



G-2

Compliance

Report



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For Hospitals, Laboratories and Physician Practices

Hospitals, Labs Get Reprieve On Pathology Technical Component Billing Change

The New Year brought good compliance news for hospitals and independent laboratories that feared an abrupt transition to new Medicare billing requirements for inpatient and outpatient anatomic pathology referrals.

The Health Care Financing Administration had intended to make the change effective Jan. 1, requiring these labs to bill the hospital, not Part B, for the pathology technical component (TC). No change was proposed for the professional component (PC), which remains separately billable to Part B.

more years (2001-02) so long as such billing arrangements were in place with a hospital on or before July 22, 1999.

This "grandfather" provision was part of the Medicare provider relief bill that was packaged into the Consolidated Appropriations Act of 2001 (H.R. 4577) and signed into law (P.L. 106-554) by President Clinton.

Under "grandfathered" arrangements, hospitals can continue, through 2002, to refer anatomic pathology work for both inpatients and outpatients to independent labs that can, in turn, bill Medicare globally for the TC and the PC.

For hospitals not falling under the "grandfather" provision, Medicare TC billing policy is now the

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Congress Saves The Day

Acting just in time, Congress passed legislation last month allowing independent labs to continue to bill Medicare for the TC for two

HHS Unveils Final HIPAA Privacy Rule

The Department of Health & Human Services (HHS) on Dec 20, 2000, released a final rule establishing confidentiality protections for an individual's health information and how it may be used and disclosed. The rule is effective on Feb. 26, 2003, but small health plans have an extra year to comply.

The privacy standards are one of several sets of standards required by the 1996 Health Insurance Portability & Accountability Act (HIPAA) and intended to facilitate health data exchange. HHS has finalized the code sets and transaction standards; others, such as the security stan-

dards, have yet to be made final.

The confidentiality rule provides what HHS hails as the first comprehensive federal protection for the privacy of medical records. It sets a "floor" of safeguards; stronger state statutes (like those covering mental health, HIV and AIDS information) still apply. Also, where states have laws requiring certain disclosures for civic purposes, these mandates are not pre-empted.

Impact Of The Rule

The privacy standards apply to "covered entities," which include

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Brush Up On Stark Physician Referrals: New Final Rules Promulgated

Hospitals and other healthcare entities will see reduced potential liability for submitting claims based on prohibited physician referrals if they neither knew nor had reason to suspect they had an indirect financial relationship with a referring doctor.

Group practices will see a broadening of the in-office ancillary services exception, including looser supervision requirements, and revised criteria affecting their structure, operations, and bonus and profit-sharing practices. The level of supervision required will be that mandated under Medicare coverage and payment rules applicable to a particular designated health service (general, direct, or personal).

Shared facilities, however, will not enjoy a separate exception, but will be permitted if they comply with the supervision, location, and billing requirements of the in-office ancillary service exception.

These are some of the major changes that appear in the long-awaited final regulations, released Jan. 3, which govern physician referrals for a range of designated health services (DHS). The rules were proposed in 1998 and drew more than 13,000 comments.

The Health Care Financing Administration calls these rules Phase I of its rulemaking on the 1993 law (Stark II) which expanded the physician referral ban from Medicare lab services (Stark I, enacted in 1989) to include more DHS as well as Medicaid referrals. Phase II should be published soon, HCFA says, and will address Medicaid as well as other issues. (Note: Final Stark I rules affecting Medicare referrals for clinical lab services were issued in August 1995.)

The Phase I rules are effective on Jan. 2, 2002 (except home health referral provisions, which take effect on Feb. 5, 2001).

Referral Restrictions

The Stark law generally prohib-

its a physician from referring Medicare and Medicaid patients to facilities with which the physician (or an immediate family member) has a financial relationship, whether by ownership or investment interest or by a compensation arrangement. It also bans submission of a claim to any payer for DHS furnished under a prohibited referral.

DHS includes these services:

- ❖ Clinical lab
- ❖ Physical therapy
- ❖ Occupational therapy
- ❖ Radiology & certain other imaging services (MRIs, CT scans, ultrasound)
- ❖ Radiation therapy
- ❖ Durable medical equipment, supplies

CPT, HCPCS Lab Service Codes Subject To Physician Referral Provisions

INCLUDED

CPT: All lab services in the 80000 series (except blood codes opposite)

HCPCS Level 2:

G0001	Venipuncture
G0026	Fecal leukocyte exam
G0027	Semen analysis
P2028	Cephalin flocculation test
P2029	Congo red blood test
P2031	Hair analysis
P2023	Blood thymol turbidity
P2038	Blood mucoprotein
P7001	Culture bacterial urine
P9612	Catheterize for urine spec
P9615	Urine spec, collect mult
Q0111	Wet mounts/w preps
Q0112	Potassium hydroxide preps
Q0113	Pinworm exams
Q0114	Fern test
Q0115	Post-coital mucous exam

Source: *Federal Register*, Jan. 4, 2001, pp. 963, 965. CPT codes © 2000 American Medical Association

