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Quest Settles Probe Into Billing Practices
Company Denies Wrongdoing In NY Case

he nation’s largest provider of clinical laboratory testing services, Quest Diagnostics Inc. (Teterboro, NJ), has agreed to settle a New York state investigation by changing its billing practices and repaying consumers who were billed for services covered or already paid by their health plans, according to New York Attorney General Eliot Spitzer.

Spitzer began the probe after receiving complaints from consumers that Quest was billing them for lab tests, even though the company was a “participating provider” in their health plans and the services were covered by the plans. Under New York law and most health plan contracts, a participating provider cannot bill a plan member for covered services, other than charges for deductibles, coinsurance or copayments.

According to Spitzer, the investigation found that Quest improperly “balance-billed” some consumers, that is, it billed them for the entire balance due when it submitted a

New Medicare ICD-9 Code Requirement Raises The Compliance Stakes For Labs

A new requirement that virtually all Medicare Part B claims, including those from clinical diagnostic laboratories, must contain a valid ICD-9-CM diagnosis code is likely to trigger substantial headaches for independent and hospital-based labs that are accustomed to submitting claims with only a physician’s narrative diagnosis, lab compliance experts tell G-2 Compliance Report. Only claims from ambulance suppliers are exempt from the ICD-9 requirement.

“This could be a real nightmare,” warns C. Anne Pontius, president of Laboratory Compliance Consultants in Raleigh, NC. “Labs are really going to have to work with ordering providers to convince them to send the necessary diagnosis information.”

Effective Oct. 1, 2003, all Part B laboratory claims must contain a valid ICD-9 code or they will be returned to the provider as “unprocessable,” says the Centers for Medicare & Medicaid Services. Currently, by law, since Apr. 1, 1989, the ICD-9 code has been required only on physician claims, including those for tests performed by a physician office lab. Independent and hospital labs have been able to submit either an ICD-9 code or a narrative diagnosis in most cases.
Quest Settles Probe, from p. 1
claim to the consumer’s health plan but re-
ceived no response. The company also double-
billed some patients whose health plan had
already paid Quest, Spitzer said.

Incorrect Billings A “Mistake”
Quest officials deny any wrongdoing, main-
taining that the errors were due to a glitch in
the company’s computer billing systems.

While Quest acknowledges that some incor-
correct billings may have occurred by mistake,
it “denies that any pattern or practice of er-
rors existed and does not accept as an estab-
lished fact the assertions contained in the 10
consumer complaints” from Spitzer’s office.

Gary Samuels, a spokesman for Quest, says
that about a year ago Spitzer had contacted
the company about the complaints and they
have all since been resolved. “We have
worked closely and cooperatively with Eliot
Spitzer’s office to resolve this situation,” notes
Samuels. “We’re a little disappointed with the
way he has characterized it.”

As part of the settlement, Quest has agreed to
discontinue the billing practices at issue, re-
imburse consumers who were improperly
billed and stop any collection efforts against
such consumers. It also has agreed to main-
tain improvements to its computer systems that
were made after the April 2001 start of the in-
vestigation, to ensure that payments are prop-
erly credited to avoid future double-billing.

Review Of Billing Messages
Also as part of the settlement, Quest must
submit all billing messages that it uses on its
consumer billing forms to the Attorney
General’s Office for review. According to
Spitzer, the investigation found that Quest’s
billing messages were “potentially mislead-
ing and confusing” and have not always given
consumers sufficient information to determine
the basis of their liability or whether they have
grounds to challenge a particular bill. In the
future, any attempts by Quest to verify a
consumer’s health plan status or seek miss-
ing information from a consumer must in-
clude a conspicuous statement that “This is
not a bill” and “Make no payment.”

Quest is further required to send notices of
the settlement terms to physicians and con-
sumers and to publish public service an-
nouncements on the settlement in newspapers
around the state.

The settlement, announced June 25, requires
the company to pay $75,000 to cover the costs
of the investigation and another $75,000 to
organizations funded by the state’s Managed
Care Consumer Assistance Program.

Resources
❖ New York Attorney General’s Office: 518-
473-5525
❖ Gary Samuels/Quest: 201-729-8363

How To Comply With New Medicare Coding Requirements For Lab Claims

**Time & Date: Tuesday, September 9, 2003, 2:00 – 3:30 pm (Eastern)**

Don’t miss this vital opportunity to get critical infor-
mation on new Medicare requirements for coding of
Part B laboratory claims that become effective this October.
During this 90-minute national audioconference, industry ex-
erts explain Medicare’s policy of returning all Part B lab
claims not containing a valid ICD-9 code, share strategies for
compliance and detail how one large laboratory system de-
veloped an ICD-9 lab coding system that has drastically re-
duced unpaid claims. Continuing education credit is available!

