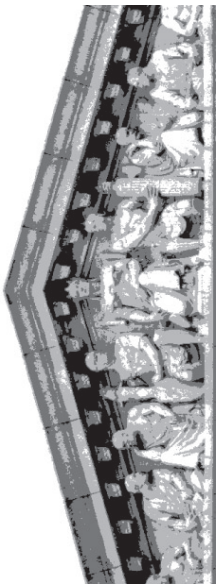

G-2 Compliance Report

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For Hospitals, Laboratories and Physician Practices

Unintended Results Of OIG Exclusion Proposal

Plan Could Force Labs To Drop Out Of Medicare

The "discriminatory billing" proposal from the HHS Office of Inspector General, which many believe is aimed at lowering fees that laboratories charge Medicare and Medicaid, could have significant unintended consequences—including forcing some labs to drop out of these programs altogether—believe industry experts.

"This could be a real nightmare," says attorney Hope Foster, a partner with Mintz Levin Cohn Ferris Glovsky & Popeo, PC (Washington, DC). Foster discussed the OIG proposal during Washington G-2 Reports' 21st Lab Institute, held Oct. 8-11 in Arlington, VA.

The controversial proposal, issued Sept. 15, would preclude hospitals, laboratories and virtually all other Part B providers from charging Medicare or Medicaid "substantially in excess" of their "usual charges" for a covered item or service (*G-2 Compliance Report, Oct 03, p. 1*). The proposal would not impact physician services reimbursed under the Medicare physician fee schedule, but it would apply to ancillary services, such as lab testing and drugs, when furnished by a physician.

Under the proposal, "substantially in excess" would be any amount more than 120% of a provider's "usual charge," which the ➥ *p. 2*

OIG Sets Focus Areas For Fiscal 2004

Lab Billing, Drug Pricing Among Targets

Examining excessive billing for laboratory and imaging services furnished to nursing home residents will be among the top priorities for the HHS Office of Inspector General in the coming year, the agency says in its latest work plan.

Noting that Medicare pays more than $200 million a year for such lab and imaging tests, the OIG says it will review a sample and study utilization patterns in nursing facilities to determine the extent and nature of any medically unnecessary services.

The plan, issued each October, is a blueprint for healthcare providers on what the government intends to audit, evaluate and investigate during the coming federal fiscal year (which runs from Oct. 1 through Sept. 30). Providers should use the work plan as a road map for ongoing internal compliance efforts, experts advise.

"The workplan is helpful because it shows where the OIG has concerns and where it will devote some of its investigative resources," says attorney Robert Rabecs with Hogan & Hartson LLP (Washington, DC). ➥ *p. 10*

Inside this issue

Hope Foster

OIG Exclusion Proposal, *from p. 1*

OIG would define as amounts billed to cash-paying patients, patients covered by indemnity insurers with which the provider has no contractual arrangement and any fee-for-service rates that a provider agrees to accept from any third party, including managed care plans.

While the OIG's goal may be to lower charges to Medicare, this proposal, if promulgated in its current form, could actually result in higher charges for all other payers, including physicians, Foster believes. "I don't think they really are trying to increase prices to others, but that could well be what happens." This could lead to more rigorous negotiations between labs and insurers, as payers seek to get the best deal possible while labs try to ensure their usual charges fall below the 120% benchmark.

In extreme cases, the OIG proposal could even force some labs to drop out of Medicare and Medicaid programs, predicts Foster. In addition, if enacted, it could lead to a proliferation of physician office laboratory testing, she notes. "If labs raise their prices to physicians, a time may come when physicians can perform the tests at a lower cost than they can buy them."

Aside from unintended consequences, the proposal also raises a number of operational and logistical questions, Foster thinks. For example, it is unclear whether a lab's calculation of "usual charges" would be by test or by CPT code. "CPT codes can cover a lot of tests. This would have to be a test-by-test measurement, but it's not clear."

It's also unclear how labs, when calculating usual charges, should treat pricing arrangements that are neither capitated nor fee-for service. "There are a variety of ways to structure pricing, so what do you do with deals that don't fall into either category?"

Deadline for comments on the proposed rule is Nov. 14. Send to OIG, HHS, Attn: OIG-53-P, Rm. 5246, Cohen Bldg., 330 Independence Ave., SW, Washington DC 20201

Unwieldy Methodology

According to an analysis from the law firm of McDermott, Will & Emery (Washington, DC), the OIG's plan would create an overly complex and unwieldy methodology for analyzing a provider's charges.