EXCLUDED

Blood Component Collection

86890	Autologous blood process
86891	Autologous blood, op salvage
86915	Bone marrow/stem cell prep
86927	Plasma, fresh frozen
86930	Frozen blood prep
86931	Frozen blood thaw
86932	Frozen blood freeze/thaw
86945	Blood product/irradiation
86950	Leukocyte transfusion
86965	Pooling blood platelets
86985	Split blood or products

Preventive Screening

76092	Mammogram
76977	Us bone density measure
G0103	PSA, total
G0107	CA screen; fecal blood
G0123	Screen cerv/vag thin layer
G0124	Screen c/v thin layer by MD
G0141	Scr c/v cyto, autosys and mdr
G0143-45	Scr c/v cyto, thin layer, rescr
G0147	Scr c/v cyto, automated sys
G0148	Scr c/v cyto, autosys, rescr
P3000	Screen pap by tech w MD superv
P3001	Screen pap by phys

- ❖ Parenteral/enteral nutrients, equipment & supplies
- ❖ Prosthetic, orthotic devices & supplies
- ❖ Home health
- ❖ Hospital inpatient, outpatient services
- ❖ Outpatient prescription drugs

Major Modifications

In addition to the changes previously cited, the Phase I final rules:

- ❖ Provide “bright line” indicators of what are DHS, including use of CPT and HCPCS codes to specify affected services in specific categories, such as lab, radiology, and radiation therapy.
- ❖ Permit physicians to refer to entities with which they have a compensation relationship, as long as the compensation paid to the physician is no more than would be paid to someone who provided the same services, but was not in a position to refer to the entity.
- ❖ Expand the in-office ancillary service exception to cover blood glucose monitors and certain durable medical equipment such as canes, walkers, and folding manual wheelchairs. HCFA says a series of changes to this exception and definitions of

“group practice” and “referral” should permit a doctor to furnish patients with covered drugs in his/her office or, in the case of erythropoietin and other specific dialysis drugs, to furnish the drugs through a physician-owned ESRD facility.

- ❖ Create new exceptions for compensation of faculty in academic medical centers, risk sharing by commercial and employer-sponsored managed care plans, and small, non-monetary gifts up to \$300 value.
- ❖ Allow independent contractors to provide the requisite supervision under the in-office ancillary service exception, so long as they have contracted with the group practice to treat group practice patients on group premises and have reassigned their claims to the group.
- ❖ Clarify that payment obligations that are secured, including those secured by a revenue stream, are among the relationships considered to be ownership or investment interests.
- ❖ Exclude services personally performed by the referring physician from the definition of “referral.”
- ❖ Interpret the “volume or value” standard to permit unit of ser-

vice or unit of time-based payments, so long they are at fair market value and do not vary over time.

The final rules cite more new exceptions which the agency says it will discuss in detail in Phase II of the rulemaking. One of these is for clinical lab services furnished in an ambulatory surgical center or an ESRD facility or by a hospice, if payment for these services is included in the ASC rate, the ESRD composite rate, or as part of the per diem hospice charge, respectively.

HCFA says that in the interest of simplification, it is considering an additional exception for any arrangement that fits squarely in an anti-kickback safe harbor and plans to address the matter further in Phase II of the Stark rulemaking.

The agency is accepting comments on Phase I if received by Apr. 4, 2001 at HCFA, DHHS, Attn: HCFA-1809-FC, PO Box 8013, Baltimore MD 21244. For more information, contact Joanne Sinsheimer, 410-786-4620.

Watch for more on the latest Stark II final rules in *Compliance Perspectives* in our February issue.

Resource

- ❖ Stark II final rules (Phase I): *Federal Register*, Jan. 4, 2001 🏠

■ Final HIPAA Privacy Rule, from page 1

healthcare providers, health plans, and claims clearinghouses that electronically transmit health information in connect with standard transactions (like a claim for payment). They apply as well in some cases to other companies doing business with these entities (formerly called “business partners,” now dubbed “business associates”).

The term “health information” is broadly defined to include any information relating to a person’s

health (past, present, and future), the healthcare provided, and the payment for such care. The rule does not apply to health information that has been “de-identified” by removing, coding, encrypting, or otherwise concealing individually identifiable information.

In major changes from the initial HHS proposal (November 1999), the final version:

- ❖ Covers individually identifiable health information created or held by covered entities in all

forms, including oral communications and paper records that have not existed in electronic form. The proposal had applied only to electronic records and any paper records that had existed in electronic form at some point.

- ❖ Requires patient consent for routine use/disclosure of their health records, as well as special authorization for non-routine disclosures. The proposed rule had allowed routine use/

disclosure without advance consent for purposes of treatment, payment, and healthcare operations (such as internal data gathering). The final rule retains the new requirement that patients must be given detailed written information on their privacy rights and how information about them will be used.

- ❖ Gives providers discretion to determine what personal health data to include when sending patients' medical records to other providers for treatment purposes. For most other disclosures, covered entities must supply only the minimum needed for the purpose of the disclosure.
- ❖ Guards against unauthorized use/disclosure for employment purposes.
- ❖ Clarifies that a covered entity does not have to actively monitor its business associates for privacy compliance, but must act if it knows of practices that violate the standards. The rule also requires fewer business associate contracts regarding privacy. Physicians on hospital medical staffs are not considered business associates of the hospital. An integrated delivery system may have a single business associate contract, sparing each provider in the system from having a separate contract with various business associates. Finally, patients do not have direct rights over their health information held by a covered entity's business associate.