**Speakers:**
❖ Christopher Young, President,
Laboratory Management Support Services
❖ Hyde Frederickson, Compliance Officer,
IHC Laboratory Services

**Objectives:**
— Find out what steps you should be taking right now to
get ready for implementation of Medicare’s new ICD-9
coding requirement for Part B lab claims
— Get tips and strategies on coding lab claims properly and
avoiding the scrutiny of federal auditors
— Learn how to develop your own ICD-9 lab coding system
— Discover techniques for overcoming physician resistance
to providing specific diagnosis information and/or accu-
rate ICD-9 codes

**Registration:** G2 Compliance Report and other G-2 subscrib-
ers, $197; non-subscribers, $247. Your single paid registra-
tion entitles you to as many listeners per site as you’d like.
To register, call 1-800-651-7916 or go online to http://
glyphics.quickconf.com/sem-online/ioma.
Abbott Labs To Settle Enteral Products Probe

Abbott Laboratories (Abbott Park, IL) is anticipating a $622 million settlement arising from a federal investigation of marketing practices by its Ross Products nutritional division.

The settlement, which still must be approved by a judge, stems from a probe into the marketing of adult nutritional products administered through feeding tubes in hospitals and nursing homes. The Federal Government began scrutinizing the Ross Products unit in 2001, alleging that it as well as rivals defrauded federal and state health insurers by using kickbacks to boost sales of pumps and supplies to feed seriously ill people.

The Wall Street Journal reported July 18 that federal investigators obtained undercover video-tapes showing Abbott Laboratories salespeople urging a medical products distributor to allegedly overcharge government insurance programs. The salespeople also allegedly gave the distributor, which was set up by undercover agents, false pricing documents that could be offered to the government if the bills were questioned.

The anticipated settlement will resolve all outstanding allegations by the government related to this matter, according to Abbott, including all Medicare and Medicaid issues. It will not affect Ross’ ongoing business with any customers, including the U.S. Government, Abbott says.

As a result of the $622 million charge, Abbott’s second-quarter profit plunged 58%, from $592 million a year ago to $247 million, the company announced July 10. Excluding the charge and other one-time items, the company earned 52 cents per share, matching the average forecast of analysts polled by the earnings tracking firm, Thompson First Call.

Resource
❖ Abbott Laboratories: 847-938-5494

HIPAA Transactions: Light Enforcement Expected At First

The U.S. Department of Health & Human Services is expected to heed the advice of a key advisory panel and go easy on enforcing compliance with final requirements of the HIPAA electronic transactions/code sets (TCS) rule in the first few months after they take effect this Oct. 16.

In a June 25 letter to HHS Secretary Tommy Thompson, the National Committee of Vital & Health Statistics called for a transition period of up to six months. The committee advises HHS on implementation of electronic data exchange provisions in the administrative simplification section of the HIPAA statute (Health Insurance Portability & Accountability Act of 1996).

The committee urged HHS to promote good-faith compliance without limiting the enforcement ability of the Centers for Medicare & Medicaid Services, the agency within HHS that is charged with enforcing the TCS rule. The panel recommends that a covered entity not be considered out of compliance if, for example, a payer accepts claims submitted in the HIPAA format, but with only the data elements that the payer requires to adjudicate the claim, or if a payer exchanges transactions with a provider in a pre-existing non-compliant electronic format.

The committee also advised HHS to remind groups covered under the TCS rule “of the necessity of establishing measurable milestones and developing a firm schedule for testing and deployment during the transition period.” In addition, it requested that HHS provide more guidance on what are considered compliant transactions under the rule, as well as guidance to help covered entities “minimize the impact of imperfect claims.”

In a separate letter, the committee asked HHS to develop methodologies and collect baseline data for analyzing the effects of the HIPAA privacy rule that took effect last Apr. 14. “An ongoing program will help refine rulemaking, implementation and enforcement strategies for the privacy rule,” the letter said.
HCA Settlement Resolves Biggest Health Fraud Case Ever

In what marks the conclusion of the largest healthcare fraud investigation and prosecution ever undertaken by the U.S. Department of Justice, HCA Inc. (Nashville, TN) has agreed to pay $631 million to settle allegations that it systematically defrauded Medicare, Medicaid and other federal healthcare programs since the late 1980s.

