicaid**

The OIG Work Plan shows that several comparisons between drug prices for Medicare Parts B and D and Medicaid will be conducted. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) mandates OIG to compare the average sales price (ASP) for pharmaceutical drugs to the widely available market price (WAMP) and average manufacturer’s price (AMP). To assist in this mandate in FY 2007, OIG will continue reviewing and evaluating drug manufacturers’ methodologies for computing the ASP.

Beginning January 1, 2007, pharmaceutical manufacturers must disclose AMP and best price to CMS on a monthly basis under new regulations imposed by the Deficit Reduction Act (DRA). The DRA requires DHS to disclose AMP to state agencies on a monthly basis. The DRA also changes the way pharmaceutical manufacturers calculate AMP and best price. It is, therefore, no surprise that OIG plans to evaluate pharmaceutical manufacturers’ methods for computing AMP and best price in FY 2007.

The pharmaceutical industry should expect more scrutiny in the areas of Medicare and Medicaid fraud as the government’s interest in these programs increases. It is imperative that pharmaceutical manufacturers ensure that their methods comply with the DRA, their rebate agreements, and CMS releases.

**Conclusion**

OIG’s decision to fund the projects discussed above shows that OIG believes that there are vulnerabilities in these areas, and that improvements can be made. Pharmaceutical manufacturers and their legal counsel can use the OIG Work Plan as a guide for identifying and assessing these new and changing risk areas. These risks areas should be addressed proactively through an updated compliance program, new policies and procedures, and additional training.

Larry Goldberg ...continued from page 22

their organizations. Ensuring that effective systems and structures are in place to avoid high-risk conduct and making board members, executives, and all levels of employees aware of their obligation to comply with federal health care program requirements is paramount to this effort. Because of OIG’s reliance upon the health care industry, OIG has placed great emphasis on developing guidance for a wide array of industry sectors regarding the major enforcement and compliance issues identified by OIG. OIG’s goal is that health care organizations will adopt a comprehensive array of effective compliance tools.

OIG looks forward to continue working with the industry to promote integrity and to effect positive change in this area.
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For the following reasons, HCCA does not lobby for or against regulations.

If we lobby, even for one regulation, we lose our unique position and our unbiased reputation. I see this as a slippery slope much like an addiction. One action leads to another. Although great arguments have been made to lobby for one issue, it could lead to more. We could end up like all the other organizations that have spent years and millions of dollars telling people what the regulations should or shouldn’t be, while their members pay millions of dollars in fines and penalties, endure ruined reputations, and on occasion, go to jail.

1) Maintaining independence and unbiased position
The compliance community, much like compliance programs, is not for or against regulations. We just make sure our organizations follow the regulations. If we take ownership of some regulations and not others, we lose our unbiased position. The compliance community’s ability to be—and remain—unbiased toward any regulation is very important.

2) Focusing time and effort on compliance activity
Lobbying takes time. Every hour spent lobbying takes away time that could be spent conducting efforts to help healthcare organizations comply with regulations. Thousands of associations invest millions of dollars each year to adopt a position or spend their time taking a position on regulations. We are one of very few associations (I personally don’t know of any others) that do not lobby. This is what sets our association and our profession apart from all others. If half the money that has been spent on lobbying was spent on complying with regulations, healthcare would not be the most fined and penalized industry in U.S. history. If there were half the fervor and passion for compliance as there is for lobbying, healthcare would not be demonized to the degree we now are.

3) Is it critical for HCCA to provide a lobbying function?
A key point here is that those who need a voice and the worthy causes that benefit from lobbying are not left out in the cold. There are many places to turn for help, including the American Health Lawyers Association, American Healthcare Association, the Medical Group Management Association, The American Medical Association, and others.

There are consulting firms, lobbying firms, law firms, lobbyist associations, non-profit organizations, and millions of individuals who can and do perform this function. This is not a service that needs our help. The fact that we are alone in our position (not lobbying) is remarkable, given the millions of dollars of fines in healthcare on a weekly basis. It seems so obvious that more help is needed complying rather than lobbying.

“Don’t forget. Don’t lobby. Don’t lobby, even one time.”

We don’t need more lobbying. There is enough (some would say too much) already. We don’t need to spend more time lobbying; we need to spend more time complying. The HCCA needs to maintain our independence and unbiased perspective. Lobbying is easy, interesting, and important. It is also a slippery slope. I have been with this organization since the name and mission were doodled on a napkin. We used my pen. However, when I am gone, it’s all yours. I will not worry or second guess. Between my position as the first President and my position as CEO, I spent two years not worrying. In fact, it was blissful. I had no problem letting go. When I move on from my position as CEO, I assure you, I will leave the worrying up to you. When I am gone, you can change and rearrange this organization without any criticism from me. As I did after I was President, I will just bask in the thrill of what we all have created. However, if you hang on to one thing that I said or did, it would be: “Don’t forget. Don’t lobby. Don’t lobby, even one time.”
A recent conviction and sentencing of a chief executive officer (CEO) and chief compliance officer (CCO) of a medical device company underscores the individual and corporate consequences of an ineffective compliance program. The convictions in *U.S. v. Caputo, et al* (October 16, 2006, Northern District Court of Illinois) were based on criminal counts of mail and wire fraud and conspiracy and the introduction of an altered or misbranded device into interstate commerce.

The evidence at trial in this case supported the conclusion that the large sterilizer had been marketed by the company throughout the United States. This marketing strategy depended entirely on inducing hospital customers to purchase the large sterilizer for "off-label" uses beyond the clearance which the FDA had previously approved for the smaller sterilizer unit. The evidence at trial included multiple instances where the CEO, the CCO, and other representatives of the company put forth statements which tended to obscure the narrow scope of clearance by the FDA for the smaller sterilizer. The evidence at trial identified multiple marketing misrepresentations and even concealment of information to hospital customers and the FDA.

Furthermore, there were numerous instances of patient health and safety problems associated with the use of the larger sterilizer. There were numerous complaints of serious eye injuries caused by a blue-green residue which developed on certain instruments sterilized in the company’s larger medical device. These customer complaints were received by the CCO and apparently ignored. There was testimony at trial that a company salesperson observed a hospital technician cleaning this blue-green residue from a hospital utensil and then immediately notifying the company’s CCO about the relationship between this residue and eye injuries to patients. The evidence at trial reflected that, not only did the CCO fail to conduct an investigation of this matter, but no complaint file was opened in connection with this incident, as required by FDA regulations.

The CCO of the medical device company, had never been approved by the FDA. The evidence at trial reflected that the CCO did not report the eye injuries, but “whitewashed” a report about the eye injuries to other hospitals.