Not only would the methodology be difficult to implement, but it also is "inconsistent with the plain language of the [Medicare] statute," says the firm in a special alert. Not including Medicare and Medicaid fees in the "usual charge" analysis adversely affects "substantially in excess" determinations under either an average charge or a median charge methodology.

"Unlike the proposed regulation, the statute does not provide for an exclusion based on charges to government programs in excess of the provider's usual charge to other than Medicare and Medicaid patients," explains the alert. "The statutory prohibition is against charging Medicare substantially in excess of a provider's 'usual charges' — without further limitation, thus presumably to all patients, including Medicare and Medicaid patients."

At a more fundamental level, the alert notes, the proposal to exclude certain fee schedule payments from the definition of usual charges reflects confusion regarding the basic distinction between charges and payments in the reimbursement schemes established by Medicare. "Fee schedule payment are not charges in the first place; they are what the payer, in this case Medicare, has elected to pay. The proposed rule fails to recognize this fundamental difference between a provider's charge and the amount a payer ultimately agrees to pay."

Resources

- Hope Foster: 202-661-8758
- McDermott Will & Emery: 202-756-8000
- OIG notice of proposed rulemaking on excessive charges, *Federal Register* (Sept. 15, 2003): *www.gpoaccess.gov/index.html*

Tips For Dealing With Lab Billing Trouble Spots
Patient Status, Carrier Jurisdiction Present Challenges

Jerry Diffley

True or false? An independent reference lab can bill Medicare for outpatient and non-patient testing referred to it by a hospital lab?

The correct answer, according to Jerry Diffley, director of billing compliance for Quest Diagnostics Inc. (Teterboro, NJ), is part true, part false. "Independent laboratories may only bill [Medicare] for work referred to them by a hospital lab on non-patients. They cannot bill [Medicare] for work on outpatients." Diffley discussed lab billing compliance during the 21st annual Lab Institute sponsored by Washington G-2 Reports and held this year on Oct. 8-11 in Arlington, VA.

So how do you know the difference between an outpatient and a non-patient?

Medicare defines an outpatient as a person who has not been admitted by the hospital as an inpatient but is registered on the hospital records as an outpatient and receives services (rather than supplies alone) from the hospital.

A non-patient is defined as someone who is not admitted to the hospital, is not registered as an outpatient and does not receive services directly from the hospital. A typical non-patient is someone who is seen in a private physician's office and whose specimen is picked up and analyzed by a hospital outreach lab, Diffley notes.

> ***"It is incumbent on the hospital to differentiate between outpatients and non-patients. The reference laboratory doesn't know the status of the patient."***
>
> ***—Jerry Diffley***

"It is incumbent on the hospital to differentiate between outpatients and non-patients. The reference laboratory doesn't know the status of the patient. The independent lab must bill outpatient work to the hospital, while non-patient work can be billed directly to Medicare."

Carrier Jurisdiction

This is another trouble spot for hospital and independent labs that do Medicare business across different carrier jurisdictions, Diffley says.

Under Medicare rules, the claim for a test is to be paid at the fee schedule rate of the carrier that has jurisdiction over the testing site or the claim should be transferred to the appropriate carrier. In reality, very few carriers transfer claims, he notes. "What they'll do is reject the claim. They won't transfer it, and they won't pay it."

A referring lab could bill a Medicare carrier in another jurisdiction, but to do so, it must first obtain a provider number from that carrier. This can be very difficult since many carriers automatically deny an application from a provider with practice locations out of their jurisdiction, he explains. "It has taken three years for the Centers for Medicare & Medicaid Services and for carriers to understand this. Carriers are only now starting to issue [such] provider numbers."

So what's the solution? Congress tried to resolve the issue by mandating that CMS consolidate lab claims processing in up to five regional carriers, but the agency has not implemented that mandate, citing a lack of funding. Now, CMS says it will require all 56 carriers to have in-house each other's fee schedules and to pay claims at the appropriate rate. The agency plans to begin implementing this new requirement in early 2004, says Diffley.

Under this proposal, referring labs would put the reference lab's address and provider number on a claim. New software would then validate the reference lab's provider number and use its zip code to determine which fee schedule should be used in assigning payment.

PSA & Pap Testing

In this billing trouble spot, the problem for a lab is to identify whether the testing is for screening or diagnostic purposes. Medicare pays for a limited number of screening tests, and these include prostate-specific antigen

(PSA) testing, Pap testing and occult blood, among others. But getting physicians to let labs know whether the testing ordered is for screening or diagnosis can often be problematic, Diffley points out, even though physicians are supposed to provide that information.