The latest agreement resolves pending issues in eight whistleblower lawsuits filed under the federal False Claims Act, according to Justice. The whistleblowers would receive a combined share of almost $151.6 million, the highest such award ever paid by the government.

When this is combined with earlier settlements, HCA will end up paying slightly more than a total of $1.7 billion, the largest recovery ever reached by the government in a healthcare fraud case. In December 2000, HCA subsidiaries pled guilty to substantial criminal conduct and paid more than $840 million in criminal fines, civil restitution and penalties. The company also has paid $250 million to the Centers for Medicare & Medicaid Services to resolve all Medicare cost report, home office cost statement and appeal issues for cost report periods ending before Aug. 1, 2001.

Cost Report Fraud

Under the settlement announced June 26, HCA will pay the following lay items:

❖ $356 million to resolve lawsuits alleging that the company engaged in a series of schemes to defraud Medicare, Medicaid and TRICARE, the military’s healthcare program, through hospital cost reports.
❖ $225.5 million to resolve lawsuits alleging that HCA hospitals and home health agencies unlawfully billed federal health programs for claims generated by the payment of kickbacks and other illegal payments to physicians in exchange for patient referrals.
❖ $17 million to resolve allegations that certain company-owned hospitals billed Medicare for unallowable costs incurred by a contractor that operated HCA wound care centers and for a non-covered drug that the contractor manufactured and sold to hospital patients.
❖ $5 million to resolve allegations concerning the transfer of patients from HCA facilities to other facilities and the claiming of excessive costs for those transfers.
❖ $5 million to resolve allegations that HCA’s Lawnwood Regional Medical Center in Fort Pierce, FL, submitted false claims in Medicare cost reports by inflating its entitlement funds to treat indigent patients and by shifting employee salary costs in order to increase its reimbursement from Medicare.
❖ $950,000 to settle allegations that HCA improperly shifted its home office costs to hospitals.

In a separate agreement, HCA will pay $1.5 million to resolve allegations that an Atlanta hospital, West Paces Medical Center, paid kickbacks for the referral of diabetes patients.

In addition, a state negotiating team appointed by the National Association of Medicaid Fraud Control Units has reached an agreement with HCA to resolve related issues with affected state Medicaid programs for $17.5 million, representing direct state losses. The terms of that agreement are being finalized and are not part of the June 26 settlement.

Resource


HHS To License SNOMED Clinical Terms From CAP

The College of American Pathologists has signed a $32.4 million, five-year contract with the U.S. Department of Health & Human Services to license its standardized medical vocabulary system and make it available without charge throughout the country.

The agreement, which will be administered through the National Library of Medicine, should help in designing standardized electronic health records, says HHS Secretary Tommy Thompson. The CAP vocabulary system, known as SNOMED (Systemized Nomenclature of Medicine) Clinical Terms, includes terms for more than 340,000 medical concepts. When built into electronic patient record products, SNOMED CT enables primary and specialty care providers and patients to share comparable data at any time, from any place, according to the College.

“This system will prove invaluable in facilitating the automated exchange of clinical information needed to protect patient safety, detect emerging public health threats, better coordinate patient care and compile research data for patients participating in clinical trials,” says Thompson.
Laboratories have become quite proficient in coding their services and knowledgeable about Medicare requirements. But as laboratory expertise has grown, so has that of the regulators. The result is more subtle government requirements and/or limitations that make claims management a much more complex task.

Laboratory management is challenged in this process because of the variety of sources that provide coding and billing information, the number of internal departments and electronic systems impacting claims, the more frequent changes in regulatory requirements and the frequent lack of regulatory clarity from the local payer.

Effective management of claims requires working closely with your third-party billing department to ensure that claims conform to current edit systems and other billing requirements. This discussion presents 10 coding and billing issues that may affect the accuracy and/or payment of claims.

1 **Modifiers:** To avoid having claims denied based on modifier use, you must determine how your local contractor is allowing use of modifier –59 and modifier –91.

According to the American Medical Association’s Current Procedural Terminology (CPT), modifier –59 is defined as a “Distinct Procedural Service,” and AMA instructs the laboratory to use it to report services “that are not normally reported together but appropriate for the circumstances.” An example given by CPT is the testing of multiple cultures from different sites.