Compliance Flexibility

The rule generally leaves it up to covered entities to craft detailed compliance policies and procedures for safeguarding personal health information, based on business type, size, and resources. As HHS notes, these entities must:

- ❖ Adopt written privacy procedures, including who has access to protected information, how it will be used within the entity, and when it will or will not be disclosed to others. Steps must also be taken to ensure that the entity's business associates protect health data privacy.
- ❖ Train employees and designate a privacy officer.
- ❖ Establish grievance processes so patients can make inquiries or complaints. Patients have the right to see and get copies of their records, request changes, and obtain a history of most disclosures of their records. They do not, under the HIPAA statute, have a private right of action to sue to enforce their privacy rights.

With few exceptions, individually identifiable health information may be used for health purposes only. Providers who see patients must obtain their consent before sharing information for purposes of treatment, payment, and healthcare operations. More specific consent must be obtained for non-routine use, such as releasing information to financial institutions or selling mailing lists. Patients have the right to request restrictions on the uses and disclosures of their health information.

Certain existing disclosure practices are permitted without individual authorization. Among these are: quality assurance, public health, research, judicial and administrative proceedings, certain law enforcement activities, emergency circumstances, identification of a deceased person or the cause of death, facility patient directories, and activities related to national defense and security.

Some entities or activities are exempt from the privacy rule: for example, procurement or banking of blood, sperm, organs, or any other tissue for administration to patients. However, blood centers

that provide patient services such as therapeutic hemapheresis and phlebotomy, crossmatching, and outpatient transfusions are covered by the rule.

Penalties for covered entities that misuse personal health information include civil money penalties (\$100 per incident, up to \$25,000 per person, per year, per standard) and criminal penalties (up to \$50,000 and one year in prison for obtaining or disclosing protected health information; up to \$100,000 and five years in prison for obtaining it under false pretenses; up to \$250,000 and 10 years in prison for obtaining or disclosing it with intent to sell, transfer, or use it for commercial advantage, personal gain, or malicious harm.

Resources

- ❖ Final HIPAA medical privacy rule: *Federal Register*, Dec. 28, 2000. Online: www.aspe.hhs.gov/admsimp
- ❖ Previous coverage in *G-2 Compliance Report*: March 2000, Perspectives, pp. 5-8. 🏠

Where to go for thorough, incisive and practical help on complying with HIPAA privacy, other requirements

Compliance FORUM 2001

Putting
HIPAA
Standards
Into
Practice

Locations: Tampa: March 22-23;
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COMPLIANCE PERSPECTIVES

HIPAA Confidentiality & Other Compliance Challenges “Don’t Miss The Forest For The Trees”



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All eyes are currently focused on dissecting the minutia of the final patient privacy rule, authorized under the 1996 Health Insurance Portability & Accountability Act (HIPAA) and released last Dec. 20 by the Department of Health & Human Services (see related story, p. 1).

At one level, this is a necessary and appropriate exercise. At another level, it is “missing the forest for the trees.”

The “trees” I’m referring to are the particulars of the authorizations which the final regulation requires providers to obtain—authorizations for routine uses and disclosures of individually identifiable health information as well as authorizations for uses and disclosure outside those necessary for “treatment”, “payment,” and “healthcare operations.”

You can also count among the “trees” those business associate arrangements that providers will need to make with those companies to which they release individually identifiable health information in the course of business.

The “forest,” however, is that, HIPAA notwithstanding, privacy/

confidentiality issues are now at center stage in the public eye. These issues forced their way into the public’s consciousness, not as a result of HIPAA, but as a result of our societal infatuation with the Internet. We collectively gloried in the prospects for success for Internet marketplaces and information portals of all types. But this euphoria was clouded after DoubleClick’s tracking of consumer habits was chronicled and questions were raised about the privacy practices of such household names as Amazon, IKEA, and RealJukeBox.

Thus, today’s consumer is attuned to privacy issues to a degree not seen before. Of equal importance, the media now consider stories about privacy violations to be very newsworthy. Otherwise esteemed healthcare organizations ranging from Kaiser Permanente to Dana Farber to the University of Washington have gotten a “black eye” from media reports of confidentiality errors.

Why You Should Care

Because of these developments, prudent healthcare organizations are implementing data privacy and security safeguards for several very practical reasons—only one of which is the effective date, some 24 months from now, of the final HIPAA rule on medical records privacy.

❖ Reason #1: Each healthcare

organization depends on patient confidence, and that confidence would be harmed by media stories suggesting that the healthcare institution had subpar arrangements in place to protect patient confidentiality. Confidentiality errors (like other errors) will happen. Thus, it is crucial that an organization be able to describe to the public its policies and procedures to prevent or correct such errors and make sure they do not recur.

❖ Reason #2: The governing board of a healthcare organization expects management to implement best practices. Even in advance of implementation, the privacy standards in the HIPAA rule have become “best practice” benchmarks.

