G-2 Compliance Report

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For Hospitals, Laboratories and Physician Practices

New Lab Policies Expand Test Coverage

More Diagnosis Codes Recognized By Medicare

New uniform Medicare policies that go into effect on Nov. 25 for 23 of the most frequently ordered clinical laboratory tests will greatly expand the list of approved diagnosis codes for most of these tests which previously were subject to local limited-coverage rules, says John McLaughlin, manager of billing compliance for Quest Diagnostics, the nation's largest independent lab company.

Speaking at the 20th annual Lab Institute, sponsored by Washington G-2 Reports on Oct. 23-26 in Arlington, VA, McLaughlin said he had reviewed 33 local Medicare carrier jurisdictions and found that 77% of the time the new national coverage decisions (NCDs) contain more covered ICD-9-CM diagnosis codes than current local medical review policies (LMRPs), while 23% of the time they contain fewer codes.

Overall, the 23 new test policies, developed via a negotiated rulemaking process, involve 66 CPT codes (*see p. 5*) and will affect about 43% of carrier lab services and 51% of carrier lab payments, he noted.

"A lot of people want to know whether the policies will improve or reduce [Medicare] coverage, but the answer may be different for you than it is for the person sitting next to you, depending on where you are in the country and what your test mix is. But generally speaking, we're moving toward more expanded coverage."

Tests with the biggest gain in ICD-9 codes recognized by Medicare as establish- *Continued on p. 4*

Inside this issue

OIG Lines Up Targets For FY 2003 Scrutiny

New Projects Triggered By Utilization Jumps

Glucose testing, emergency room diagnostic testing and long-distance physician claims are just three of the new areas that the HHS Office of Inspector General plans to target for close scrutiny in fiscal 2003, according to the agency's latest work plan.

The work plan, issued each October, is a blueprint for providers on what the government intends to audit, evaluate and investigate in the coming year. Of 160+ areas slated for review in FY 2003, several are carry-overs from FY 2002. Of the new areas, many have caught the OIG's eye due to increased utilization of specific procedures, notes attorney Jill Karpa with Foley & Lardner (Orlando, FL).

"Providers are well advised to study the work plan carefully to identify areas of high risk and vulnerability, and to use it as a road map for ongoing internal compliance efforts," she says.

Here's a rundown of what the OIG will be scrutinizing in select areas:

Laboratory Services

❖ ***Part B claims for glucose testing:*** A new project area—to what extent

Continued on p. 11

New Start Date To Be Set For ABN Use

Medicare Official Offers Insight, Clarification

The Centers for Medicare & Medicaid Services plans to issue more instructions on the proper use of Medicare's new standardized Advance Beneficiary Notices (ABNs), including a new mandatory start date, an agency official told attendees at Lab Institute 2002, convened by Washington G-2 Reports on Oct. 23-26 in Arlington, VA.

"We are still accepting ABNs on old forms, but we plan to come out with some additional instructions [that will establish] a date when we will no longer accept the old notices," said Denis Garrison, director of the division of consumer protections in the health plan policy group within the CMS Center for Beneficiary Choices.

The agency previously had announced that providers had to begin using the new ABN formats as of this Oct. 1. Though CMS will continue to allow use of the old forms for now, Garrison urged providers to switch to the new ones as soon as possible.

The new ABNs—one for general use, the other specific to lab services—inform a beneficiary that he or she may be financially responsible for a service in the event Medicare denies the claim. The signature of the beneficiary (or authorized representative) on the form acknowledges his or her agreement to be financially liable.

In most cases, Garrison stressed, providers should not submit an ABN to their local Medicare carrier, but should keep the original ABN, signed and dated, on file. "You should not be sending in an ABN on a routine basis. You should be sending in either the GA modifier or occurrence code 32 [on a claim]." Use of the GA modifier or code 32 on the CMS-1500 claim form indicates that you expect Medicare to deny the claim as not reasonable and necessary and you have a valid ABN on file.

Garrison also addressed a number of ABN-related questions submitted by Institute participants:

Q *Why are there two ABNs – one for labs and one for physicians?*

A CMS developed the lab form (CMS-R-131-L) as a convenience for laboratories, but its use is optional. Labs may use either the lab-specific form or the general-use form (CMS-R-131-G). The advantage of the lab form is that it contains pre-printed reasons why a test might not be covered by Medicare. It also relieves providers of the burden of listing frequency limits on tests; providers using the general form must cite frequency limits when indicated as a reason why a test might not be covered. Moreover, the lab ABN contains a statement that if the beneficiary refuses to sign and does not receive the test, the beneficiary will notify his or her physician.

Q *What happens when a beneficiary signs an ABN but later says he or she did not understand that by signing it, he or she was assuming responsibility to pay for the test? What happens if a beneficiary refuses a test by not signing an ABN even if it is medically necessary and would, therefore, likely have been covered by Medicare?*

A The whole point of having beneficiaries sign an ABN is to ensure that they understand their responsibilities. Instructions released in July (Transmittal AB-02-114) discuss in detail potential problems in delivery of the ABN. "It is the laboratory's responsibility to make sure the beneficiary understands the form," Garrison explained. "You haven't delivered the ABN until the beneficiary has actually received it and understood it." Disputes over ABNs between providers and beneficiaries will probably have to be decided by an administrative law judge or a hearing officer. In cases where a beneficiary refuses to sign, providers should use the witnessing procedures detailed in the instructions to document the lack of a signature.

Q *Should a lab always try to obtain an ABN when a test is subject to a frequency limit?*

A If there is a frequency limit on a test, providers may obtain an ABN on a routine basis whether or not the provider expects the claim in question to be denied on the basis of frequency.