Modifier –91 is for a physician-ordered repeat test within the same 24-hour period. It is not to be used for confirming a result, since this is a quality assurance step and not a medically necessary physician-ordered repeat test. Modifier –91 may be used only for clinical laboratory services, while modifier –59 may be used for both clinical and anatomical laboratory services.

The Centers for Medicare & Medicaid Services (CMS) basically agrees with the CPT definitions and has instructed its local Medicare contractors regarding the correct application of the modifiers through Program Memorandum AB-02-030, “Administrative Policies Related to Processing Claims for Clinical Diagnostic Laboratory Services” (http://cms.hhs.gov/manuals/memos).

The problem for labs is that there is no uniformity in how local contractors interpret the CMS instructions. Some limit modifier –59 to microbiology and surgical pathology, while a few others do not recognize modifier –59 for clinical laboratory services at all.

The wording in the instructions for modifier –91 indicates that whenever several of the same CPT codes are billed, modifier –91 should be used. This has occurred because CMS inserted “(CPT code)” after the words “same services.”

Many contractors have interpreted the insert to mean that when a CPT code is reported multiple times on the same claim, modifier –91 should be used, regardless of whether it is a “repeat” or “distinct procedural service.”

The differences in interpretation may be causing certain claims to be denied. To avoid denials based on modifier use, check with your local Medicare payer.
**2 CCI Edits**: The National Correct Coding Initiative (CCI) is a series of edits developed by CMS and updated quarterly. The edits apply to all Medicare Part B claims by commercial and physician office laboratories and are also included in the Outpatient Code Editor (OCE) for hospital outpatient and non-patient claims. The CCI edits have become a primary mechanism for defining how services are to be billed.

The CCI edits are arranged in two tables. One is the comprehensive/component table that lists the comprehensive code representing the major procedure or service and the related component code(s) that are considered part of the comprehensive service. For example, *Procainamide; with metabolites* is comprehensive to *Procainamide* and the edit reads:

\[ 80192 \ 80190 \ 1 \]

The second table lists codes that are considered mutually exclusive of each other. These are codes for services that typically are not performed together. For example, a determination of fecal occult blood by the peroxidase activity method and by the immunoassay method would not be performed for the same patient on the same date of service. Therefore, the codes are mutually exclusive and would not be reported together. This mutually exclusive edit reads:

\[ 82274 \ 82270 \ 0 \]

The superscript “0” indicates that a modifier is not allowed to bypass the edit and a superscript “1” indicates that an appropriate modifier will bypass the edit. Many laboratory claims are not paid because the codes do not indicate the appropriate modifier.

Because of quarterly changes to the CCI edits, your laboratory should stay current with the edits and work with the billing office to ensure proper use of the modifiers when indicated. To learn more about subscribing to the quarterly CCI updates, contact the National Technical Information Service in Springfield, VA, or visit its Website at www.ntis.gov.

**3 Therapeutic Drugs**: In 1993, CPT code 80299, *Quantitation of drug, not elsewhere specified*, was added to the CPT Therapeutic Drug Assay section. CPT recognized the need for the generic code because of the rapid proliferation of new therapeutic drugs and the inability of the CPT process to maintain a current listing. HCFA (now CMS) agreed that this code had to be available to laboratories and assigned a payment amount to the code.

Over the years, however, many labs and some local Medicare payers have misinterpreted this code as a miscellaneous code because it ends in “99”. Code 80299 is not a miscellaneous code but rather a generic code, much like the generic codes found in the CPT Chemistry section.

When a therapeutic drug is not specifically named in the Therapeutic Drug Assay section, your lab should use 80299, rather than a generic method code from the Chemistry section. The exceptions to this are the few therapeutic drugs listed in the Chemistry section. These codes include a number of older therapeutic drugs, such as flurazepam, and therapeutic drugs that may also be drugs of abuse, such as amphetamines and barbiturates.

Billing a therapeutic drug with the chemistry chromatography method code may result in overcoding the service.

**4 Total Protein**: The year 2004 will bring some welcome relief to those laboratories that have been frustrated by denials of claims for a CSF total protein when billed in conjunction with a serum total protein that was ordered either as part of a comprehensive metabolic automated panel or as an individual test. These denials have been especially vexing because often neither modifier –59, distinct and separate service, or modifier –91, repeat test, will allow a bypass of the edit.