In general, there are two approaches to getting the information you need, he tells labs. Either distinguish between screening and diagnostic tests on a requisition form or offer a single test option and let computer software determine whether to submit a HCPCS code (screening) or a CPT code (diagnostic) based on the reason given for the testing.

Either choice has pitfalls, he acknowledges. With two test offerings, physicians often check off a diagnostic test but indicate a screening ICD-9 diagnosis code, which results in a denial by Medicare. Offering a single test on a requisition can sometimes result in a physician supplying ambiguous or contradictory ICD-9 codes, which can lead to a test getting submitted as diagnostic rather than screening. In this case, Medicare will not check its Common Working File to see if the patient has had the screening test within the prescribed frequency limit.

"It's bad enough now, but could get worse, because on the horizon—supposedly—is a [Medicare] benefit for lipid screening, and we'll probably see the same problems with that," Diffley says.

This billing conundrum can put labs in an untenable position with both the ordering physician and the patient, he notes. What's more, labs are often forced to rework and resubmit a claim, which can be time-consuming.

"As an industry, we need to continue raising awareness of this issue with CMS. Officials there don't really understand the problem; they think the system works, but it doesn't."

Resource

❖ Jerry Diffley: 631-369-2405

OSHA Reiterates Policy On Sharps Disposal

A new safety and health information bulletin issued Oct. 16 by the Occupational Safety and Health Administration (OSHA) reiterates the agency's policy on disposal of contaminated needles and blood tube holders.

"Removing contaminated needles and reusing blood tube holders can pose multiple hazards," said OSHA Administrator John Henshaw in issuing the bulletin. "Single-use blood tube holders, when used with engineering and work practice controls, simply provide the best level of protection against needlestick injuries. That is why the standard generally prohibits removing needles and reusing blood tube holders."

OSHA's Bloodborne Pathogens Standard prohibits the removal of contaminated needles from medical devices unless an employer can demonstrate that it is necessary for a specific medical or dental procedure.

For blood drawing procedures, OSHA requires the disposal of blood tube holders with a safety needle attached immediately after each patient's blood is drawn.

In the bulletin, OSHA explains that while engineering controls exist to significantly reduce injuries to healthcare workers, hazardous work practices continue to cause injuries. The manipulation required to remove a contaminated needle, even a safety-engineered needle, from a blood tube holder may result in a needlestick with the back end of the needle, which is only covered with a rubber sleeve.

The bulletin details OSHA's requirements for the disposal of contaminated needles and includes an evaluation toolbox that provides guidance on the evaluation, selection and appropriate use of engineering and work practice controls in order to provide the highest degree of control.

Resource

OSHA bulletin on disposal of contaminated needles and blood tube holders used for phlebotomy, *www.osha.gov/dts/shib/shib101503.html*.

COMPLIANCE PERSPECTIVES

What You Need To Know About Chargemaster Compliance

Diana W. Voorhees, MA, CLS, MT, SH, CLCP, is a coding and compliance consultant and principal of DV & Associates in Salt Lake City, Utah

The autumn of another year settles in, and personal digital assistants should provide a "tickler" that it's time to examine current chargemaster/charge description masters (CDMs) and determine what changes to implement for billing in 2004.

Every chargemaster has a listing of services provided by a healthcare entity, and each service is aligned to a billing number, procedural description, procedural coding and a charge. Some facilities include additional information such as a cost center identifier, productivity values, units of service and specific billing options by payer. Hospitals also include revenue codes that are required for Medicare billing.

The billing number typically relays associated information (coding and charge) from the laboratory information system to the billing system. Thus, if the chargemaster information is incorrect, billing will be incorrect. Since coding changes annually, compliance programs should have a protocol for assuring continued chargemaster accuracy. Since coding also impacts reimbursement, budgets should be reviewed.

The Third-Party Billing Compliance Guidance from the HHS Office of Inspector General indicates that billing personnel must have the resources needed to bill accurately. Therefore, the first step toward chargemaster compliance is to obtain updated CPT, HCPCS and ICD-9 manuals, along with other reputable publications to assist with accurate billing.

CPT Codes

In preparing for 2004, determine which CPTcodes will be deleted, added and altered by description changes. Appendix B of CPT may be of assistance since it summarizes all CPT coding changes. You should then determine which of these changes will impact the services your facility provides, and process paperwork to implement appropriate changes.