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The Court found that the CEO and the CCO effectively carried out a bait-and-switch scheme on the FDA and their hospital customers by obtaining clearance on the smaller sterilizer, but using the clearance to sell the larger, unapproved sterilizer to unsuspecting customers. The Court further found that the defendants continued to sell the larger uncleared sterilizer, not only in defiance of law and specific FDA directives, but by using a pattern of deception and falsehoods until the FDA effectively shut down the company. The Court in its decision also extensively discussed the United States Sentencing Guidelines for individuals and organizations for false and fraudulent conduct. The Court found that the CEO had specifically selected the CCO for that role and manipulated the CCO throughout the execution of the fraudulent scheme to sell the unapproved larger sterilizer. The Court identified overwhelming evidence that these defendants had engaged in a prolonged, massive fraud upon the FDA and its customer hospitals by marketing an illegal sterilizer that ultimately put the general public and patients at risk for their health and safety. The Court found that the CEO and the CCO ignored repeated admonitions and warning letters from the FDA and effectively placed themselves above the law, believing that they had better scientific industry knowledge than the FDA. The Court found that both defendants viewed the regulatory scheme as a nuisance, which they could neutralize through various misleading and false submissions and slick marketing. The Court concluded that both defendants were motivated by individual economic greed and the desire to capture market share, and placed these goals over and above the regulatory scheme for protecting the health and safety of patients. It was particularly important to the Court that the fraudulent scheme went beyond basic economic harm to the market place, but also involved direct physical harm to patients and hospitals. The Court concluded that it was hard to imagine a more egregious corporate crime.

The Court went on to discuss that the average federal sentence faced by corporate executives had more than tripled in recent years, as a direct result of the U.S. Sentencing Commission’s 2002 Economic Crime Amendments and the impact of the Sarbanes-Oxley legislation. The Court also discussed at length the recommendations of the advisory group to the Sentencing Commission (as required by the Sarbanes-Oxley legislation), which resulted in the 2004 Amendments to the Sentencing Guidelines for organizations for effective compliance programs. The Court noted that these amendments emphasized that an organization must both promote an organizational culture that encourages ethical conduct and exercise due diligence to prevent and detect misconduct. The Court enumerated in its decision the following enhanced compliance requirements called for by the Sentencing Guideline Amendments of 2004:

1. Standards and procedures to prevent and detect criminal conduct
2. Adequate resources and authority for organized compliance programs
3. Personnel screening related to the goals of compliance
4. Training in the standards and procedures at all levels
5. Non-retaliatory internal reporting systems
6. Periodic auditing, monitoring, and evaluation of the program’s overall effectiveness
7. Incentives and discipline to promote compliance and ethical conduct
8. Reasonable, responsive, and preventive steps upon detection of a violation

“The court in this case discussed the fact that the compliance officer allowed himself to be manipulated by the CEO,” said Assistant United States Attorney Jim Sheehan. “This type of risk is really what compliance systems and controls should address in an organization.”

The Court also discussed at length the total failure of corporate compliance in this medical device company and specifically pointed out the fact that the CEO selected the CCO for all the wrong reasons, including (1) that the CCO could be dominated and manipulated by the CEO; (2) that the CCO did not have any real training as a compliance officer; and (3) the fact that, before beginning work in the health care industry, any training the CCO had was in marketing.

The Court further pointed out that compliance officers are the corporate “fire personnel” and are an organization’s “first responder” and must focus on both proactive and reactive efforts to be effective. The Court discussed that the proactive efforts necessary for effective compliance must emphasize the goals of crime detection and prevention and organizational ethical behavior. The Court noted that the reactive efforts of a compliance officer must be measured by how well a corporation reacts when it learns that questionable and potentially illegal corporate conduct has occurred. The Court found instead that the CEO and the CCO in this case subverted these basic standard compliance goals in an effort to ensure that the company could proceed with this illegal marketing scheme in direct violation of FDA regulations. The Court found that the CEO and CCO’s actions were criminally inadequate and that the evidence showed that the CCO continually failed to prevent the ongoing illegal marketing of the company’s sterilizer. The Court, in fact, said that the evidence showed that the CCO aided and abetted the illegal marketing scheme and that the CCO chose to use whatever regulatory expertise he had to shield and cover up the alleged offenses, which were later proven at trial. The Court found that instead of self-
reporting potential violations of the law and misconduct, the CCO actively avoided any such reporting of adverse scientific and healthcare results of the sterilizers to the FDA. In fact, the Court found that the CCO directly and willfully participated in the submission of numerous misleading regulatory filings with the FDA and that these actions were taken at the behest and with the approval of the CEO.

Finally, before upholding each of the sentences in this case, the Court made special mention of the efforts by Congress and the United States Sentencing Commission to deter corporate crime. The Court highlighted the need for both general and specific deterrence in the area of corporate crime and the need to support regulatory efforts in the healthcare industry. The Court noted that corporate officials accused of criminal and civil fraudulent conduct in the healthcare industry often answer such charges with broad assertions of lack of criminal intent in the face of repeated and unheeded factual red flags. The Court stated that corporate America should be aware that this type of defense will be effectively undercut by the use of a standard “ostrich” jury instruction. The Court then cited the instruction which was given, in this case, as follows:

“Knowledge may be proved by the defendants' conduct and by all the facts and circumstances surrounding the case. You may infer knowledge from a combination of suspicion and indifference to the truth. If you find that a person had a strong suspicion that things were not what they seemed or that someone had withheld some important facts yet shut his eyes for fear of what he would learn, you may conclude that he acted knowingly as I have used that word. You may not conclude that the defendant had knowledge if he was merely negligent in not discovering the truth.”

The Court’s highlighting of this jury instruction was not only to put corporate America on notice that it will be held accountable for disregarding potential warning signs of non-compliant activity, but that such an instruction was especially appropriate where both the CEO and CCO raised the general defense that they did not realize that their actions were illegal. The underlying message of this case is clear—compliance problems which are not proactively and reactively addressed may result in both individual and organizational liability.  

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Editor's note: Gary W. Herschman is Chair of the Health and Hospital Law Practice Group at Sills Cummis Epstein & Gross PC. Alexandra Miller Khorover is an Associate in the Group. Mr. Herschman may be reached at gherschman@sillscummis.com or 973-643-5783 and Ms. Khorover may be reached at akhorover@sillscummis.com or 973-643-5481.

Earlier this year, two federal courts decided two separate lawsuits involving physicians who attempted to evade the terms of their physician recruitment agreements with hospitals. In both cases, the courts upheld the right of the hospitals to enforce the physician recruitment agreements in the event of a breach by the recruited physicians.

These cases are significant because they demonstrate the importance of drafting compliant physician recruitment agreements and, in particular, of enforcing their terms in the event of a breach. Set forth below is a brief description of the two cases, followed by a list of practical recommendations for hospitals to ensure ongoing compliance and to avoid the types of liabilities and defenses asserted by physicians in these types of cases.