Q *Does a lab have to obtain a signed ABN if it does not plan to bill the patient for denied claims?*

A "If you aren't going to collect anything from the beneficiary, that means you're giving them free care," Garrison said. "If you're giving them free care, then you're not billing Medicare, so there won't be a denial and there's nothing to give an ABN for." In other words, if a provider bills Medicare, it should also bill the beneficiary if the claim is denied.

Q ***Is an ABN necessary for screening services?***

A In general, no. For screening tests that are not covered by Medicare, a provider may charge the beneficiary for the test and does not need to complete an ABN. "It's not an ABN issue if it's not a covered benefit," Garrison noted. For Medicare-covered screening tests, such as mammograms and Pap smears, obtain an ABN if you have genuine doubt that Medicare will pay for the procedures in a particular instance.

Resources

- Denis Garrison: 410-786-5643
- Approved ABN formats: *http://cms.hhs.gov/medicare/bni*
- ABN implementation instructions (CMS Transmittal AB-02-114): *http://cms.hhs.gov/manuals/memos*

Compliance Officer Survey

COs More Experienced, Better Compensated
Survey Shows Room For Increased Training

Corporate compliance officers in healthcare organizations are more experienced and better compensated than ever before, due in large part to compliance program growth and maturity, according to the fifth annual *Profile of Health Care Compliance Officers*.

In 2002, there are five times as many compliance officers who have been on the job three or more years (44%) as were able to make that claim in 1999, notes the profile, compiled from a survey of compliance officers.

The survey, conducted each year by the Health Care Compliance Association and Walker Information, reflects the responses of 700 healthcare compliance professionals.

Compensation has grown as well, probably due to the increased experience, says the profile (*see chart*). In 2002, mean compensation for chief compliance officers ranged from $106,330 in small organizations (1,000 or fewer employees) to $172,140 in large organizations (5,000 or more employees).

For compliance administrators—those responsible for the day-to-day operation of compliance programs—the mean compensation ranged from $68,940 in small organizations to $109,460 in large organizations.

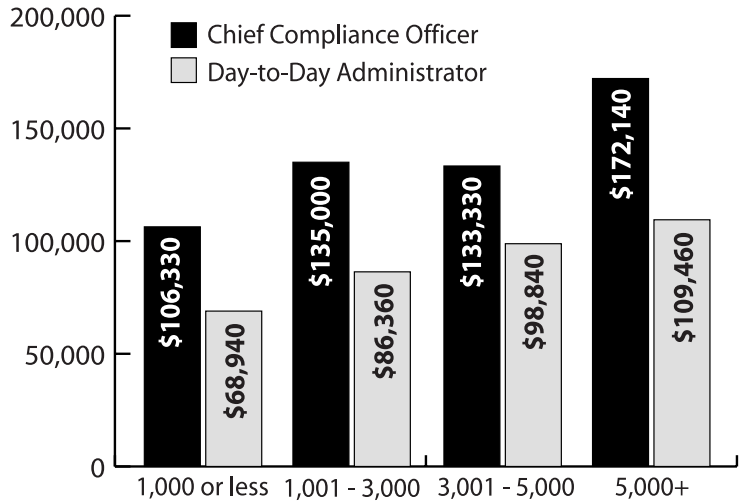
This year marks the first time the profile includes separate compensation data for each position—compliance officers and compliance administrators. In 2001, the average salary for them combined was $98,200.

Challenges, Training

Compliance programs nationwide continue to be challenged by the federal privacy regulations under HIPAA (the Health Insurance Portability & Accountability Act), notes the profile. In 2002, 68% of respondents reported that HIPAA is the biggest issue their program faces, with 89% identifying HIPAA as a specific program goal.

Other key issues include monitoring/auditing (43%), assessing compliance program effectiveness (39%) and education/training (33%).

Mean Compensation By Size of Organization – # of Employees



Source: *2002 Profile of Health Care Compliance Officers*

Compliance training has grown in recent years, with about nine of every 10 organizations providing regular training updates, even beyond initial formal training, the survey shows. Training is offered annually in the vast number of cases (79%) and sometimes more frequently (16%). However, notes the report, there appears to be room for more training since most workers receive either 1-3 hours of training per year (in 48% of the organizations) or less than one hour (in another 41%).

The majority of compliance programs have training components beyond basic employee updates and new employee compliance introductions, including training for manager/leaders (69%) and topic-specific, in-depth training (78%). In-person classroom instruction by the compliance officer (76%) or another instructor (60%) is still the norm for compliance awareness training. Video training is used by 53% of organizations, while 46% report using computer- and Web-based methods.

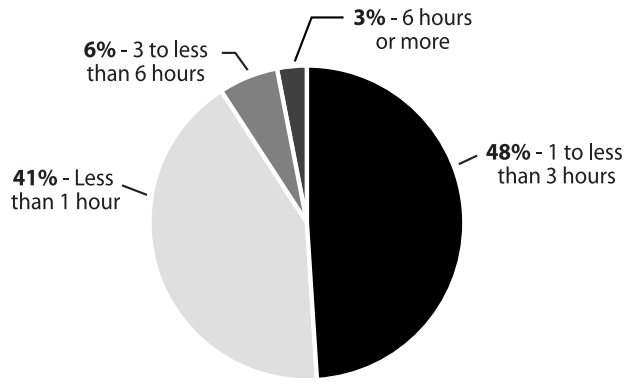
Program Trends

The number of organizations having stand-alone compliance departments is up to 63% overall, according to the profile. A majority of compliance officers responding say they report directly to the CEO (56%) or to the Board (10%).