CPT identifies *deleted codes* in parentheses in the various specialty sections. These parenthetical comments may remain through several updates of the CPT manual; thus, it is difficult to identify the most recent deletions from those of previous years. Appendix B will identify the latest deletions. Replace deleted codes with valid codes and remember to review any changes in descriptions or code additions when you reassign a code. On occasion, CPT may refer to another code that may have also been deleted. For this reason, never assign codes from the index; always read the full description in the body of the text prior to code selection. CPT may also defer a deleted code to an "unlisted" code. These are miscellaneous codes not recognized by Medicare and do not affect reimbursement.

Peruse *new codes* in CPT which are identified by a "●" to the left of the code. Determine if a newly added code more closely or specifically identifies a procedure or a service listed in the CDM and reassign a new code, where appropriate.

Examine *codes with a description change*; these are identified with a "▲" to the left of the code. The change may alter or negate the accuracy of current coding assignments and require reassignment of another code. Always assign codes with the description that most specifically describes a service. Do not assign a methodology code if a more specific code exists.

Six new CPT laboratory codes will be recognized in 2004 by the Centers for Medicare & Medicaid Services. These codes relate to kidney function, gastroenteritis, blood platelets

and Trichomonas infection. Medicare will reimburse them via the Part B lab fee schedule.

New Code	Procedure
84156	Protein; urine
84157	Protein; other source
85055	Reticulated platelet assay
87269	Infectious agent antigen detection by immunoflourescent technique; Giardia
87329	Infectious agent antigen detection by enzyme immunoassay technique; qualitative or semiquantitative, multiple step method, Giardia
87660	Trichomonas vaginalis, direct probe technique

Options for Medicare payment for these new tests were discussed in a public meeting last July, and written comments were accepted through Sept. 24. The outcome of the discussions is that CMS recommends that payment for each of the six new codes be crosswalked to existing payment for similar procedures (fees below are the national fee caps for 2003; unless Congress intervenes, the fees are due for an inflation update in 2004).

New Code	Crosswalk Code	2003 Natl. Limitation Amt.
84156	84155	$ 5.12
84157	84155	5.12
85055	86361	37.41
87269	87272	16.76
87329	87328	16.76
87660	87470	28.02

The crosswalk of the new protein codes to payment for the existing protein code makes sense. Another option for the reticulated platelet assay, 85055, was CPT 88180 (flow cytometry) rather than 86361 (T cell with absolute CD4 count). One of the decision factors may have been to retain payment under the lab fee schedule vs. the physician fee schedule, which reimburses flow cytometry. The two codes for Giardia were crosswalked to current codes which include Cryptosporidium. The new codes will allow separate identification when testing for Giardia vs. Cryptosporidium. Payment for the direct probe for Trichomonas was linked to another direct probe procedure.

Be certain to scrutinize the CPT 2004 manual when it arrives. The above items are not the only new codes projected. The Cytopathology Section should include a new code for selective cellular enhancement technique for non-GYN preparations. Additionally, numerous changes have been forecast for the Reproductive Medicine Section.

Don't overlook *Category III codes* for the laboratory in CPT. Billing these codes allows payers to track emerging technologies and allows providers to bill procedures that may not yet be FDA-approved but have value to the patient. These codes are updated semiannually by the American Medical Association and should be used in lieu of an unlisted code, if applicable. If utilization demonstrates merit, these codes would become a permanent CPT code used for routine billing. Presently, reimbursement is at the discretion of individual Medicare contractors.

HCPCS Codes

While the AMA owns and updates CPT codes, CMS is the keeper of *Level II HCPCS codes*. Be aware that CMS may not recognize all CPT codes. While the updated CPT is usually available in October or November, the updated HCPCS may not be available until December or the first of the following year. The Level II codes can change annually as well as throughout the calendar year. It is important to examine any of these coding changes and alter coding assignments as needed for billing government payers. These codes have the greatest impact in the immunohematology and cytopathology disciplines. Be especially aware of changes to the following sections:

Coding Section	Content
"C"	Blood bank products
"G"	Venipuncture, screening procedures, including Paps
"P"	Blood bank products, screening Paps
"Q"	Physician-performed microscopy

As of Jan. 1, 2004 and in response to requirements of HIPAA (the Health Insurance Portability & Accountability Act), all Level III modifiers and codes will no longer be accepted by Medicare contractors.

Modifiers

The application of modifiers may be somewhat confusing, especially since Medicare contractors promote varying interpretations for their use. On occasion, a modifier may be "hardcoded" in the CDM. This includes numeric modifiers from CPT and alpha modifiers from CMS. Review any of these modifiers that may be assigned to the CDM and determine their merit for retention.