The cardiothoracic surgeon

A cardiothoracic and vascular surgery group in Ohio entered into an Exclusive Services agreement with a nearby hospital to establish an open-heart surgery program. To ensure economic viability for the new program: (a) the hospital agreed to pay certain operating expenses of the group related to the program, including salaries of support personnel and the cost of equipment; and (b) the group agreed to recruit a cardiothoracic surgeon to staff the program, who would be required to enter into a physician recruitment agreement with the hospital pursuant to which the hospital guaranteed the surgeon's compensation for three years.

Subsequently, the group recruited a qualified surgeon and entered into an employment agreement with him. However, due to a miscommunication between the hospital and the group, the surgeon was not informed about the need to sign a physician recruitment agreement prior to executing the employment agreement. When the recruitment agreement was presented to him, approximately four months later, the surgeon refused to sign it. Unable to reach a satisfactory agreement with the group and the hospital, the surgeon resigned and sued the group and the hospital for monetary damages, alleging fraud, wrongful (constructive) discharge, breach of contract, and tortuous interference with an employment relationship.

The surgeon argued that he was fraudulently induced to sign the employment agreement because of the failure to inform him about the physician recruitment agreement and the terms of the Exclusive Services agreement prior to his employment with the group. The court agreed that the group had a duty to disclose the terms of the Exclusive Services agreement and the existence of the recruitment agreement, because this information was material to the physician's decision to become an employee of the group. However, the court ruled that the group's conduct did not constitute fraud, because it lacked the requisite intent to deceive.

The surgeon further alleged that the recruitment agreement was illegal under the Anti-kickback and Stark Laws, and that he was, therefore, constructively terminated for refusing to sign an illegal agreement. The court examined the terms of the physician recruitment agreement, and found that it was legal because: (1) it substantially complied with the anti-kickback safe harbor for physician recruitment agreements (the agreement met all of the requirements, except that it was not located in a health professional shortage area (HPSA); and (2) it satisfied all requirements of the Stark Law's physician recruitment exception. Thus, the surgeon lacked a basis for his constructive discharge claims.

Finally, the surgeon brought a tortuous interference claim, alleging that the hospital's refusal to pay the group certain of its operating expenses in the absence of a signed recruitment agreement improperly interfered with the surgeon's employment relationship with the group. The court rejected this argument, ruling that the hospital was required to refrain from making any payments unless and until the recruitment agreement was signed. To do otherwise would have constituted a violation of the Anti-kickback and Stark Laws, and would have subjected the hospital to potential penalties and liability.

As a result, the physician's action was dismissed in its entirety. The dismissal was affirmed by a federal appeals court and recently denied review by the United States Supreme Court.

The OB/GYN recruit

An OB/GYN group in southern California recruited a physician to work at its practice. As a condition of employment, the physician was required to enter into a relocation agree-
ment with an area hospital that was affiliated with Tenet Healthcare Systems. Under the relocation agreement, the hospital agreed to pay the physician’s relocation and marketing expenses and make certain collection guarantees. In return, the physician agreed to maintain a full-time practice within the hospital’s service area and to maintain privileges at the hospital for at least three years. If the physician terminated the agreement early, the hospital could recover as liquidated damages all amounts it paid to the physician.

Upon execution of the agreements, the physician relocated from Pennsylvania and the hospital paid $86,500 under the relocation agreement. The physician automatically turned over this amount to the group practice, as required by her employment agreement. Approximately one year later, the group practice terminated the physician. She briefly sought alternative employment in the hospital’s service area, but eventually decided to return to Pennsylvania.

The hospital filed an action to recover the $86,500 that it had paid to the physician. The physician argued that the hospital could not enforce the relocation agreement because it violated the Anti-kickback Law. As evidence of illegality, she cited a recent OIG settlement involving Tenet hospitals were found to have violated the Anti-kickback Law. However, the court held that this evidence alone was insufficient to support the physician’s claims, ruled in favor of the hospital, and required the physician to return the money.

Practical recommendations
These two recent court decisions demonstrate the importance of drafting compliant physician recruitment agreements. Physicians are becoming more aggressive in using the fraud and abuse laws in the courts as a means to challenge the terms of physician recruitment agreements when deals fall through. To avoid the types of claims and defenses asserted by physicians in these cases, hospitals should consider the following recommendations:

1. Draft compliant agreements. Physician recruitment agreements that comply with the provisions of the relevant Stark Law exception and Anti-kickback Law safe harbors are unlikely to give rise to liability. Physician recruitment agreements and accompanying documents should be reviewed by outside legal counsel before being presented to the physician, and prior to making any modifications.

2. Maintain an open flow of communication among the hospital, the group practice, and the recruited physician. Physicians who are aware of all the provisions of the physician recruitment agreement and any ancillary/related agreements will be less likely to use compliance issues as a basis for asserting employment-related claims or for defending lawsuits seeking the return of recruitment payments.

3. Execute all agreements simultaneously. Work with the group practice to ensure that all related physician recruitment documents are presented to the recruited physician and signed contemporaneously.

4. Monitor the agreement. The physician recruitment agreement and all related documents should be reviewed periodically to ensure ongoing compliance.

5. Cease payments to the group practice if the physician recruitment agreement is breached. Any payments made to the group practice pursuant to recruitment arrangements are illegal unless a valid physician recruitment agreement is in place. If the recruited physician leaves the hospital’s service area or otherwise violates the agreement, all ancillary payments under the related agreements must cease until the dispute with the physician is settled, or if permitted under the terms of the agreement, until a substitute physician is recruited in his or her place.

6. Enforce the terms of the physician recruitment agreement. If the recruited physician violates the terms of the agreement, the hospital must seek to enforce its terms and recover prior payments. Failure to do so could potentially be viewed as illegal remuneration in exchange for referrals from the physician and/or group practice.

Conclusion
Physician recruitment arrangements present an excellent opportunity for hospitals to work collaboratively with physicians and group practices, and at the same time, to enhance the availability of medical services to the community. By working closely with the physicians and group practices, and by taking the time and care to draft compliant agreements, hospitals can help protect their interests in the event that the terms of the agreements are not being followed, or if the agreements need to be terminated for any reason.

The views and opinions expressed in this article are those of the authors and do not necessarily reflect those of Sills Cummis Epstein & Gross P.C.

Correction
Please note that the December 2006 Compliance Today omitted Lourdes Martinez, Esq., Partner, Garfunkel, Wild & Travis, P.C., as one of the authors of “What every compliance officer needs to know about the Deficit Reduction Act of 2005”.