Overall, the average compliance program has not grown this past year, continuing to have four full-time employees (FTEs). Staff size ranges from two employees in smaller organizations to about eight in the largest.

Departmental budget growth has also leveled this past year, the sur-

Average Time Spent By Employees On Compliance Training



Source: *2002 Profile of Health Care Compliance Officers*

vey shows, with "the poor getting poorer." Compliance budgets went down for the second straight year in the under 1,000 employee group to average just $118,990, a 10% drop from last year and 22% less than the average in 2000. The budgets in mid-sized organizations (1,001 to 3,000 employees) dropped 5% to about $247,000. In contrast, the largest organizations budgeted an average $682,780, only 1% less than last year's average, and the average budget in the 3,001-5,000 employee segment actually increased 4% to $372,920.

The role of the compliance committee remains largely unchanged from last year, with compliance officers overseeing the committees in 85% of the cases, and the majority of committee members coming out of finance, human resources, billing and administrative functions.

Resource

❖ *2002 Profile of Health Care Compliance Officers*, *www.hcca-info.org*

New Lab Policies, *from page 1*

ing medical necessity under the 23 NCDs include prothrombin time, iron studies and GGT, according to McLaughlin. Tests whose ICD-9 coverage will be reduced include lipids and CA 125 (*see table*).

Meantime, corrections and revisions to ICD-9 codes under the NCDs are in the works at the Centers for Medicare & Medicaid Services, according to a CMS official who shared the podium with McLaughlin. Jacqueline Sheridan-Moore, a technical advisor in the coverage and analysis group within the CMS Office of Clinical Standards & Quality, said the agency plans to release these changes as part of quarterly software and coding manual updates.

CMS also anticipates adding more national coverage policies for lab services, she told the audience. "We think there will be a need for additional lab policies, and we expect requests for additional NCDs in the future. We don't want to convene a negotiating committee every time we want to do a lab policy, so new NCDs will be developed through the [regular] NCD process."

Instructions on how to submit a request for an NCD are available on the CMS Website at *http://cms.hhs.gov/coverage/default.asp*. Requests must include a full description of the service, the applicable Medicare benefit category, a compilation of supportive medical and scientific information, a description of any clinical trials underway and the status of any FDA activity affecting the service (approved, pending, investigational, etc.).

Enforcement Delay

While the 23 new policies take effect Nov. 25, enforcement by contractors will be delayed until Jan. 1, 2003, Sheridan-Moore reminded the audience. By then, a software edit module will be available to enable contractors to process claims for the 23 tests in a uniform manner.

To avoid problems in the interim, labs should use "GY" and "GZ" modifiers to distinguish claims that aren't covered under the NCDs, she advised. Erroneous payments will be recovered through post-payment reviews in 2003.

Claims submitted after Nov. 25 for services furnished before that date will be processed under the LMRP in effect at the time the service was provided.

CMS also is delaying implementation of provisions regarding consistent remittance advice messages and procedures for asking physicians for documentation. The agency is working on related instructions and anticipates implementing them in mid-2003, she explained.

Resources

❖ John McLaughlin: 484-676-7575
❖ Jacqueline Sheridan-Moore: 410-786-4635

Lab Tests Most Affected By NCDs

Test	Avg. # ICD-9 codes Under LMRPs	Avg. # ICD-9 codes Under NCDs
Pro time (PT, PTT)	464	1,977
Iron studies (iron, iron binding capacity, ferritin, transferrin)	118	1,393
GGT	230	1,167
Lipid & cholesterol	395	324
CA 125	20	11

Source: John McLaughlin, Quest Diagnostics

COMPLIANCE PERSPECTIVES

Getting Ready For New Uniform Lab Coverage Policies: A Case Study

Kathy Gollinger, MBA, MT(ASCP), is manager of business services for Presbyterian Laboratory Services in Charlotte, North Carolina

Across the country, laboratories are preparing for the Nov. 25, 2002 effective date of new uniform coverage policies for 23 clinical lab tests that are among the most frequently billed to Medicare Part B. The policies flow from the work of a negotiated rulemaking committee established under the 1997 Balanced Budget Act. They were published as national coverage decisions (NCDs), along with numerous administrative provisions, in a final rule in the Nov. 23, 2001 *Federal Register*. The NCDs replace varying, often conflicting local medical review policies (LMRPs) that local Medicare contractors—carriers and fiscal intermediaries—have crafted for these tests.

This is the story of how Novant Health's Presbyterian Laboratory Services (PLS) has prepared to implement the new NCDs, date-of-service stipulations and documentation/recordkeeping requirements.

Background

❖ **National Coverage Decisions:** The NCDs were developed to promote consistency and standardization of medical necessity determinations for the 23 tests nationwide. The policies follow a uniform format, including test name and description; HCPCS codes affected; clinical indications for the test and limits on use; ICD-9-CM diagnosis codes covered, not covered or not supporting medical necessity; coding guidelines; and documentation requirements. Twenty-two NCDs are inclusionary, *i.e.*, they specify the diagnosis codes covered. One NCD (blood counts) is exclusionary, *i.e.*, so many diagnosis codes are covered that only the non-covered codes are specified.

The NCDs are binding on all Medicare contractors, competitive medical plans and peer review organizations. Contractors may not develop or maintain any LMRPs that conflict with the NCDs. They may, however, supplement an NCD if it is silent, for example, on frequency guidelines or secondary diagnosis codes. In some cases, where there already was an LMRP, the list of covered diagnosis codes for the comparable NCD will be expanded.