❖ Reason #3: Risk management demands it. To date, tort claims involving breaches of confidentiality have been limited—in part by the lack of a community standard of care and in part by a lack of understanding of the issues by the plaintiff bar. Both of these conditions have changed. The HIPAA privacy rule has created standards against which negligence can be measured. Moreover, the standards will now be widely known, whereas previously they varied greatly from state to state.

❖ Reason #4: The HIPAA privacy rule is final and Congress is unlikely to overturn it. Thus, by

February 26, 2003, compliance will be in force for virtually all healthcare providers, health plans, and claims clearinghouses. Between now and then, various accrediting bodies will also take up the theme.

Meshing HIPAA With Current Compliance Efforts

A compliance program for HIPAA confidentiality (as well as for HIPAA security, the subject of a proposed rule which the government is expected to finalize soon) flows naturally from other programs for anti-fraud and abuse compliance.

In all these realms, for instance, a healthcare organization is required to spend time documenting its policies and procedures. The final privacy rule requires what has always been the best practice in developing such policies and procedures—namely, that they take into account the specific challenges of the organization based on its business, size, and resources.

There are six other areas where the convergence of these compliance efforts is notable.

1 Corporate compliance programs generally, the HIPAA final privacy rule, and the HIPAA draft security rule all call for organizational oversight, usually vested in a single individual or organizational role. The privacy rule requires the designation of a privacy officer.

2 Corporate compliance programs focus on training and education. The draft HIPAA security regulation emphasizes security awareness training as well as training on specific issues such as virus protection and password management. The final rule on patient privacy requires training no later than the compliance date for the organization, training for new hires, new training when a material

change in policy occurs, and documentation of each training session.

3 Corporate compliance programs emphasize the establishment of lines of communication. In the HIPAA security regulation, the covered entity is challenged to document instructions for reporting security breaches so that security violations are reported and handled promptly. In the privacy realm, the final rule requires a complaint process.

4 Corporate compliance programs address enforcement and discipline. The draft security regulation picks up this theme and calls for sanction policies and procedures, including notification to law enforcement officials and to regulatory, accreditation, and licensure organizations. The final privacy rule also requires covered entities to apply appropriate sanctions against members of its workforce who fail to comply with the entities' privacy policies and procedures.

5 Corporate compliance programs incorporate an audit and monitoring function. The draft security regulation reaches these issues through requirements for security testing, physical safeguard testing and revision, as well as in-house review of system activity. In the final privacy rule, such a function will find its way into the "appropriate" administrative and technical safeguards that are required.

6 Corporate compliance programs include procedures for response and corrective action. In the draft security regulation, covered entities must document actions taken as a result of a security incident report. Comparable documentation is required under the final privacy rule for complaints (and their disposition). Moreover, the issue is addressed in that rule's requirement of documentation of the covered entity's attempts to

mitigate the harmful effects of inappropriate use or disclosure of individually identifiable information.

Take A Broader Look

One final area of privacy risk management requires a "forest," not a "trees" perspective. The final regulation requires that covered entities give notice to patients of the uses and disclosures of personal health information that the organization will allow.

The "trees" within the regulation address explanations of all the permitted uses of the information as well as a patient's access and amendment rights. Many healthcare organizations have long had such policies. They will, of course, need to bring them up-to-date from a HIPAA perspective.

But aside from HIPAA, what these organizations should not overlook is that these policies will be the basis for breach of contract or other claims, should they be violated. Again, the Internet economy is instructive. Such claims have been made against Internet companies whose policies were more ambitious than their practices.

Electronic risk management for healthcare organizations is, of course, not limited to implementation of privacy and security programs. These topics get the lion's share of attention, but compliance necessarily runs deeper.

For instance, providers that have developed Websites need to review them in several respects. References to other providers need to be reviewed from a fraud and abuse perspective. Recommendations can trigger the anti-kickback statute. A typical issue is whether a hospital can give preferential listing to those providers who are "big admitters."

Counsel might also be obtained prior to linking your site to other Websites. Linking agreements are

one risk management technique. In the other direction, risk management is concerned with dangers to visitors to a site. The site will want to identify the date and source of content. It may also want to disclaim responsibility for the accuracy of content supplied by others, although it could state that it deems the content to be reliable. Also, disclosure as to when the visitor is leaving the site is important.

A major issue for some health-care sites is whether professional licensure laws are being complied with, given the potential for visits from persons in other states. Attention needs to be paid to the nature of the professional's interaction with persons over the Internet. Is a doctor/patient relationship be-

ing formed? Is the site simply providing educational information, or is it abetting the diagnosis of persons in other states?

Healthcare entities should review risk management strategies for their Websites with counsel as well as their insurance broker. New coverage forms are available to relate to such exposure, but they need to be reviewed closely against the activities that are planned.

Conclusion

Healthcare organizations have increasing opportunities for relating to their suppliers and customers electronically. These opportunities should, however, be evaluated from both a financial and a risk management perspective.

Privacy issues are among the most prominent of the risks to be evaluated. However, don't focus on them to the exclusion of other risks.

Moreover, compliance with HIPAA privacy standards can be effectively related to your other compliance efforts. In doing so, however, bear in mind that, perhaps even more than government rules, patient/customer and media attention to privacy issues will drive the installation of privacy/confidentiality policies and an administrative structure to support these policies.