The 2004 CPT will contain new CPT codes for “total protein, other source” and “total protein, urine” that should clarify the billable tests for the payers and allow payment for both of these procedures within the same 24-hour period. Your laboratory should be attuned, however, to the possibility of new CCI
edits that relate to the serum, urine and other source total protein codes, once these codes become active in 2004.

**5 Manual Differential Blood Count:** The correct billing of CPT code 85025, *Blood count; complete (CBC), automated (Hgb, Hct, RBC, WBC and platelet count) and automated differential WBC count,* has been the focus of much discussion since the publication of the CPT 2003 update.

The issue surrounding this code is the correct billing of the CBC with differential when the instrument parameters are exceeded and the laboratory performs a manual differential.

When this occurs, many labs have incorrectly assumed they could change the billing code 85025 to 85027, *Blood count; complete (CBC), automated (Hgb, Hct, RBC, WBC and platelet count)* and 85007, *Blood count; blood smear, microscopic examination with manual differential WBC count.* These labs assumed this was an allowed practice if the CBC and the manual differential were listed as a reflex test on the lab requisition, as indicated by the HHS Office of Inspector General. However, the OIG’s general guidance does not apply when there are Medicare restrictions on certain procedures.

In this case, the lab’s policy for billing the physician-ordered CBC and differential must consider the instructions in the Medicare Intermediary Manual, section 3628 L and the Medicare Hospital Manual, Chapter IV, section 437L.

These two identical sections state that code 85025 includes the manual differential code 85007. In addition, labs must consider the CCI edits which list 85025 as the comprehensive code and 85007 as one of the component codes. The “0” superscript indicates that 85007 cannot be billed separately.

The CMS position is that when a physician orders a “CBC with differential,” the order is for an automated differential. If it is necessary to complete the physician’s order for the “CBC with differential” by also performing a manual differential, then this becomes a component of 85025. The 85027, CBC, and 85007, manual differential, should be billed only when the manual differential is specifically ordered by the physician.

**6 Stool Culture:** CPT has provided two codes for billing stool cultures to reflect the scope of work performed by the microbiology lab. Yet, many labs are billing only a single code, regardless of the required testing.

Correct coding of the stool culture is based on the physician’s order. When the physician orders a stool culture for Salmonella and Shigella only, the laboratory should bill the single code 87045, *Culture, bacterial; feces with isolation and preliminary examination (eg, KIA, LIA) Salmonella and Shigella species.*

When the physician order is for Salmonella and Shigella and any additional pathogens, such as Campylobacter, Yersina, E. coli 0157, etc., the lab will bill each additional plate required to complete the order, using code 87046, *Culture, bacterial; stool additional pathogens, isolation and preliminary examination.* For example, the correct coding for a physician stool culture order for Salmonella and Shigella plus Campylobacter, E. coli 0157 and Vibrio would be billed as 87045, plus 87046 x 3 for each additional plate.

It is not appropriate to use 87046 when screening for a single stool pathogen. When a physician orders a culture for a single pathogen, such as E. coli 0157, the lab should bill code 87081, *Culture, presumptive, pathogenic organisms, screening only.*

**7 Clotest:** The Clotest is a presumptive screening culture for *Helicobacter pylori.* The specimen is cultured directly to a gel culture media containing a bacteriostatic agent, which prevents growth of other bacteria. A positive culture is indicated by the gel media turning red as a result of *H. pylori*-produced urease. The correct code for reporting the Clotest is 87081, *Culture, presumptive, patho-
genic organisms, screening only, because no further diagnostic testing for presumptive or definitive identification is required.

CMS has incorrectly assigned to the waived Clotest the CPT code 87077, the definitive identification culture code. Waived labs must use the incorrect waived code to obtain payment for the Clotest. However, labs that are CLIA-certified for moderate and high complexity testing should not use 87077 to report the Clotest because this is overcoding the procedure and will create an overpayment situation.

8 Anaerobic Culture: Whenever an anaerobic culture is ordered, it is standard medical practice for microbiology labs to also set up an aerobic culture because the infection may include both aerobic and facultative anaerobic bacteria. Many labs bill for both cultures because it is standard medical practice.

However, the CCI edit indicates you may bill both cultures only if each culture is a distinct and separate service, i.e., separate orders with separate specimens, and then you would use modifier -59. The CMS position is that the descriptor for 87070, the presumptive identification code, does not specify whether it includes aerobic only or aerobic and anaerobic cultures. Therefore, CMS interprets the presumptive identification code description to include both aerobic and anaerobic cultures performed on a single specimen.