Tests Under Medicare's Uniform Lab Policies

	HCPCS Code
Culture, bacterial, urine	87086, 87088, 87184, 87186
HIV prognosis, including monitoring	87536, 87539
HIV testing, diagnosis	86689, 86701, 86702, 86703, 87390, 87391, 87534, 87535, 87537, 87538
Blood counts	85007, 85008, 85013, 85014, 85018, 85021, 85022, 85023, 85024, 85025, 85027, 85031, 85048, 85590, 85595
Partial thromboplastin time	85730
Prothrombin time	85610
Serum iron studies	82728, 83540, 83550, 84466
Collagen crosslinks, any method	82523
Blood glucose testing	82947, 82948, 82962
Glycated hemoglobin/glycated protein	82985, 83036
Thyroid testing	84436, 84439, 84443, 84479
Lipids	80061, 82465, 83715, 83716, 83718, 83721, 84478
Digoxin therapeutic drug assay	80162
Alpha-fetoprotein	82105
Carcinoembryonic antigen (CEA)	82378
Human chorionic gonadotropin (hCG)	84702
Tumor antigen by immunoassay, CA 125	86304
Tumor antigen by immunoassay, CA 15-3 (27.29)	86300
Tumor antigen by immunoassay, CA 19-9	86301
Prostate specific antigen (PSA)	84153
Gamma glutamyl transferase (GGT)	82977
Hepatitis panel/acute hepatitis panel	80074
Fecal occult blood	82270

Source: CMS Transmittal AB-02-110, July 31, 2002

Major Clarifications By CMS

Since the rule on uniform lab policies was finalized in the Nov. 23, 2001 *Federal Register*, the Centers for Medicare & Medicaid Services has issued five Program Memoranda (PMs) to clarify certain provisions:

- ***March 2002:*** AB-02-030 details some of the "provider friendly" administrative policies that went into effect on Feb. 23, 2002.
- ***June 2002:*** AB-02-087 announces delay in Medicare contractors' enforcement of the 23 National Coverage Decisions (NCDs) until systems can be built with appropriate edits for claim processing.
- ***July 2002:*** AB-02-110 contains the 23 NCDs with technical corrections received by CMS. In addition, CMS named Computer Sciences Corporation to develop the NCD edit tables, which are to be available on Jan. 1, 2003.
- ***September 2002:*** AB-02-129 clarifies the matching of diagnosis to procedure, 'screening' terminology and implementation of date-of-service requirements.
- ***October 2002:*** AB-02-134 presents in a Q&A format the main inquiries CMS has received about the previous four PMs.

Source: CMS, *http://cms.hhs.gov/manuals/memos*

❖ **Date of Service:** The Centers for Medicare & Medicaid Services has clarified that this should be reported as the date the specimen was collected. The collection date should be provided by the person obtaining the specimen and be supplied to the entity billing Medicare. Where the collection period spans more than 24 hours, the date of service should be reported as the date when the collection began.

Finally, for lab tests ordered on stored specimens, the date of service should be reported as the date when the specimen was retrieved from archives. CMS is unclear about the length of time a specimen has been stored before it qualifies for this exception. The final rule does not define this period of time, but does state that local contractors may clarify this at their discretion.

❖**Documentation, Recordkeeping:** The laboratory is required to maintain any documentation received from a test-ordering healthcare provider. If clarification is required prior to filing a claim, the lab must also document and maintain any additional information received. The healthcare provider ordering a lab test is responsible for documenting and maintaining this in the patient's medical record.

If the Medicare contractor believes the information submitted by the lab is insufficient, the contractor—not the lab—is responsible for obtaining additional information from the physician.

> ***"By far the most challenging aspect of our effort was to ensure that the different computer systems at PLS were updated with the NCDs"***

Preparing For The Changeover

PLS began its outreach program in 1986 as an arm of Presbyterian Hospital. The initial goal was to serve physician offices in a 30-mile radius of Charlotte. This later expanded to a 90-mile radius. By this time, the lab was growing short on space and, in 1998, moved off the Presbyterian Hospital campus. PLS remains part of Novant Health, which was formed in 1997 by a merger of Presbyterian Health Services and Carolina Medicorp Inc. of Winston-Salem.

With implementation of the 23 NCDs, the coverage policies in North Carolina will change from 30 LMRPs to a total of 40 LMRPs and NCDs. This necessitated formation of a team to investigate the likely operational changes. In early January 2002, PLS formed an NCD Team. The first meeting generated a list of seven operational issues to be addressed in order to meet the Nov. 25 deadline:

❖ Update computer systems.
❖ Address date-of-service provisions.
❖ Address test frequency limits.
❖ Update the clinical requisition.
❖ Update LMRP/NCD publication for clients.
❖ Educate employees.
❖ Notify clients.

1 Update Computer Systems: By far the most challenging aspect of our effort was to ensure that the different computer systems at PLS were updated with the NCDs. The update involved three different systems: the laboratory information system (LIS), the billing system and the physician office system. The first to be tackled was our LIS.

❖ ***LIS—Cerner***

Prior to spring 2002, a computerized, up-front medical necessity screening process was not in use at PLS's physician office labs (POLs) or patient service centers (PSCs). Using a Medical Necessity Guidelines notebook printed by PLS, employees manually checked for medical necessity by comparing the diagnosis on the requisition against either an alphabetic or a numeric list of diagnosis codes. While staff were fairly proficient at this, it was not the most efficient method. After investigating several computerized options to check medical necessity, we selected Info X in conjunction with Cerner and planned for an April 2002 installation.

At the same time that the LIS department outlined the installation process, another team audited the workflow processes at 26 POLs and seven PSCs. To use Cerner and Info X to check for medical necessity, order entry had to be performed *before* specimen collection. Results of the workflow audit showed that 90% of the POLs and 100% of the

PSCs performed order entry *after* the specimen was collected. To ensure that the work processes at each site would be compliant by April, several key changes were needed.