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Quick Guide To Use/Disclosure Requirements Of The Final HIPAA Privacy Rule

Covered Entities

Healthcare providers, health plans, claims clearinghouses that transmit any health information in electronic form in connection with a HIPAA standard transaction.

"Protected" Health Information (PHI)

Information that relates to past, present, or future physical or mental condition or payment for the provision of healthcare (whether oral or recorded in any form or medium) and that is created by a covered entity, employer, life insurer, or public health activity IF IT IS individually identifiable or there is a basis to believe it can be used with other information to identify the individual.

Routine Consent

- ❖ Obtain prior to using or disclosing PHI for treatment, payment, or healthcare operations unless there is an indirect treatment relationship, an emergency, or communication problems.
- ❖ Inform as to use of PHI for treatment, payment, and healthcare operations, list privacy policy

and rights, including right to request restriction of use (non-binding).

- ❖ Must be signed, dated, and visually separate from most other permissions, and is revocable.
- ❖ A few uses of PHI are deemed so innocuous they do not require written consent. Oral consent or opportunity to object will suffice. Examples: use of name, location, and condition in a facility's directory; disclosures to family members, close personal friends of PHI relevant to care and payment.

Consent To Non-Exempted Uses/ Disclosures

- ❖ Treatment, payment, enrollment, or benefits generally cannot be conditioned on this consent.
- ❖ Content must include plain language, identify the PHI used; name or class of persons at the covered entity making the disclosure; name or class of persons receiving the PHI; expiration date; revocation right; warning that re-disclosure could occur;

disclosure of any remuneration for the disclosure.

Disclosures To Business Associates Without Consent

PHI can be disclosed if there is a contract that binds the business associate to: follow the rules that covered entities follow; not further disclose unless the contract permits it or law requires it; report inappropriate uses; require contractors to agree to the same restrictions; make books and records available; return or destroy PHI at the end of the relationship; authorize termination if the covered entity determines the business associate violated the terms of the contract.

"Minimum Necessary" Standard Constrains Most Uses/Disclosures

Covered entities must make "reasonable efforts" to limit the PHI used or disclosed to the minimum necessary to accomplish the intended purpose, unless the disclosure is to a provider for treatment purposes or to the individual or the HHS Secretary. ♣

Hospital Giant Settles Largest-Ever Healthcare Fraud Case

In the largest Medicare criminal probe to date, HCA-The Healthcare Company (formerly Columbia/HCA; headquarters: Nashville, TN)—has agreed to pay the government \$840 million to settle alleged improper billing practices. HCA is the largest U.S. for-profit hospital chain, owning or operating 200 hospitals and other healthcare facilities in 24 states (and overseas) and employing 168,000 workers.

Two of HCA's inactive subsidiaries—Columbia Management Companies Inc. and Columbia Homecare Group Inc.—will plead guilty to several criminal counts, including cost report fraud and kickbacks to physicians, and will be excluded from federal healthcare programs.

The government can still go after any individuals who might be linked to the criminal investigation, and the settlement is subject to court review.

Settlement Terms

The settlement, announced Dec. 14, includes \$95 million in criminal penalties and fines and \$745 million to resolve civil charges of billing fraud. HCA agreed to the latter amount last May, contingent on the ability of the company and the U.S. Department of Justice to resolve criminal matters by year's end.

Many of the civil charges that were settled arose from whistleblower lawsuits. Their share of the recovery (up to 25%) is undetermined, pending further negotiations or court proceedings. Several other civil issues are still unresolved, including allegations of fraudulent Medicare cost reports and kickbacks to physicians to refer patients to HCA facilities.

In a side agreement, HCA will enter into an 8-year corporate integrity agreement which HHS Inspector General June Gibbs Brown calls "unprecedented in [its] scope and level of detail" (the text is posted on the company's Website, www.hcahealthcare.com).

HCA also will divest itself of one of its Miami hospitals which allegedly engaged in fraud.

Finally, the company agreed in principle to resolve related issues with state Medicaid programs. Medicaid's portion is approximately \$36.3 billion; states involved in the case will get about \$13.6 million, representing their share of Medicaid funds.

Practices Faulted

HCA agreed to pay the following sums related to civil claims:

- ❖ \$95 million for outpatient laboratory billings for tests that were

not medically necessary or were not ordered by physicians, as well as other billing violations involving Medicare, Medicaid, the Defense Department's Tricare program, and the Federal Employees Health Benefits Program.

- ❖ \$403 million for upcoding, in particular on pneumonia claims to the above payers.
- ❖ \$50 million for Medicare claims for non-reimbursable marketing and advertising costs that the government says HCA disguised as community education. Medicare reimburses providers for costs to educate the community at large about public health issues, but not for advertising and marketing a hospital's services.
- ❖ \$90 million for Medicare claims for non-reimbursable costs incurred in the purchase of home health agencies owned by Olsten Corp., as well as other agencies in Florida, Georgia, and Alabama.
- ❖ \$106 million for claims to Medicare and other federal payers for home health visits for ineligible patients or for visits not made.