January 2007
Inpatient Prospective Payment System Changes for 2007

By Gloryanne Bryant, RHIA, CCS

Editor’s note: Gloryanne Bryant is the Corporate Director of Coding HIM Compliance for Catholic Healthcare West in San Francisco. She can be reached at gbryant@chw.edu.

Some significant changes to the Inpatient Prospective Payment System (IPPS) were implemented on October 1, 2006 (IPPS Final Rule, Federal Register August 1, 2006). The Medicare Payment Advisory Commission (MEDPAC) made several recommendations to the Centers for Medicare and Medicaid Services (CMS) for changes with IPPS, which CMS has agreed to do. CMS laid out some major revisions to the structure of the Diagnostic Related Groups (DRG) in the IPPS Final Rule. These changes are important to a variety of hospital staff and key stakeholders: Health information management (HIM), finance (including the chief financial officer), compliance, case management, quality control, decision support, cost reporting, and data analysts, to mention a few.

First, the relative weight (RW) for the DRG, which traditionally was based on “resource consumption” using charge data, will now be using data from the “costs” that the hospital reports. The new weights will be phased into the IPPS over a three-year period:
- 1/3 Cost for fiscal year (FY) 2007
- 2/3 Cost for FY 2008
- 100% Cost for FY 2009

This new approach will increase the importance of accurate and standardized hospital charging practices and cost reports. CMS has refined the methods used to determine average costs-per-case at the DRG level for relative weights. For example, CMS expanded the number (from 10 to 13) of distinct hospital departments used in the calculations, included more hospital data in the final calculations by applying less stringent criteria for eliminating statistical outliers, and accounted for hospital size when evaluating the mark-up of charges over costs. The IPPS Final Rule provides a table listing the revenue codes and department charges used for this analysis. This table is also important for hospitals to review, because it will help to guide consistent inpatient charging practices and to establish internal policies to support those practices.

In addition, CMS is announcing steps to further evaluate hospital-charging practices—particularly for expensive items like medical devices—as part of considering further improvements for 2008.

The second major part of the IPPS reforms involves more accurate accounting for the severity of a patient’s illness, which has a significant impact on cost of care. For FY 2007, CMS is moving toward more complete severity adjustments by adding 20 new groups to the current DRG system. As a prelude to making more comprehensive severity-adjustment changes that will better account for patient severity in the DRG system by FY 2008, CMS will conduct an evaluation, with public input, of alternative “severity” systems. The RAND Corporation has a contract to research, analyze, and make recommendations to CMS on the type of “severity-system” that IPPS should have. The RAND project will include a panel of health care industry experts who will help evaluate several aspects of patient severity capture for DRGs of the future.

Beginning with patients discharged on October 1st, 20 new DRGs were instituted, many of these with high relative weights and high volumes. Then, 32 DRGs were revised and the DRG relative weights were adjusted.

A combination of approaches and the proposed severity DRGs were used to construct the 20 new DRGs and refine the base DRGs, such as:
- Subdividing existing DRGs through the use of diagnosis codes
- Subdividing DRGs based on specific surgical procedures
- Selecting cases with specific diagnosis, and/or procedure codes and assigning them to a new DRG that better accounts for their resource use and severity

In creating these new DRGs, CMS conducted data analysis and identified which cases had higher average charges than other diagnosis and/or procedures within the same DRGs. If the data analysis supported creating separate DRGs for a given diagnosis and/or procedure, the CMS medical advisors reviewed the clinical data to make the final determination.

The following are the new DRGs within certain Major Diagnostic Categories (MDC). Some abbreviations are used in the following lists (RW=relative weight, LOS=length of stay [in days], CC=complications/comorbidities, O.R.=operating room)

MDC 1: Diseases and Disorders of the Nervous System

NEW: DRG 560 Bacterial & Tuberculosis Infections of Nervous System, RW 2.9031 LOS 8.2
DRG 561 Non-Bacterial Infections of Nervous System Except Viral Meningitis, RW 2.2176 LOS 7.4
DRG 562 Seizure age >17 with CC,
RW 1.0582 LOS 3.7
DRG 563 Seizure age >17 without CC, RW .6432 LOS 2.6
DRG 564 Headaches age >17, RW .6933 LOS 2.6
DRG 577 Carotid artery stent procedure, RW 1.7844 LOS 1.6

MDC 4: Diseases and Disorders of the Respiratory System
NEW: DRG 565 Respiratory System Diagnosis with Ventilator Support 96+ Hours, RW 5.2294
DRG 566 Respiratory System Diagnosis with Ventilator Support < 96 Hours, RW 2.3335

MDC 6: Diseases and Disorders of the Digestive System
NEW: DRG 567 Stomach, Esophageal & Duodenal Procedures, age >17 with Complication/Comorbidity with Major Gastrointestinal Diagnosis, RW 5.2173 LOS 12.7
DRG 568 Stomach, Esophageal & Duodenal Procedures, age >17 with Complication/Comorbidity without Major Gastrointestinal Diagnosis, RW 3.3635 LOS 8.3
DRG 569 Major Small & Large Bowel Procedures with CC with Major Gastrointestinal Diagnosis, RW 4.3425 LOS 11.9
DRG 570 Major Small & Large Bowel Procedures with CC without Major Gastrointestinal Diagnosis, RW 2.6978 LOS 8.4
DRG 571 Major Esophageal Disorders, RW 1.1126 LOS 3.8
DRG 572 Major Gastrointestinal Disorders and Peritoneal Infections, RW 1.3378 LOS 5.6

MDC 11: Diseases and Disorders of the Kidney and Urinary Tract: Major Bladder Procedures
NEW: DRG 573 Major Bladder Procedures, RW 3.3457

MDC 16: Diseases and Disorders of the Blood and Blood Forming Organs and Immunological Disorders
NEW: DRG 574 Major Hematologic/Immunologic Diagnoses Except Sickle Cell Crisis and Coagulation Disorders, RW 1.2698 LOS 4.3

MDC 18: Infections and Parasitic Diseases Systemic or Unspecified Sites: O.R. Procedure for Patients with Infectious and Parasitic Diseases
NEW: DRG 575 Septicemia with Mechanical Ventilation 96+ Hours Age >17, RW 5.9388 LOS 13.2
DRG 576 Septicemia without Mechanical Ventilation 96+ Hours Age >17, RW 1.5953 LOS 5.5
DRG 578 Infectious and Parasitic Diseases with O.R. Procedure, RW 4.8492 LOS 12.8
DRG 579 Postoperative or Post-traumatic Infection with O.R. Procedure, RW LOS 8.4
DRG 543 title was changed to “Craniotomy With Major Device Implant or Acute Complex CNS Principal Diagnosis” RW 4.3496 and LOS 7.9

This title change was the result of implantable dual-array neurostimulator pulse generator procedure cases reported with ICD-9-CM procedure codes 02.93 and 86.95 and the need to reassign DRG 543 Craniotomy with Major Device Implant or Acute Complex CNS Principal, rather than DRG 1 DRG 2.