First, at most of the sites, the order entry terminal was moved to the specimen collection location. At one of the PSC sites, the entire floor plan had to be altered to accommodate up-front medical necessity checking. Second, and almost more difficult, was getting buy-in from the staff. Ironically, the staff felt comfortable with the manual checking process and saw up-front order entry/medical necessity checking as a hindrance to serving patients in a timely manner.

To overcome employee resistance, we selected a PSC pilot site where staff were most eager to accept the change in workflow. Employees there were also computer-literate and not afraid to learn new tasks. After a half-day of training and after fixing a few minor glitches, we deemed the pilot project a success. Employees liked not using the Medical Necessity Guidelines notebook and found that the new process was actually faster and more efficient. These employees were encouraged to talk with employees at the other sites. Slowly but surely, the change took hold and, by the middle of April, all but one site was fully functional in the new computerized process. The remaining PSC site was the one needing a floor plan change. We completed installation at this site in late September.

❖ ***The Billing System—Quadax Inc.***

PLS outsourced its outreach billing in July 2000 to Quadax Inc. (Cleveland, OH). Briefly, the billing process entails sending a daily Cerner file of all outreach orders to Quadax, where the test orders are held in a charge repository until the billing information is updated. Employees at PLS use the Quadax system to update patient encounters. Since PLS receives specimens from clients other than a POL or a PSC, a back-end medical necessity check is necessary. Each evening when the billing process runs at Quadax, medical necessity edits are performed. Those procedures that fail the edits are split from the other procedures and placed on a failed-medical-necessity hold. Procedures placed on hold are printed by client and mailed out each month. They are later billed if the client provides additional information.

To implement the NCDs, Quadax identified 13 LMRPs that overlapped with the NCDs for North Carolina. For each overlapping LMRP, Quadax has entered an end date of 11-24-02, which is established by the date of service. The NCDs have been entered into the system with an effective date of 11-25-02, which is also driven by the service date. Finally, Quadax will review the system changes and audit the database to ensure full compliance.

Our fiscal intermediary (Palmetto GBA) was contacted about the claims filing process between 11-25-02 (the effective date of the NCDs) and 01-01-03 (the contractors' enforcement start date). According to Dr. Edward Humpert, Palmetto will retire any LMRPs that conflict with NCDs on 11-25-02. To avoid potential post-payment review, Quadax will only submit claims affected by the NCDs if the appropriate diagnosis is obtained or if the beneficiary has signed an ABN and occurrence code 32 is applied.

❖ ***Physician Office System***

We are currently undergoing a beta project with another company to create a physician office system for order entry/medical necessity checking, results and billing. The order entry/medical necessity module is fully functional and has been piloted successfully at five different sites. Implementation of the NCDs is relatively simple and involves entering the 11-24-02 end date for overlapping LMRPs and loading the NCDs with the 11-25-02 effective date.

2 Address Date-of-Service Provisions: The date-of-service change has been fairly easy to address. PLS has used the date of collection as the date of service and has educated clients to do likewise. A review of specimen collections over a 24-hour period has shown that the date of service is recorded as the date when the collection began, but this point will be emphasized as part of our client notification.

The date of service for archived specimens has always presented a problem for PLS. Most specimens at PLS are only stored for one to two weeks, depending on the specimen type. Typically, if a physician adds a test to a stored specimen, PLS has used the date of service as the date

Impact Of Enforcement Delay

The new National Coverage Decisions (NCDs) apply to services furnished on or after Nov. 25, 2002. But as previously announced by the Centers for Medicare & Medicaid Services, a software module with edit tables won't be available to local Medicare contractors until Jan. 1, 2003. This will enable them to process affected claims in a uniform manner.

So between Nov. 25, 2002 and Jan. 1, 2003, claims submitted for tests subject to the NCDs should be screened for medical necessity, and the appropriate modifiers—GA, GZ or GY (or occurrence code 32 for Part A claims)—should be used to prevent these claims from being paid erroneously. If contractors conduct a post-payment review, adjustments could be made to recoup any overpayments.

Also, with regard to the NCD for urine culture, the edit module will not edit CPT codes 87184 and 87186. Contractors are free to edit these locally.

when the specimen was collected. Unless we hear otherwise from our Medicare intermediary, on Nov. 25 the date of service for these specimens will be changed to the date when the specimen was retrieved from storage for testing. For recordkeeping, a footnote for add-on tests will be included as part of the patient's test results, identifying the original date when the specimen was collected.

3 Address Test Frequency Limits: Since test frequency limitations have not yet been established as part of the edit tables to be used by contractors, this action item has been placed on hold until after the first of the year. However, employees and clients will be made aware of the NCDs that have frequency limits.

4 Update The Clinical Requisition: The clinical requisition used by PLS indicates LMRP tests in red print. At the time the NCD Team reviewed the requisition, not all the NCDs were even listed. The team discussed the pros and cons of adding all the NCDs to the requisition and decided that better compliance would be achieved if all were included. The requisition has been updated to include all NCDs and LMRPs in red print.

5 Update LMRP/NCD Publication For Clients: Annually, PLS publishes a Medical Necessity Guidelines notebook for all clients. It includes an introduction explaining medical necessity concepts, a test code section that lists all LMRP diagnoses alphabetically and numerically, test descriptions, a copy of the Advance Beneficiary Notice (ABN) and a price list. The notebook has been reviewed, any overlapping LMRP has been removed and the NCDs have been added. The notebooks will be ready for distribution by the second week of November.