The investigation of Columbia/HCA surfaced in 1997 with government raids on company facilities and seizure of internal documents. Chief executive Richard Scott and other top management later resigned. Thomas Frist Jr., MD, a founder of Hospital Corp. of America which later merged with Columbia, stepped in to handle the dispute with the government and to restructure the company and refurbish its image.

Resources

- ❖ U.S. Justice Dept: www.usdoj.gov
- ❖ HCA: 615-344-9551; Website, www.hcahealthcare.com
- ❖ Previous coverage in *G-2 Compliance Report*: Jun-Jul '00, p. 4; Jan '00, p. 11. 🏠

Nursing Home Chain Settles

National Healthcare Corp. (Murfreesboro, TN), which owns, leases, or provides services to 105 nursing homes nationwide, will pay \$27 million to resolve false claims allegations that it submitted falsely inflated cost reports to Medicare. The company also will enter into a corporate integrity agreement with the HHS Office of Inspector General.

According to the government, cost reports overstated the number of hours that nursing home staff spent caring for Medicare patients, and certain personnel at some homes were billed as performing therapy on Medicare patients when they did not do that type of work.

The suit was brought in 1996 by Philip Charles Braeuning, former administrator of a facility then managed by NHC. The government joined the suit in 1997 and has agreed to pay Braeuning 20% of the recovery. 🏠

Medicare Moving Closer To A Uniform, Standardized ABN Form

For those working in lab service billing units, compliance with Medicare Part B requirements for obtaining an advance beneficiary notice (ABN) should become easier soon.

The Health Care Financing Administration is getting closer to finalizing a uniform, standardized ABN that labs would have to use to obtain consent from Medicare beneficiaries before billing them for tests denied by Medicare on grounds that the tests were not medically necessary or were non-covered.

The comment period closed Dec. 26 on the agency's second draft ABN (proposed Oct. 26). A final version is slated for one more round of clearance at the Office of Management & Budget. "Then," said Joanne Glisson of the American Clinical Laboratory Association (ACLA), "we would get another bite at it."

Among laboratory associations, there is general agreement that HCFA has been responsive to industry concerns in refining Medicare ABN policy. The Oct. 26 proposal was seen as improving on HCFA's first draft (circulated earlier this year but not formally published). Along with presenting a draft ABN form, the proposal included text to inform beneficiaries of their options, including their financial responsibility for denied tests.

At a Nov. 28 meeting held by HCFA to discuss its work, ACLA, which represents large national and regional independent labs, put forth three main concerns and submitted a substitute form that it thinks addresses problems in HCFA's version.

HCFA's proposed two-page ABN would make the lab responsible for informing the beneficiary why Medicare is not likely to pay for the

test, the cost of performing the test, and the patient's financial obligation. Further, the lab would have to document the patient's decision and notify the individual's physician of that decision.

ACLA's Concerns

The draft ABN leaves the test names blank and does not specifically link the reasons for denial to the tests that were ordered. This creates two problems. First, depending on what the physician writes down as the test name, there could be confusion about which test is actually subject to an ABN. Second, if several tests are ordered and several reasons are given for denial, it is impossible to determine which reasons go with which tests.

ACLA proposed that pre-printed test names be on the form itself, grouped under headings designating a likely reason for denial: for example, Medicare does not pay for this test for your condition; or does not pay for this test as often as this; or does not pay for experimental or research use.

All a physician would have to do is check off the reason.

Beneficiaries would have two options: I want to receive this test (and the financial responsibility is spelled out) or I have decided not to receive this test.

ACLA backed giving labs flexibility to adjust the list of pre-printed tests to reflect limited coverage situations, such as local medical review policies and test frequency limits. "These area-specific modifications are already a regular feature of laboratories' requisition-based ABNs," ACLA argued.

The association cited additional minor problems, including the demographic data collected, the

requisition number, and the form's design:

- ❖ A beneficiary's name, requisition date, and HIC number are unnecessary. The patient's name and HIC number should be enough.
- ❖ A physician who obtains the ABN should not insert a requisition number; the lab later assigns that number when the specimen is accessioned.
- ❖ Those sections of the form for the physician to complete should be shaded. "This would draw the physician's attention to the one or two areas on the form that require a check-off or other notation," said ACLA.

More Suggestions

Others have taken sharper issue with HCFA's proposal. C. Anne Pontius, who heads Laboratory Compliance Consultants (Raleigh, NC), is very concerned about the agency's draft ABN form.

"HCFA has removed a laboratory's creative ability to be flexible in designing something that works in their practice," she told us. The ultimate goals are to make sure that a beneficiary is notified where payment may not occur and to make the form usable within the work facility, Pontius said, so flexibility is essential.

She also objected to labs having to tell a patient what a test would cost. "If you are sending the test to a reference lab, you may have no idea of the actual cost." Instead, labs should simply be required to give the beneficiary the reference lab's telephone number, she said.

Resources

- ❖ Joanne Glisson, ACLA: 202-637-9466
- ❖ C. Anne Pontius: 919-859-3793, caplcc@aol.com 🏠

Free Services By Hospitals Aren't Always Illegal Remuneration

In two separate advisory opinions, the HHS Office of Inspector General (OIG) recently addressed the question of whether hospitals may offer certain services for free, without risking federal sanctions.