Many of the above DRGs will be impacted by having complete and specific clinical documentation, so the pressure to improve physician documentation continues strong and loud with these DRGs.

The following three DRGs were renamed or revised:
DRG 303 Kidney and Ureter Procedures for Non-Neoplasm with CC, RW 1.9755 LOS 5.0
DRG 304 Kidney and Ureter Procedures for Non-Neoplasm with CC, RW 2.3454

LOS 5.8

The following DRGs have been deleted 2007:
DRG 20 Nervous System Infection except Viral Meningitis, RW 2.7865, LOS 8.0
DRG 24 Seizure and Headache, age >17, with CC, RW 0.9970 LOS 3.6
DRG 25 Seizure and Headache, age >17, without CC, RW 0.6180 LOS 2.5
DRG 148 Major Small and Large Bowel Procedure, with CC, RW 3.4479 LOS 10.0
DRG 154 Stomach, Esophageal, and Duodenal Procedures, age >17, with CC, RW 4.0399 LOS 9.9

With this much change and more coming next year, hospital and compliance staff need to look at potential areas of risk and vulnerability.

The following are some short-term actions to take:
- Run a DRG data report for deleted DRGs
- Identify the number of cases with specific ICD-9-CM predicted diagnosis or procedure codes (see the list within the Federal Register) that were removed and utilized in the analysis
- Know the percentage of cases that will be impacted
- Project the financial impact using these figures and your specific base rate
- Talk with HIM Coding see if there are documentation issues
- Address issues, seek ways to improve documentation concurrent with physician

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The following are some long-term actions to take at the hospital:
■ Audit coding and coding practices (ongoing) prospective and retrospective
■ Assess your IPPS practices for consistency and establish policies to support your practices
■ Do a cost report – policies and procedures

As mentioned above, improving clinical documentation awareness and educating physicians and other clinicians is key. Hospitals need to establish an internal process for concurrent clinical documentation improvement that is imbedded into their framework. Formalizing a program and allocating appropriated trained and educated staff to assess documentation and address issues with physicians will be of high importance.

We continue to face challenges in healthcare and clearly IPPS will be an area of focus over the coming years. Compliance, finance, HIM, and other hospital disciplines need to work together and establish ways and means to address these challenges and these changes. In closing I’d like to share this quote: “The time is always right, to do what is right” (Martin Luther King Jr.). In compliance, we have the charge to do what is right and work with others to also achieve that end.

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We’d like to introduce the following individuals, who make up the Compliance Today Editorial Advisory Board.

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Associate U.S. Attorney since 2003
Philadelphia, PA
Hotlines: An important part of your overall compliance program

By Lisa A. Taylor, JD

Editor’s note: Lisa A. Taylor is Program Administrator/Staff Attorney in the Corporate Compliance Department at Children’s Medical Center in Dallas, Texas. She may be reached by telephone at 214/456-1382.

Hotlines are necessary in today’s compliance world. The Federal Sentencing Guidelines state that an organization shall take reasonable steps “to have and publicize a system, which may include mechanisms that allow for anonymity and confidentiality, whereby an organization’s employees and agents may report or seek guidance regarding potential or actual criminal conduct without fear of retaliation”. Additionally, the Office of Inspector General’s Compliance Program Guidance for Hospitals encourages the use of hotlines to maintain open lines of communication.

According to the Deficit Reduction Act of 2005, entities annually receiving $5 million or more in Medicaid payments are required to put in place a compliance program (or at least certain parts of it). Entities are also required to train personnel on how to become whistleblowers, which makes having an effective hotline a crucial part of your compliance program.

Benefits of a hotline

Many organizations are sensitive to today’s ever changing health care compliance arena and have taken note of the government’s recent increase in prosecutions of hospitals, physicians, and other health care providers who violate the law. Having an “effective” compliance program in place, as set forth under the Federal Sentencing Guidelines, may reduce your organization’s potential “punishment” by the government. One of the items used as proof of an effective compliance program is the existence of a reporting mechanism for anyone seeking guidance or reporting potential non-compliant activity. A hotline is the best and easiest way to meet this requirement.

Let’s face it. As a member of your entity’s compliance department, you are not able to identify all potential areas of non-compliance, because you may not be able to physically visit every area of your organization. Therefore, another benefit of an effective hotline is that it provides the compliance department with additional information from front-line staff and/or individuals in the trenches who identify compliance issues daily. A hotline makes it easier to report those issues promptly.

Another benefit of a hotline is that, if you have a hotline system that alerts the individual to the outcome of the investigation, whether or not they reported anonymously, the individual is more invested and has ownership of the process and of overall compliance at your organization. It shows individuals that compliance works and that it is taken seriously.

An effective hotline is set up so that anyone can choose to report anonymously or may leave their name and number. Individuals may be more likely to report a potential concern if they have the opportunity to remain anonymous. Even though an entity cannot retaliate against anyone for reporting a concern, individuals continue to believe that they may get in trouble for reporting issues. If you have an anonymous reporting system, they are more comfortable with contacting you and reporting problems.

Outsourcing the hotline

Many health care organizations struggle with the decision of whether or not to outsource the hotline. Several issues should be considered when deciding whether to outsource your hotline. In some cases, you may choose not to outsource your hotline, because the organization is small, and it either does not make sense to outsource the hotline or it is too expensive.

The next item to consider is the culture of your organization. This is easier said than done. Are the individuals in your organization comfortable with calling an internal number or would an outside number be more acceptable? Do not be misled by your own internal belief that you are a nice, approachable person. Ask around. Distribute a questionnaire. Do a survey. Then decide what would work better for your organization.

Another consideration is that if you outsource your hotline and the caller has reported anonymously, you have the ability to provide information back to the original caller or ask for additional information from the caller to continue your investigation. This works by giving the caller a report number from the hotline service at the time of the initial report. At any point in your investigation, you can contact the hotline service and let them know you need additional information from the caller to continue the investigation. When the caller checks the hotline for any developments with their issue, they provide the report number and receive the information from you regarding the investigation. You can also provide the caller with information regarding the outcome of the investigation (if any) and whether or not the investigation is still active or if the investigation is closed.

What to do when you receive a call

You must have a system in place to document all issues relating to each call received. A log
should be maintained that documents the day and time of call, what the call was regarding, the investigation into the issues presented (if any), the outcome of the investigation, and the communications back to the initial caller. The log could be a simple paper file for each contact you receive, an Excel spreadsheet, or a detailed and complex Access database to track all information and electronically file all documentation surrounding an issue. However simple or complex you make it, the important thing is to ensure that you are documenting each call to the hotline and the outcome. Several providers offer an electronic software product that you can use to track hotline calls, if you want to purchase a tracking mechanism.