9 Bacteriuria Screens: Bacteriuria screens by non-culture technology are often performed in conjunction with a physician’s order for a routine urinalysis and urine culture. The bacteriuria screens are valuable for screening out contaminated samples prior to culturing, thus reducing laboratory costs.

Be aware, however, that your lab will not be paid for the screen when performed at the same time as a urinalysis. There is a CCI edit that will not allow payment for both procedures and a modifier will not bypass the edit for 81002 or 81003, the manual or automated dipsticks, and 81007, the bacteriuria screen.

The reason for the edit is that the urine dipstick tests for leukocyte esterase, a byproduct of lysed leukocytes, and a positive result may suggest a urinary tract infection. When the bacteriuria screen is also run, it appears to be duplicate testing, even though it is recognized that the precision of the leukocyte esterase test is considered poor and the additional bacteriuria screen is a more appropriate testing protocol.

10 Surgical Pathology Consults: Billing for the professional surgical consultation is based on whether the laboratory is the referring lab or is functioning as the reference lab. A professional consult fee may be charged by the consulting lab for slides or tissue referred to it from another hospital when a consult is requested because the referring pathologist feels the final interpretation is beyond his/her expertise. This is often the case when a slide requires interpretation by a pathologist skilled in a related subspecialty, such as dermatopathology. When slides are referred for quality control reasons, they may not be billed.

Unlike clinical laboratory services, there is no direct billing requirement for services subject to Medicare’s resource-based relative value scale (RBRVS). Consulting pathologists may direct-bill the consult to Medicare or may bill the referring hospital. If they bill Medicare, they are paid at the Medicare rate. If they bill the hospital, they are usually paid at the consulting pathologist billed fee rate. The rate of payment is usually why the professional pathology consult services are billed back to the referring hospital.

When the referring hospital is billed the professional consult fee, the referring hospital must absorb the cost of the consult and bill only for the services provided by the in-house pathologist. The hospital may not bill Medicare for the consult interpretation that is purchased from another pathologist. Only the pathologist who performs the service may bill the Medicare program.

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Medicare Reform Legislation Boosts Healthcare Anti-Fraud Funding

Federal funding to combat healthcare fraud could increase over the next several years, depending on the fate of Medicare reform legislation that, at press time, is in the hands of a congressional conference committee. The committee's task to reconcile different versions of the legislation passed separately by the House and the Senate.

The Senate bill (S. 1) would hike funding for the Health Care Fraud & Abuse Control Account (HCFAC), which provides money to the U.S. Department of Health & Human Services and the U.S. Department of Justice for Medicare and Medicaid fraud-fighting efforts. A majority of the money goes to the HHS Office of Inspector General.


Civil Penalties Raised

The Senate measure would raise civil penalties for healthcare providers found guilty of fraud or abuse. After Jan. 1, 2004, the minimum civil penalties under the federal False Claims Act (FCA) would rise from $5,000 to $7,500; the maximum penalties from $10,000 to $15,000.

In addition to FCA penalties, the Senate bill would increase civil monetary penalties assessed by the OIG after Jan. 1, 2004. Maximum penalties for each item or service involved would go from $10,000 to $12,500. Maximum penalties for individuals who provide false or misleading information would rise from $15,000 to $18,750. In some circumstances, the OIG can now assess maximum penalties of up to $50,000; that threshold would increase to $62,000 under the Senate bill.

Compliance Program, Provider Relief Provisions

Both the Senate bill and the House bill (H.R. 1) contain a number of other provisions addressing healthcare fraud, Medicare appeals, regulatory relief and contracting reform. The measures would require private health plans participating in future managed care and drug benefit components of Medicare to implement fraud and abuse control programs as part of compliance with federal program rules. Both bills would eliminate penalties and interest related to overpayments and inappropriate claims if a provider or supplier reasonably relied on written guidance from HHS or a Medicare contractor that later turned out to be inaccurate. Both measures would modify how Medicare regulations and guidance are communicated as well as the procedures used to resolve payment disputes, and would establish various provider appeal processes, particularly for those who face termination of Medicare participation or denial of their application to participate in the program.

Along with attempting to minimize Medicare’s administrative burden, the Senate and House measures would give HHS the authority to competitively contract for claims processing services with any qualified entities, require that these contracts be competitively bid (at least every six years in the Senate bill, every five years in the House bill) and place new requirements on Medicare claims processing contractors, including an increased emphasis on provider education.