Federal anti-kickback law makes it a crime to offer anything of value to reward or induce referrals for items or services reimbursable under any federal healthcare program.

Advisory opinions are limited to the situations described by the parties requesting them and may be relied on only by those parties, but they also shed light on how the OIG analyzes potential kickback situations.

Free Transportation

In Advisory Opinion 00-7, the OIG found that a rural nonprofit hospital's free transportation system for chronically ill patients did not constitute grounds for sanctions under either the civil monetary penalty provision prohibiting inducements to beneficiaries or the anti-kickback statute.

Nonetheless, the opinion underscores what many in the healthcare legal community have been arguing for some time: "Free transportation potentially raises compliance and fraud and abuse issues," Steven Chanie, a partner with Garfunkel Wild & Travis (Great Neck, NY) told us.

"A lot of lawyers have healthcare clients who have fought that proposition," he said. But the OIG opinion, which he predicts will be a precursor of many others on this matter, shows that "providing free transportation is potentially a fraud and abuse and compliance issue."

In the situation discussed by Ad-Op 00-7, the hospital offered free transportation to certain patients referred to it for extended

courses of treatment involving chemotherapy, dialysis, radiation therapy, cardio/pulmonary rehabilitation, or certain similar services. The hospital serves not only the city where it is located, but also a 10-county rural area of more than 8,000 square miles containing medically underserved areas and populations.

The OIG's analysis hinged on several factors:

- ❖ In the geographic area where the free service is provided, there is limited or no economical means of public transport. The area also is limited to the hospital's historic primary service area and to other areas that include patients for whom the hospital is the nearest provider of the prescribed treatments. "If you're going five counties over or into the next state, that is going to be a problem," Chanie observed.
- ❖ The free service is not marketed or advertised. "Doing either can be a red flag that you're trying to induce referrals," Chanie warned. The service is available only to individuals already referred to, or being treated at, the hospital, and then only if a hospital official has made an individualized determination of need.
- ❖ The free service is available to all qualified patients requiring a course of multiple treatments and is not targeted at, or limited to, particular profitable treatments or patient populations.
- ❖ The cost of the service will not be claimed directly or indirectly from, or otherwise be shifted to, any federal healthcare program.

Chanie pointed to one important factor in the OIG's analysis: the hospital's role as primary medical provider in a large, rural, medically underserved area. "In all likeli-

hood, if you are in a major city, you will go several miles and pass five drawing stations, three labs, and two hospitals ... Passing other providers is problematic in denser, more urban areas, and you have to consider that."

Free Ambulance Restocking

In Advisory Opinion 00-9, the OIG found that a hospital's free ambulance restocking of drugs and medical supplies directly related to emergency pre-hospital services did not warrant anti-kickback sanctions.

The nonprofit hospital in this case is the only hospital in the greater geographic area. It gets more than 85% of the patients that emergency medical service (EMS) ambulances in the area carry. It also participates in an EMS regional council and is a "sponsor hospital" for 12 area EMS services under an agreement with state authorities.

Four of the 11 EMS transport services carrying patients to the hospital are volunteer ambulance services that do not charge patients or insurers for their services. Under the proposed arrangement, the hospital will restock these volunteer services with free medical supplies used with emergency pre-hospital services (including blood collection tubes; intravenous solutions and tubing, catheters, and needles; oxygen cannulas and masks; intramuscular syringes, etc.). With regard to the other EMS ambulance services, the hospital will continue to restock them with similar supplies and medications at fair market value.

In scrutinizing the arrangement, the OIG found that:

- ❖ Its relationship to the community's EMS system provides adequate assurance that it is designed to improve the delivery of EMS for the benefit of the

entire community, and not solely to benefit a single provider or group of providers.

- ❖ The hospital offers free restocking only to volunteer EMS ambulance companies that do not bill for their services. The hos-

pital has a legitimate interest in containing the cost of its ambulance restocking program, and limiting the free restocking to the non-billing volunteer services is a reasonable distinction not related to the value or vol-

ume of referrals or other business generated by the hospital.

Resources

- ❖ OIG Advisory Opinions 00-7, 00-9: www.hhs.gov/progorg/oig
- ❖ Steven Chananie: 516-393-2224 🏠

More Settlements In Major Federal Healthcare Anti-Fraud Initiatives

Operation LabScam

Bringing to a close the last of the original LabScam investigations into Medicare billing and marketing practices, Quest Diagnostics Inc. (Teterboro, NJ) has agreed to pay \$13.1 million to settle fraud allegations against Nichols Institute (San Juan Capistrano, CA), which Quest acquired in 1994.

The government accused Nichols of routinely billing for laboratory tests that were not medically necessary. These billing practices began in 1989, the government said, and ended in 1995 soon after Quest purchased Nichols.

Operation LabScam targeted lab unbundling, or separate billings for groups of lab tests performed together, in order to receive higher reimbursement. All together, the government has recovered more than \$850 million from the Nation's largest clinical labs, including SmithKline Beecham Clinical Labs (which Quest acquired in 1999) and Laboratory Corp. of America (for predecessor companies Roche Biomedical Labs and National Health Labs).