Whether you document in writing or electronically, it is best to create a standard hotline form to document all issues and collect the same information for each reported issue. You always want to document clearly and thoroughly, as if at some future point you may be challenged by an outside party, based on what you have investigated and the steps you took in your investigation.

This information should then be presented to your corporate compliance committee, the chief executive officer, and the board of directors, so they are aware of the compliance investigations and initiatives at your organization.

Other items to consider
To make your hotline successful, you need to advertise. Place postings throughout your organization. Provide information at new employee orientation, in the Code of Conduct, and in yearly compliance reminders to inform employees that they may contact the hotline to report any concerns, ask questions, or discuss issues. Make the hotline available to everyone—employees, vendors, patients, parents, visitors, etc.

Another outsourcing consideration is whether or not you need to have the reporting mechanism available in different languages and not just English. Some companies offer hotline services that provide interpreters in many languages. You should consider the population you serve and the cultures of your employees, vendors, and medical staff. If you offer a hotline service in multiple languages, you may also want to post information about its availability in multiple languages.

Remember, you may not be able to guarantee total confidentiality of the hotline call when governmental employees may be involved in an issue (unless the caller was anonymous and you have no way of knowing who they are).

Another consideration is naming your hotline. It may be called the hotline or the helpline. Some entities are creative in the way they name their hotline. Again, this is really a question of your culture. What type of entity do you work for? Will the employees identify with the hotline? Will your medical staff identify with the hotline? You may want to market your hotline differently if you are a hospital rather than a nursing home, lab, home health agency, etc.

Once your hotline is in place you may receive a great deal (if not a majority) of Human Resources (HR) calls. These should be tracked as usual and referred to your HR department for proper handling. You may also want to consider that some individuals may not use the hotline properly. For example, someone may call in a false complaint just to get back at another employee with whom they are having a disagreement. The lesson to be learned in these cases is to take every case seriously and investigate thoroughly, knowing that, in the end, you may find that the report was erroneous in the first place.

Think outside of the box regarding your hotline. Many organizations are now considering other ways for individuals to report issues. They include suggestion boxes, e-mails to a “general” compliance address, etc.

When your hotline is up and running, remember to test it periodically to ensure that it is working appropriately. Systems failures can happen for a variety of reasons, and it is important that you make sure your hotline is accessible. If you outsource your hotline, you can also measure the effectiveness of the reports you receive and the time it takes to receive hotline reports after a call is made.

Words of wisdom
When putting a hotline in place or updating the management of an existing hotline, remember that training is key. Training should include information on your reporting policy, including the steps to take when identifying a possible issue (i.e., talking to their supervisor, contacting HR, calling the compliance officer directly, calling the hotline, etc.) Let your staff know that they have a responsibility to the organization to report any issues they identify. Individuals must know that they have a place to report issues, discuss concerns, and ask questions. Training must include repeated assurances that those who report concerns in good faith will not be retaliated against. You must ensure that employees know that they will not be fired, patients/parents/legal guardians will not receive substandard care, and medical staff members will not be asked to step down for reporting any concern.

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National Provider Identifier—Will your organization be ready?

By: Elizabeth A. Kastner, Esq

Editor’s Note: Elizabeth A. Kastner is an associate in the Health Law Practice Group with Schottenstein Zox & Dunn, LPA in Columbus, OH. She may be reached by telephone at 614/462-4927 or e-mail at ekastner@szd.com.

This article is intended to provide information regarding the NPI. However, the information contained in this article is of a general nature and should not be considered legal advice as to any specific matter, organization, or provider.

The May 23, 2007 compliance date for the National Provider Identifier (NPI) is quickly approaching. Will your organization be ready? Often a health system is comprised not only of one or more hospitals, but also a network of affiliated physician groups, clinics, home health, or other health care businesses. When it comes to NPI implementation, such diverse types of health services can raise questions regarding who needs an NPI and who is responsible for obtaining needed NPIs. Health systems or other organizations faced with the need to obtain multiple NPIs need an effective NPI implementation compliance strategy.

Background on the NPI

The purpose of the NPI is to uniquely identify a healthcare provider in standard transactions, such as healthcare claims. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires that covered entities (i.e., health plans, healthcare clearinghouses, and those healthcare providers who transmit any health information in electronic form in connection with a HIPAA standard transaction) use NPIs in standard transactions by the compliance dates. The compliance date for all covered entities except small health plans is May 23, 2007; the compliance date for small health plans is May 23, 2008.

Steps for NPI implementation

Step 1. Determine who needs an NPI.

Which organizations within the health system need an NPI? Generally speaking, any health care provider who is a covered entity under HIPAA is required to obtain an NPI. This means that not only organization health care providers (such as hospitals), but also individual healthcare providers (such as physicians) need to obtain an NPI, if they transmit health information electronically in connection with any of the HIPAA standard transactions.

Organization healthcare providers within the health system must determine if they have “subparts” that need to be uniquely identified with their own NPI in standard transactions. If they do, the organization healthcare provider must ensure that a separate NPI is obtained for each subpart. Examples of subparts of a hospital can include hospital departments, psychiatric units, and laboratories. Hospital subparts are often separately licensed or certified and bill independently of the hospital of which they are a part. The Centers for Medicare and Medicaid Services’ Web site (available at http://www.cms.hhs.gov/NationalProvIdentStand/) contains a useful Fact Sheet to help organization health care providers determine if they have subparts that need separate NPIs.

Step 2: Decide what the health system’s role will be in obtaining needed NPIs.

After determining which of the health system’s organizations need an NPI, the health system will need to determine what its role will be in obtaining needed NPIs for these organizations. Will the health system gather the information needed to complete the NPI applications or coordinate obtaining needed application signatures? Will each organization instead be expected to assume all responsibilities for obtaining its NPI?

The answer to these questions will depend largely on the health system’s structure and operations. For example, in one health system, there may be one individual who oversees billing for the hospitals and a different individual who oversees billing for the physician groups and other healthcare businesses. For this health system, it may make sense to have two individuals be responsible for NPI implementation. In a health system with four affiliated physician groups and four different practice managers, it may make the most sense for the practice manager of each group to assume responsibility for obtaining that group’s NPI.

There is no right answer for what the health system’s role should be in obtaining needed NPIs. What is important is that the necessary communication takes place to ensure that someone is responsible for obtaining each needed NPI. Without such communication, a provider organization within the health system is comprised not only of one or more hospitals, but also a network of affiliated physician groups, clinics, home health, or other health care businesses. When it comes to NPI implementation, such diverse types of health services can raise questions regarding who needs an NPI and who is responsible for obtaining needed NPIs. Health systems or other organizations faced with the need to obtain multiple NPIs need an effective NPI implementation compliance strategy.