6 Educate Employees: All PLS employees will be made aware of the new NCDs and date-of-service changes by e-mail. Employees directly affected by the changes—POLs, PSCs, Client Services and Billing—will attend more in-depth in-service training on the changes.

7 Notify Clients: We have drafted a client notification letter to be sent to all PLS clients during the second week of November. A copy is reprinted here; it can be altered to suit your organization's needs.

Reminder: A grace period of up to 12 months from Nov. 25, 2002 is allowed for providers that need extra time to implement system changes required by the final rule or subsequent clarifications to it. But you must request the extension by contacting your carrier or intermediary in writing on or before Nov. 25. The request must include a description of the system changes, actions already taken and a work plan with a timeline for how and when required changes will be fully implemented.

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Client Notification Letter

Dear Valued Client,

The purpose of this letter is to educate you about the Medicare National Coverage Decisions that become effective on Nov. 25, 2002. National Coverage Decisions (NCDs) for laboratory tests are national policies similar to the Local Medical Review Policies (LMRPs) already in existence. The NCDs were developed to promote consistency and standardization of laboratory medical necessity policies nationwide. There are 23 NCDs that will be binding on all laboratories. They affect the following tests:

Acute hepatitis panel	AFP
Blood counts	CA 15-3 (27.29)
CA 19-9	CA-125
CEA	Collagen crosslinks
Culture, urine	Digoxin
GGT	Glucose testing
HCG	Hemoglobin A1c
HIV testing, diagnosis	HIV prognosis, including monitoring
Iron studies	Lipid testing
Occult blood	PSA
PT	PPT
Thyroid testing	

The key highlights are:

- Blood counts policy (CBC): Since the covered diagnosis codes are so expansive, the diagnoses listed in the CBC policy contain only those codes that are non-covered.
- Any current LMRPs that conflict with NCDs—for example: blood counts, digoxin and glucose—will be retired on Nov. 25.
- The list of covered diagnosis codes for NCDs is more expanded than current LMRPs that are to be retired.
- North Carolina currently has 30 LMRPs. On Nov. 25, 2002, there will be a total of 40 combined (LMRP and NCD) policies.

In the next few weeks you will be receiving an updated list of the medical policies. If you have any questions about this notification or the updated materials, please contact your Customer Service Representative.

Tips On Responding To A Government Inquiry
Internal Investigation Key To Developing Defense

A government investigator arrives at your facility without an appointment, flashes a badge and begins asking employees to answer some "routine questions" and/or provide certain documents.

Sound frightening? Unfortunately, this scenario is not all that uncommon, says David Glasel, an attorney with Hiscock & Barclay (Albany, NY) and a former government official.

So, what should you do?

First, advise employees that they may speak to any investigator they choose, but may decline an interview if they wish. "Don't tell them they should not discuss the investigation with anyone," Glasel warns. "If they take you literally and tell the government you told them not to speak, it could be viewed as an obstruction of justice."

Second, contact your attorney as soon as possible. If you have in-house counsel, you may also need to hire outside counsel experienced in criminal and fraud & abuse matters.

Third, launch an internal investigation immediately. This investigation, which is separate from the government's, is a factual and legal review of the potential problem and should involve inside counsel (and outside counsel where appropriate), your compliance officer and the internal audit team, advises attorney Michael Kendall with McDermott Will & Emery (Boston, MA).

"It's important to start the internal investigation immediately," he says. "The goal is to stop any possible wrongdoing immediately, implement remedial action, prepare a legal defense and determine what should be disclosed to the government."

Glasel and Kendall elaborated on how to respond to a government investigation during the Fraud & Compliance Forum, held in Washington, DC on Sept. 29-Oct. 1 and sponsored by the American Health Lawyers Association and the Health Care Compliance Association.

Subpoenas & Warrants

How you respond to a subpoena can have a bearing on the outcome of an investigation, Glasel cautions. In general, the government issues three basic kinds of subpoenas in healthcare cases:

- An HHS Office of Inspector General subpoena, which is generally used early in a probe to see if civil or criminal charges should be brought.
- A Grand Jury subpoena, used when a criminal investigation is underway.
- A Department of Justice subpoena, authorized by HIPAA (the Health Insurance Portability & Accountability Act of 1996). This subpoena is used for criminal investigations but can be shared with civil investigators.

Employees should be instructed that no subpoenaed document should ever be altered or destroyed and that any employee engaged in this conduct will be terminated and his or her actions will be reported to the authorities.

While it's important to provide investigators with requested documents, never create a document to comply with a request. Keep an inventory of all relevant materials and ensure that all documents are date-stamped and copied, Glasel says.

As a rule of thumb, it's also a good idea to ask for more time to respond to a request for documents as soon as you receive a subpoena, Kendall points out. Typically, providers underestimate the amount of documents they will need to produce and the time it will take to comply with the government's request. "It is far easier to get an extension of time in which to produce documents than it is to negotiate a reduction in the types of documents to be produced."

David Glasel

Michael Kendall

In some cases, investigators will use search warrants, which may signal that they have a concern about the destruction of records or believe there is evidence of widespread criminal activity.

If an agent presents a warrant, your facility's administrator and the compliance officer should be contacted immediately, and they in turn should contact counsel. Staff should not obstruct or interfere with the warrant's execution, though they may decline to be interviewed if they wish, Glasel adds.

The supervisor involved should send non-essential employees away from the area, Kendall advises. "Agents cannot detain employees, but sometimes act as if they can."

Your facility's administrator or the compliance officer should always get the names of agents and a copy of the warrant, and let council decide whether to consent to a search beyond the scope of the warrant, Kendall emphasizes.