OIG Approves Air Transport Plan

A hospital and an ambulance company may proceed with joint plans to provide emergency helicopter transports for trauma patients in a specific rural area, the HHS Office of Inspector General said in a July 3 advisory opinion (No. 03-14).

The two entities proposed a partnership in which the ambulance company would purchase, own, operate and staff a helicopter equipped with a mobile intensive care unit, and the hospital would provide a landing pad, crew quarters and limited other hospital resources. The ambulance company could provide services to any hospital or entity, and the resources made available by the hospital would be accessible by any helicopter ambulance transport company.

While the OIG said the proposal risks violating the federal anti-kickback statute, it concluded that several provisions in the arrangement limited the risk of abuse and that it offered a significant community benefit.

CMS says the new ICD-9 coding requirement is needed for consistency with specifications established for electronic transactions and code sets under HIPAA (the Health Insurance Portability & Accountability Act of 1996). The final rule governing these transactions and code sets takes effect this Oct. 16. CMS announced the ICD-9 coding requirement in three program memoranda released in June: B-03-045, B-03-046 and AB-03-091 (the latter is an annual update of ICD-9 codes for Medicare contractors).

Under the new requirement, labs must assign an ICD-9 code to the “highest degree of specificity.” CMS clarifies that this means assigning the most precise ICD-9 code that most fully explains the symptom or diagnosis to the highest degree of accuracy and completeness. ICD-9 codes contain 3, 4 or 5 digits. According to program memo B-03-046, “If a 3-digit code has a 4-digit code that further describes it, then the 3-digit code is not acceptable for claim submission. If a 4-digit code has a 5-digit code that further describes it, then the 4-digit code is not acceptable for claim submission.”

If the physician does not such coding information, the lab must request it and document the contact. If the physician provides only a narrative diagnosis, the lab may translate this to an appropriate ICD-9 code. If, however, a physician provides an ICD-9 code, the laboratory may not change the code, even if it’s believed to be wrong. Instead, the lab must contact the ordering physician to get a “valid” code.

The bottom-line, says CMS: “A lab may not report on a Medicare payment claim a diagnosis code in the absence of physician-supplied diagnostic information supporting such code.”

Compliance Risks

Christopher Young, president of Laboratory Management Support Services in Phoenix, AZ, believes Medicare’s change in coding policy could present substantial compliance risks for independent and hospital labs.

“Some labs think this isn’t a big deal, because they get codes on a high percentage of their requisitions. But what they’re missing here is that CMS defines what a valid or effective code is. That’s the root of the issue.”

While CMS wants codes to be as specific as possible, Young cautions against being too aggressive when translating narrative diagnosis information to an ICD-9 code or adding a fourth or fifth digit to codes received from physicians without first contacting them. “The main concern is that in a post-payment audit, the laboratory would not have sufficient documentation to support the source for ICD-9 codes that appear on its claims.” Submitting a claim with a code that is inappropriately or inadequately documented could be considered a false claim by government investigators, he adds.

“You’ve got to have policies and procedures that establish what someone can and cannot do. You also need personnel who are trained and understand coding practices.”

To limit the possibility of a coder assigning an inappropriate diagnosis to a claim, Pontius advises labs to require physicians to provide an ICD-9 code on requisitions rather than narratives.

Run A Sample Audit

Young recommends that labs perform a simple audit to determine how much of a problem the new coding requirement might present. He suggests that coding specialists randomly select a 5% sample of requisitions and determine whether an ICD-9 code was submitted and, if so, whether it was a valid code with the necessary degree of specificity.

If a narrative diagnosis was provided, the coder should determine if it was sufficiently detailed to allow it to be translated properly according to coding conventions, Young says. In addition, he advises noting how many of the tests or requisitions involved contain tests covered by national coverage determinations or local medical review policies so these can be analyzed separately to determine if there is a difference in physician behavior.

“This [simple audit] will give your laboratory an idea of how many test rejections you could be facing after Oct. 1, and you can begin planning accordingly.”

Resources

❖ C. Anne Pontius: 919-859-3793
❖ Christopher Young: 602-277-5365
❖ CMS Program Memos B-03-045, B-03-046 and AB-03-091: http://cms.hhs.gov/manuals/memos
JCAHO Shifts Focus On Unannounced Surveys

Beginning next year, the Joint Commission on Accreditation of Healthcare Organizations plans to change the way it conducts random unannounced surveys. Under the current accreditation process, JCAHO identifies fixed and variable performance areas by looking at grid areas, or top Type I violations. Starting next year, its surveyors will target critical focus areas instead of grid elements, the Commission said July 7.