Continued on page 44
system could falsely assume that “someone in corporate” will obtain its NPI, when, in fact, the health system’s corporate administration is operating under the assumption that each provider would obtain its own NPI.

While the health system can coordinate obtaining NPIs, it is ultimately the responsibility of each covered healthcare provider to obtain its own NPI. For example, if a health system hospital is a party to a joint venture (such as an imaging facility) it is the responsibility of the legal entity that is the joint venture to obtain its own NPI. However, as a partial owner of a joint venture, the hospital will want to be sure that someone has assumed responsibility for obtaining the NPI, even if it is not the hospital. Moreover, even if the health system decides to coordinate obtaining an NPI for an organization, an authorized official of the organization must still sign the application and be responsible for verifying that the information on the application is correct. An authorized official must be a general partner, board chairman, chief financial officer, chief executive officer, a direct owner of a 5 percent or greater interest, or someone who holds a position of similar status and authority within the organization that is applying for an NPI.

Step 3. Decide whether NPIs will be obtained for individual providers. As with organization healthcare providers, it is the responsibility of each individual provider (not the hospital at which the provider is on staff or the provider’s employer) to obtain an NPI. However, if desired (and assuming the applicable providers agree), the health system can apply to become an electronic file interchange organization (EFIO, a so called “bulk enumerator”) and obtain NPIs for individual providers who need them, such as employed or staff physicians. An EFIO is an organization that applies for NPIs on behalf of providers. In other words, rather than a provider submitting a paper or Web NPI application, the EFIO obtains an NPI for the provider via the submission of an electronic file. An EFIO can submit NPI application information for many providers all at one time in a single electronic file or a series of electronic files. For organization healthcare providers that wish to apply for NPIs or submit NPI updates using the Web-based process on behalf of individual employed health care providers, CMS has developed a helpful Tip Sheet, available on its Web site at http://www.cms.hhs.gov/NationalProvIdentStand/04_education.asp.

**Step 4. Obtain NPIs.** NPIs can be obtained, free of cost, in one of three ways:

2. By completing a paper copy and mailing it to the NPI Enumerator (the entity that assigns NPIs). Request an application by:
   - Phone (1-800-465-3203)
   - E-mail (customerservice@npienumerator.com), or
   - Mail: NPI Enumerator, P.O. Box 6059, Fargo, ND 58108-6059
3. Via an electronic file using the “bulk enumeration” process described above.

### NPI implementation planning chart

A successful NPI implementation strategy depends not only on effective communication but also on effective documentation. The planning chart below is an example of one way a health system can organize its NPI implementation strategy by documenting which health system organizations need to obtain an NPI (or have obtained an NPI) and who is responsible for obtaining each NPI.

The chart below is organized into four categories:

1. “Hospital and Hospital Subparts” means any hospital in the health system as well as any subparts of a hospital. This may include, for example, not only a hospital within the health system, but also a psychiatric unit within the hospital.
2. “Joint Venture Entities” means limited...
Editor’s note: Jerry Ballman is Vice President of John Sterling Associates LLC. He may be reached by telephone at 800/909-5763.

The following information has been adapted from a booklet we provide to clients and other interested parties. The booklet is designed for the Human Resource and Compliance personnel who regularly screen new hires, and is written in plain English to simplify their task. All quotations are from the US Office of the Inspector General (OIG) unless otherwise indicated. We have emphasized key phrases from these quotation in bold.

This article is the second part of a two-part article. The first part ran in the December issue of Compliance Today on pages 24-27.

What you “should have known”
There are even more pitfalls to avoid in new-hire screening, and they are all related to the concept of what you “should have known.”

OIG’s Civil Monetary Penalties defines this term as a “reckless disregard” of information. Keep this in mind. These databases work on alphabetical matches. You are very likely to get a “false negative” result if you enter an incorrect, inaccurate, or incomplete name.

“False negative” means you get a misleading negative answer to a query, because the name submitted is not the complete name or the name has been somehow changed. It amounts to an imperfect check that leaves you vulnerable to hiring and employing excluded persons. You need to meet the higher standard of what you should have known.

Short form names: Ted may be Theodore
We live in an age where informality reigns. When it comes to first names, many people elect to be known by shortened forms of their actual given names. Unfortunately, you might check and clear the applicant Ted Smith (who is actually excluded by OIG under his correct name of Theodore Smith) and miss a possible exclusion.

That can be a big problem, because the federal databases are more likely to show the person’s correct first name. They likely will list William and not Billy, Daniel and not Danny, Deborah and not Debbie, Susan and not Sue.

Whenever possible, try to verify the first name when it appears to be a shortened version. If the applicant is present, press the point. If the first name on the application is different from the identification in his file (drivers license, birth certificate, passport, etc) be sure to check both versions of his first name.

And just to be safe, checking other alternative first names is a good practice. For example, Peggy should also be checked as Margaret, and Jack should also be checked as John.

First initials: F. Scott Fitzgerald
The name Francis S. Fitzgerald is not well known, but the alternative spelling certainly is. Deliberate or not, a first initial instead of the real first name can defeat thoughtless screening.

Yes, check the applicant’s name as presented (F. Scott as the first name), but whenever possible, have the applicant also provide his actual first name and check it. In this example, you would check him as Francis Fitzgerald.

A good practice in cases like this is to check under F Fitzgerald. Another is to just enter the surname (Fitzgerald) and see if any results are possible matches to the applicant.

Surname changes: Marriage and divorce
It’s a fact of life. Last names often change after either marriage or divorce. Mary Smith marries and now is known as Mary Jones. Susan Taylor divorces and again goes by her birth name of Susan Johnson. Or, she remarries and becomes Susan Lopez. Any of these occurrences can easily throw off a system based on checking only current names.

Watch for middle names that could be maiden names. For example, if the applicant Amy Doe lists her middle name as “Smith,” also check her as Amy Smith. Checking her under the surname “Smith Doe” is also a good practice.

We recommend that the application form require the applicant to provide any other surnames ever used, and then check them all.

Surname variations: Hyphenated and compounded surnames
In recent years, there has been a trend towards hyphenated surnames. Linda Adams marries and takes the name Linda Adams-Baker. And it is increasingly common for males to do the same thing.

The problem for checking is that she can legally choose to use the surname Adams, Adams-Baker, Adams Baker, or Baker. She could easily be on a federal exclusion list under any one of those surnames. So, the best practice is to check all these variations. Those variations continued on page 46.
are part of what you “should have known” when screening.

**Handling certain ethnic names**

Maria Gomez-Garcia also has a hyphenated surname. But Latino surnames have a cultural significance which requires special understanding.