He also advises that you keep a log detailing when the search began, the names of individuals involved and their agency affiliations, the time the search was concluded, documents deemed privileged, a record of all documents seized and objections made to seizure. *Continued on p. 10*

Attorney Response

Once the government has contacted your organization, have your legal counsel get in touch with the investigating agency, Glasel urges. "Don't ignore it and hope it goes away. It won't."

Typically, counsel will ask for the factual and legal theory for the investigation and, if appropriate, indicate that you will cooperate. If it is a criminal probe, you have a right to ask if you are a target, subject or witness and to have the government confirm the response in writing. "Unless you have reason to believe otherwise, treat all government investigations as potential criminal matters," Glasel suggests.

Internal Investigation

Glasel and Kendall advise that providers under fire begin an immediate internal investigation of the same issues the government is looking into and, if possible, do it at a faster pace than the government.

"You need to quickly determine whether you have any potential liability, discover facts that are favorable to you and know what the facts are, if at a later date you decide to engage in settlement discussions," Glasel says.

Most of the time, agents will tell you generally what they are investigating, but if they don't, you can make an educated guess by interviewing employees and examining the scope of the document request/search warrant. If the investigation is directed at one facility, you should expand your investigation to other facilities with similar characteristics.

In conducting the internal investigation, it's important to maintain the attorney-client privilege, Kendall stresses. Any communication with your attorney is confidential and does not have to be shared with government investigators. Agents may pressure you to disclose any written reports resulting from the internal investigation, but such documents are confidential and do not have to be disclosed, he says.

Finally, while a provider should take steps to protect itself during a federal inquiry, it is generally a good idea to cooperate with the government as much as possible, Glasel notes. "Cooperation may actually lead to a quicker resolution of the investigation. In all probability, there is a better chance of a fair settlement if you have cooperated than if you have not."

Resources

❖ David Glasel: 518-429-4250
❖ Michael Kendall: 617-535-4085

CLIA Update

Improvement Seen In Waived Testing
Revised QC Rules Expected Soon

Follow-up education has helped laboratories with quality problems in CLIA-waived testing improve their compliance with CLIA requirements, said CLIA official Judy Yost in a Lab Institute 2002 presentation. Yost is division director for laboratory and acute care services at the Centers for Medicare & Medicaid Services.

"We found that providing education to those labs seemed to improve their compliance 75% of the time. It was just a matter of providing them with good information on basic laboratory practices."

In previous surveys, more than 50% of labs performing CLIA-waived testing had quality problems, such as not following manufacturers' instructions or not performing quality control as required.

To advance the educational effort, CMS is preparing a clearinghouse of existing educational programs to be posted on its Website within the next few months, Yost said.

Meantime, CMS is continuing its review of a 2% sample of labs performing waived testing. Of the 174,504 labs enrolled in CLIA, about 93,129 (55%) hold a certificate of waiver, Yost noted. Currently, 40 tests have waived status (see listing at *www.fda.gov/cdrh/clia*).

"We are collecting much more comprehensive information at this time because we found such significant problems," Yost continued. "A lot of people said when we started, 'Okay, so they're not following manufacturers' instructions, so what does that mean? Where are the dead bodies?' Well, unfortunately, we have some." In fact, several deaths in nursing homes have been attributed to misuse of glucose machines, as well as delayed cancer diagnoses due to use of expired reagents, she added.

In other CLIA developments, Yost noted:

❖ Long-awaited revised CLIA quality control regulations are in the final clearance process and should be published by year's end. "The good news is that most of the standards [for QC, quality assurance and patient test management] are not changed. We've reorganized them so they actually follow the path of a specimen through the lab. In addition, quality assurance is interwoven among all the phases of testing."

❖ In 2001, the government's lab registry listed 221 labs that had enforcement actions against them, up from 207 the previous year. "We found that we have a few more labs than [we] traditionally [do], and we feel it's because we're beginning to deal with repeat offenders."

❖ CMS has adopted some new tools to help labs with compliance, including a hearing decision master index, which contains summaries of CLIA hearings and links to hearing documents. The tools and compliance contacts are available at *www.cms.hhs.gov/clia.*

Resource

❖ Judy Yost: 410-786-3407

OIG, *from page 1*

have claims for fingerstick testing been billed as more complex testing procedures?

❖ ***CLIA certification:*** Follow-up from previous years—to what extent are laboratories performing tests and billing within the scope of their certification under the Clinical Laboratory Improvement Amendments? The OIG will compare claims with certification records to quantify any improper payments and lost CLIA certification fees, and to evaluate existing program controls.

❖ ***Proficiency testing:*** A continuing assessment—are laboratories complying with CLIA requirements to participate in PT?

Hospitals

❖ ***Expansion of DRG payment window:*** Should all hospital admission-related services rendered up to 14 days before a Medicare beneficiary's admission be treated as inpatient services? Current Medicare rules prohibit hospitals from billing Part B for certain preadmission services furnished within three days prior to admission. In a previous review, the OIG found that many non-physician outpatient services were rendered 4-7 days before admission.

❖ ***Diagnostic testing in emergency rooms:*** Medicare pays approximately $85 million per year for standard imaging and an additional $70 million for advance imaging (such as MRIs and CT scans). Are billings to Medicare for diagnostic tests performed in hospital emergency rooms medically necessary? Are the tests interpreted contemporaneous with the patient's treatment?

❖ ***DRG abuses:*** The OIG will examine DRGs with a history of aberrant coding, determine coding payment error rates and incorporate the results of a recent review by quality improvement organizations.

❖ ***Procedure coding for outpatient and ambulatory surgery center services:*** A past OIG review identified a 23% nationwide rate of inconsistency between hospital outpatient department procedure coding and physician procedure coding for the same outpatient services. Just how significant are the differences?