For 2004, the fixed performance areas that will be targeted are:

- Staffing
- Infection control
- Medication management
- National patient safety goals relevant to an organization’s care and services

A sample of 5% of organizations accredited under JCAHO’s ambulatory care, behavioral healthcare, home care, hospital and long-term care programs are randomly selected for unannounced surveys each year. This will change in January 2006, when JCAHO will start conducting all regular accreditation surveys on an unannounced basis.

Medicare Drug Benefit “Invitation For Fraud”

The Medicare prescription drug benefit now pending before Congress could present new opportunities for fraud and abuse in the healthcare sector, a federal prosecutor told attorneys attending the American Health Lawyers Association annual meeting July 1.

Billed as the largest expansion of federal entitlements ever, the legislative proposal to cover prescription drug expenses for more than 40 million Medicare beneficiaries “is an invitation for fraud,” warned James Sheehan, associate U.S. attorney for the Eastern District of Pennsylvania.

The Federal Government has already stepped up anti-fraud and abuse activities in the marketing of drugs and devices to healthcare professionals, he noted. The new drug benefit could create opportunities for even more violations, in his view.

While his office is not overly concerned with minor perks extended to customers, Sheehan warned that he will continue to focus on cases involving improper remuneration of healthcare professionals, those involving overly aggressive or fraudulent marketing schemes and those where patient safety or quality of care are compromised.

Effective July 18, 2003, Medicare Part B claims with multiple primary payers must be submitted on paper instead of being submitted electronically, the Centers for Medicare & Medicaid Services says in a recent Program Memorandum (Transmittal B-03-050).

CMS addressed the issue of how to handle multiple primary payers in Transmittal AB-03-011 (Feb. 3, 2003), but has since determined that the 837 claim file, version 4010, cannot support claims with multiple primary payers. According to CMS, there may be situations where more than one primary insurer to Medicare makes payment on a claim; for example, an employer group health plan make a primary payment for a service and, subsequently, another group health plan also makes a primary payment for the same service.

“Claims with multiple primary payers cannot be sent electronically to Medicare,” says the latest CMS transmittal. “A hard copy claim must be submitted on Form CMS-1500. Physicians and suppliers must attach the other payers’ EOB, or remittance advice, to the claim when sending it to Medicare for processing.”
AstraZeneca settling Pricing Dispute: AstraZeneca Pharmaceuticals LP (Wilmington, DE) has agreed to pay $355 million to resolve allegations that it provided physicians with free samples of its prostate drug, Zoladex, knowing that the doctors would then bill Medicare for the drug. The company pled guilty on June 20 and says it accepts responsibility for any improper sampling conduct.

Outlier Payment Guidance: The Centers for Medicare & Medicaid Services has issued instructions to fiscal intermediaries about determining whether acute care hospitals under the inpatient and long-term care prospective payment systems qualify for outlier payments, according to a July 3 program memo (Transmittal A-03-058). The memo is based on revised rules published in the June 9 Federal Register. Specifically, CMS provides instructions for applying cost-to-charge ratios (CCRs), including use of alternative CCRs at CMS’s discretion, use of statewide averages and notifying hospitals about updates. The memo is available at http://cms.hhs.gov/manuals/memos.

Guidant Enters Into CIA: Medical device manufacturer Guidant Corp. (Indianapolis, IN) has entered into a five-year corporate integrity agreement with the HHS Office of Inspector General. The compliance accord wraps up a $92.4 million settlement between the government and Guidant subsidiary EndoVascular Technologies (Menlo Park, CA). The company was charged with covering up thousands of incidents in which a medical device used to treat aneurysms in the aorta malfunctioned. Problems with the device were blamed in 12 deaths.

More Medical Device Charges: The government has intervened and filed a complaint alleging that two Ohio hospitals improperly charged Medicare for experimental cardiac devices, the U.S. Department of Justice announced July 1. The complaint, part of a federal False Claims Act lawsuit, alleges that between 1990 and 1995, Cleveland Clinic and University Hospitals of Cleveland charged Medicare for millions of dollars worth of procedures involving these devices that were not reimbursable under Medicare.