The case against Nichols was conducted jointly by the Justice Department and U.S. attorney's offices in Portland, Houston, and San Francisco, aided by other federal investigative units, including the FBI, the HHS Office of Inspector General, and the Defense Department's criminal probe unit.

According to Quest spokeswoman Julie Clarkson, the com-

pany denies the allegations, "which we think were routine practices common in the industry," but settled to put the issue behind it and "move on." The cost of the settlement, she noted, is covered in an indemnification agreement with Corning Inc., which spun off Quest in December 1996.

Operation Bad Bundle

In the latest recovery under this probe of hospital outpatient laboratory billings to Medicare and other federal healthcare programs, the government stands to collect \$2.5 million from various hospitals in the Eastern District of Missouri. The recovery was announced by the U.S. attorney in St. Louis, Audrey Fleissig.

According to the government, the probe by federal and state agencies had disclosed that a number of hospitals had improperly billed the federal programs for medically unnecessary lab testing and/or had unbundled and separately billed for component tests of chemistry test panels and hematology tests.

Civil settlements were reached with 22 hospitals, including nine in the St. Louis area.

Operation Bad Bundle began in 1994 as a national project involving the HHS Inspector General, the Justice Department, and U.S. attorney's offices. It targeted unbundling of automated chemistry profiles (CPT 80002-80019, since deleted and replaced with four automated panels) and in some states included hematology tests and uri-

nalysis. In some states, the probe also has involved the FBI, state auditors, and Medicaid fraud units.

While Bad Bundle has been active in prosecuting and settling cases in states such as Missouri, Ohio, and Virginia, it was dropped in Illinois and Texas because of bad data from Medicare fiscal intermediaries. 🏠

■ Pathology TC Billing, from page 1

same for inpatient and outpatient pathology services. It is no longer separately billable. HCFA contends that the TC is now reimbursed under prospective payment rates, and independent labs must arrange with the referring hospital to get paid for it.

A Longer Reprieve?

Meantime, Congress directed the General Accounting Office to study the effect of the "grandfather" provision on hospitals and labs as well as on fee-for-service beneficiary access to pathology services. GAO is to make recommendations on whether this proviso should continue after the 2-year period for either (or both) inpatient and outpatient pathology referrals and whether it should be extended to "non-grandfathered" hospitals.

Reference

- ❖ *Congressional Record*, Dec. 15, 2000, Nos. 154-155: Conference Report on H.R. 4577, pp. H12100ff. Pathology statutory provisions: p. H12383. 🏠

The Back Page

News-At-A-Glance

Back In Business: The HHS Inspector General is again accepting requests for advisory opinions. Its statutory authority to issue such opinions expired last August, but has been renewed permanently by the omnibus spending bill for 2001, recently signed into law by the President (P.L. 106-554).

The rules governing the advisory opinion process and a checklist of requirements can be found at www.hhs.gov/oig/advopn/index.htm

VA Hotline: The Department of Veterans Affairs has awarded a 4-year, \$421,712 contract to National Hotline Services Inc. (Fredericksburg, VA) to set up and run a nationwide compliance hotline for the VA health system. Once activated, the hotline will be in service 24 hours a day. NHS was founded in 1992 by former HHS Inspector General Richard Kusserow. It provides round-the-clock hotline services for more than 200 clients with one million employees. Most are hospitals

or other healthcare organizations.

Over four million veterans are enrolled in the VA healthcare system, which includes 172 medical centers. Each year, the VA serves more than 111,000 veterans in its nursing homes and domiciliaries and handles 37 million outpatient visits at its clinics.

Escaping Double Damages: By voluntarily disclosing improper Medicare/Medicaid payments, Chicago's Rush Presbyterian-St. Luke's Medical Center has avoided double damages, but still must pay \$800,000 to settle false claim allegations. The settlement, announced Jan. 9, involves claims submitted from May 1993 through May 1999 for post-operative outpatient physician services provided by Rush's University Transplant Medical Service Plan when an attending doctor was not physically present and for upcoding those services. After the confidential voluntary disclosure, a worker at the transplant clinic filed a whistleblower lawsuit, alleging the same fraud along with other accusations, but the fraud claims were dismissed and the government de-

clined to join in pursuing the other charges.

HIV Discrimination: A neurosurgery group in Tulsa, OK, can no longer refuse surgical services to people with HIV and will pay \$50,000 in compensation and fines under an agreement filed Dec. 22 with the Justice Department.

This resolves a lawsuit charging Neurological Surgery Inc. (NSI) with violating the Americans with Disabilities Act. The suit arose from a complaint filed with Justice in 1998. The individual, who had a back condition and was referred to a neurosurgeon with NSI for possible surgery, alleged that upon learning of his HIV, the physician refused to provide any further medical services, citing a policy of refusing to treat HIV-infected persons. NSI must pay the individual \$40,000 in compensation, plus a \$10,000 civil fine to the government. The physician in the case must attend HIV-related training. "A discriminatory refusal of medical care is especially egregious," said Bill Lann Lee, assistant attorney general for civil rights, "where, as here, the refusal affects a population so dependent on the availability of medical services." 🏠

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