Physicians

❖ ***"Long distance" physician claims:*** The OIG will review Medicare claims for face-to-face physician encounters when the practice setting and the beneficiary's location were separated by a significant distance.

❖ ***Services and supplies incident to physicians' services:*** Physicians may bill for services provided by allied health professionals, such as nurses and therapists, as "incident-to" the physician's professional services. Incident-to services, which are paid at 100% of the Medicare physician fee schedule, must be provided by an employee of the physician under the physician's direct supervision. Because there's little information on the types of services thus billed, questions persist about the quality of the services and the appropriateness of these billings. The OIG wants to evaluate the conditions under which physicians bill "incident-to" services and supplies.

❖ ***Financial arrangements between physicians and ambulatory surgery centers:*** Does physician ownership in these centers affect utilization and the cost of outpatient surgeries? The OIG will evaluate whether there's a relationship between physician investments and the number of certain surgical procedures performed, compared to national norms.

❖ ***Consultations:*** Physician consultations comprised $2 billion of Medicare allowable charges in 2000. The OIG will continue its review of the appropriateness of billing for consultations.

Resources

❖ Jill Karpa: 407-423-7656

❖ OIG Fiscal Year 2003 Work Plan: *http://oig.hhs.gov/publications/docs/workplan/2003/WorkPlan2003.pdf*

Can a hospital assign "non-patient" status to patients who are present just for lab draws and not "incident to" a physician encounter at the facility, thus allowing the hospital to have its reference laboratory direct-bill Medicare for the testing? A reader who is a lab manager of a medium-sized rural hospital put this question to us, noting that the hospital typically gets Medicare reimbursement that is only a fraction of what it is charged by the reference lab, resulting in significant financial losses.

The answer hinges on whether the individual is considered a "non-patient" or an outpatient under Medicare billing rules, says attorney Hope Foster with Mintz Levin Cohn Ferris Glovsky & Popeo (Washington, DC).

For outreach laboratory services where the hospital has no relationship with the patient, the individual is considered a "non-patient" and the testing lab may bill Medicare directly.

If the individual is an outpatient of the hospital, the hospital is responsible for billing Medicare. An outpatient is defined as an individual who has not been admitted by the hospital as an inpatient, but is registered as an outpatient and receives services from the hospital. A hospital may not assign "non-patient" status to an outpatient for billing purposes.

For a more complete discussion of "non-patient" vs. outpatient status, see the Medicare Intermediary Manual, Chapter VII, Bill Review, online at *www.cms.hhs.gov/manuals/13%5Fint/a3628.asp*.

Have a compliance question you'd like answered? E-mail it to Kimberly Scott, managing editor, at kimscott@yahoo.com.

The Back Page

News-At-A-Glance

Kickback Risk: A pharmaceutical manufacturer's proposal to subsidize financially needy patients' cost-sharing portions associated with use of a particular drug would likely generate prohibited remuneration under the anti-kickback statute, the HHS Office of Inspector General warned in an Oct. 4 advisory opinion (No. 02-13).

The proposal "poses all the usual risks of fraud and abuse associated with kickbacks," the OIG said. Chief among the concerns: the plan clearly gave the manufacturer's product a financial advantage over competitors because of the proposed benefits to patients. The opinion is available at *http://oig.hhs.gov/fraud/docs/advisoryopinions/2002/ao0213.pdf*.

Blood Scam: Owners of a Los Angeles-area medical laboratory agreed in October to plead guilty to federal charges that they submitted about $19 million in false claims for blood tests to Medi-Cal, the state's Medicaid program. The scheme was the largest of its type in California history, according to Debra Wang, U.S. attorney for the Central District of California. Luisa Gonzalez and former husband Juan Carlos Ciraolo operated the Los Angeles Bio-Clinical Laboratory in Glendale in the mid-1990s. The owners of two medical clinics who aided the couple were also charged in the scheme.

Free Safety Products: An infusion therapy company can provide free safety equipment to hemophilia patients as long as it does not exceed the maximum value of free goods that providers may give beneficiaries, the HHS Office of Inspector General said in an Oct. 7 advisory opinion (No. 02-14).

In an Aug. 29 special advisory, the OIG warned providers that free products and services to beneficiaries of federal healthcare programs may not exceed $10 per item and an aggregate of $50 per patient per year (*GCR, Oct. 02, p. 1*). The opinion is available at *http://oig.hhs.gov/fraud/docs/advisoryopinions/2002/ao0214.pdf*.

Hospitals Settle Device Claims: Seven hospitals will pay more than $5.4 million to resolve allegations that they billed Medicare for medical procedures involving experimental cardiac devices in violation of the False Claims Act, the Department of Justice said Oct. 16.

The agreement resolves allegations that between 1986 and 1995, the hospitals unlawfully charged federal healthcare programs for procedures using devices that had not been proven safe and effective by the Food & Drug Administration.

The seven hospitals are Beth Israel Deaconess Medical Center (Boston, MA), LDS Hospital (Salt Lake City, UT), General Hospital Center (Passaic, NJ), Hackensack University Medical Center (Hackensack, NJ), Daniel Freeman Hospital (Los Angeles, CA) and Good Samaritan Hospital (Santa Clara, CA).

Drug Settlement: Pfizer Corp. has agreed to pay $49 million to resolve allegations that a company it had acquired violated the False Claims Act by overstating the price of the drug Lipitor to the Medicaid rebate program. The government alleged that Parke-Davis Laboratories, a subsidiary of Warner-Lambert, which was subsequently acquired by Pfizer, did not pay the full rebates owed to state and federal governments for the cholesterol-lowering drug.

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