Generally, the first part (Gomez) comes from her father and the second part (Garcia) is from her mother. While she may elect to be known simply as María Gomez, she would never call herself María Garcia as that would be disrespectful to her father. Therefore, you may not need to check her as María Garcia.

Note that on her employment forms she may have written her first name as “Ma”, a contraction of the name Maria. Since the federal databases are more likely to list the name as María, you should also check “Ma” as María.

Many Asians have a first name with two elements, such as Gai-Fu Yang (sometimes a blank space replaces the hyphen). The federal databases often incorrectly place the second element as a “middle name.” Proper checking involves using all possible combinations. Thus, check for both first names, Gai-Fu and Gai.

Asian custom can reverse the order of writing (e.g. “Yang Gai-Fu”). Be sure you adjust such names into standard American format when checking.

**Here’s the good news**

On average, 95% of your checks will not result in any possible matches, and therefore, will be quick to perform. Most likely you can get them done in a minute or two. The remaining 5% will take some effort and a little more time, but that can save you and your facility a great deal of time and trouble down the road. By doing a thorough screening today, you will avoid potentially huge problems in the future. And that is very good news indeed!

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**National Provider Identifier ...continued from page 45**

liability companies or other legal entities in which an organization within the health system is an investor/owner. This may include, for example, an imaging or cardiac facility that is partially owned by a health system hospital.

(3) “Physician Group Practices” means health system-affiliated physician group practices. This may include, for example, a physician group that is structured as a subsidiary of a hospital within the health system.

(4) “Misc. Affiliates” includes any healthcare business that the health system considers to be an affiliated healthcare provider that does not fall within one of the three categories above, such as a home health agency, hospice, or other nonhospital provider within the health system.

With a little advance planning, good communication, and good documentation, the process of obtaining and implementing NPIs for your organization should go smoothly.

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The HCCA will hold its next Audit & Compliance Committee Conference on February 26–28, 2007, in Scottsdale, Arizona at the Chaparral Suites Resort.

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Carrie Ellen Prante, RN, CHC


Carrie Ellen Prante, Regional Compliance Director for Tenet Healthcare Corporation's California Region, passed away unexpectedly on November 21, 2006, following a motorcycle accident. She is survived by her husband Jeff, a son Keith (19), and daughter Sarah (17), all of Huntington Beach, California.

Carrie was a long-term employee of Tenet Healthcare. She began her career with Tenet as Director of the Medical Floor and Education for Fountain Valley Regional Medical Center in Fountain Valley, California. She later transitioned to Director of Quality Performance Improvement for Fountain Valley and was promoted to Chief Nursing Officer for Western Medical Center in Anaheim, California, before taking the role of Regional Compliance Director for Tenet’s California region in 2003. Carrie was the first of nearly 100 compliance personnel hired by then Chief Compliance Officer, Cheryl Wagonhurst, following Tenet’s decision to expand its compliance function in 2003. Carrie quickly and efficiently hired a staff of 19 hospital compliance officers for Tenet’s California region. She was celebrated as a caring, compassionate, and gifted leader by those hospital compliance officers at a December 3, 2006, memorial service.

“Carrie was an amazing person” said Tenet’s former Chief Compliance Officer, Steve Ortquist. “She was one of those rare people who just got it—she knew when something was an issue and when it wasn’t. She was amazing with people even in difficult situations, and she was just fun to be around. Carrie told me recently that she felt like she had come into her own as a compliance officer and she was right. I’m privileged to have been able to call her a friend.”

Carrie had two catchphrases that she used often with her staff in Tenet’s California region that capture her zest for life and enthusiasm about the job she was doing. She could often be heard telling her staff that an appropriate response to a challenging situation was to “put on your rose colored glasses.” And when you called her and got voice mail, and often when you spoke with her directly, you would hear Carrie respond with her favorite “Create a Great Day.” She did so, not only for herself, but for many around her, and she will be sorely missed by all who knew her.
The Health Care Compliance Association welcomes the following new members and organizations. Please update any contact information using the Member Center on the Web site, or e-mail Karrie Hakenson (karrie.hakenson@hcca-info.org) with changes or corrections.

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- Urton Anderson, AXA Assistance
- Don Billingsley, Protiviti
- Sheila K. Coggins, Brazospart Regional Health System
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- Dimple Desai, Clark, Thomas & Winters, PC
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- Elizabeth A. Downing, Hillcrest Baptist Med Center
- Jimmy D. Eaton, Wise Regional Hlth System
- Susan Elke, BSN, MJ/IL RN, Univ of TX Southwestern Med Ctr - Univ Hosp St Paul
- Linda Farley-Fisher, BSN, RN, Children’s Medical Center
- Richard B Fidler, Protiviti
- Brian Flood, TX Health & Human Svcs Commission
- Robert Fontenot, MA, BA, BA, Northeast Medical Ctr.
- Michael J. Gaisbauer, United American Insurance Co
- Gail E. Garcia, RHIA, Tomball Regional Hospital
- Peter Gray, CHE, St Joseph Regional Health Center
- John Hall
- Timothy A. Hartin, JD, Baylor Health Care System
- Brenda Hightower, HCSC Ins Svcs Company (HISC)
- Tanya L. Hilton, Tomball Regional Hospital
- Priscilla A Johnson, Nexus Health Systems
- Dan Lacy, LifeCare Mgmt Services
- Brandy Liss, Regency Hospice-Home Health
- Antoinetta D. Lovelady, CIA, CCSA, M D Anderson Cancer Ctr
- Elizabeth M. Madzik, Presbyterian Hospital of Dallas
- Richard P. Maniscalco, Renal Care Group-SC Region
- Carol I. Maxwell, Cook Children’s Hlth Care System
- Marilyn M. McCaig, RN, BSN, MPA, Driscoll Chldrens Hospital
- Pamela McGlemmon, RN, CLC Healthcare Inc.
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- Hardy Thomas, Kaiser Permanente - CSC-FW
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- Patricia Sautel, CPHRM, Culpeper Regional Hospital
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- James Epperson, MultiCare Health System
- Sharon Felts, UW Medical Center
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- Brenda Baker, RN, CPC, VA Salt Lake City Hlth Care System
- Trent Casper, Intermountain Healthcare
- Matthew R. Denison, Community Health Centers, Inc.
- Katherine Gorris, Intermountain Healthcare
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- Jennifer R. Sharp, Univ of AR for Medical Sciences

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- Tina Corea, Rural/Metro
- Mary Jo Ghory, Childrens Clinics for Rehab Services

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- Joan Shapiro, St. Joseph's Hospital
- Carol Smith, University Physicians Healthcare
- Leslie Weigt, John C. Lincoln Health Network

Continued on page 50
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- Gail Rosenblum, Bench International
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