ICD-9 Codes

These codes also change annually, but their effective date is Oct. 1. While these codes do not impact the chargemaster, they do impact payment. Therefore, scrutinize any changes so that billing personnel are aware of potential reimbursement concerns. It is important to assign these codes with specificity and certainty. This means coding to the 4th and 5th digits when possible. However, coders must be careful to not assign a code to a patient that is not applicable. Documentation must "back up" coding assignments.

Revenue Codes

If services are provided in a hospital setting, review all revenue code assignments. Especially review those for blood bank services and products, cytopathology and surgical pathology since these services are most impacted by incorrect coding assignments. These codes may be found in the Medicare Hospital Manual and the Medicare Intermediary Manual at cms.hhs.gov/manuals.

Certification Codes

These codes demonstrate disciplines within laboratory medicine in which a laboratory has been certified to perform testing. They do not apply to hospitals. If a laboratory performs testing in a discipline in which it is not certified, it has violated its government license. While these codes do not directly impact the chargemaster, it is appropriate to reassess that all services on the CDM fall within licensed testing categories. It is fraudulent to bill Medicare for analyses performed in a laboratory specialty in which the laboratory is not certified.

Charges

Healthcare professionals frequently underestimate the value of reviewing their charges or fees. Hospitals are notorious for implementing a 10% "across the board" annual increase. At some point, charges may become inflated and no longer reflect the services they represent. While charge does not equate to reimbursement, it does have a PR impact on the patient population.

Also, "non-participating" providers must be careful not to exceed the limiting charge when billing Medicare. Current charges must not be too high or too low. What is reported today enters the database for determining future reimbursement. Charges should reflect the amount of work, time and resources expended in providing a service.

And of course, every provider should know the cost of performing a service. Cost is a big factor regarding the provision of discounts, and knowing costs is a requirement for participating in the Medicare program.

Descriptions

Scrutinize billing descriptions in the chargemaster. Correct and precise descriptions trigger fewer questions during *audits*, both internal and external. Descriptions are frequently limited to 30 characters in a billing system. This description is typically reported on an itemized bill (patient use) and frequently reported when billing commercial and managed care payers. A misleading description may lead to mistaken denials of payment.

Some acronyms are not universally recognized; care should be taken to limit their use. Insurance adjudicators may not realize that H & H represents a hematocrit and hemoglobin. As of this year, even laboratory professionals have a difficult time discerning the content of a CBC.

Panels & Code "Explosions"

A CDM entry may reflect a composite of tests. The component tests (for the composite or panel) may be linked to a separate entry/billing number for each individual test. Sometimes, several panels include the same component test; each panel refers to the same or perhaps a different billing number for an individual test. On other occasions, a service may be associated with multiple units for billing; a procedure may be billed twice, six

times, etc. It is important to examine these units of service during a chargemaster review. Additionally, these "exploded" services should be audited to ascertain that linkages or bridges are functioning properly for billing.

Revenue Impact

Determine the revenue impact due to coding changes, alterations in fee schedule reimbursement and changes in managed care contracts. If contracts do not exist, consider their merit. They may allow "carve-outs" or limitations on services to be identified. A spreadsheet analysis can estimate revenue fluctuations by comparing current to anticipated reimbursement.

Most Medicare contractors or CMS publish updated fee schedules by November of each year. Such an analysis allows laboratory administration to determine the positive or negative impact of coding on revenue and relate the comparison to current budgets.

It is not uncommon to find healthcare professionals who are more concerned about departmental productivity estimates than revenue. This is because the finance department is usually equating departmental budgets to productivity (how many procedures are performed a year and what is the related revenue). Resulting budgets limit purchases of equipment/instrumentation and curb increases in staff.

Many chargemaster entries are assigned a relative value. These assignments may be aligned to older technology, bundled services or services that are incorrectly or incompletely coded. The source of such data should be determined and steps taken to employ relevant data.

Billing Office

It is crucial for departmental personnel and administrators to routinely communicate with billing office personnel as well as personnel within finance and facility administration. Query the billing office regarding payment denials. Determine the cause of the denial (coding, modifier use, medical necessity, coverage issues, use of Advance Beneficiary Notices or ABNs, billing process, date of service, etc.) and implement steps to assure appropriate payment.

Conclusion

Consider establishing a chargemaster management protocol as part of a corporate compliance program. Such a protocol should include purchase of coding, billing and reimbursement resources. Include internal and external education of staff as an incremental part of compliance. Review the chargemaster at least annually and implement appropriate changes.

Each healthcare entity should have a process in place to request and control chargemaster changes. Examine descriptions and charges to verify appropriateness. Determine the presence or absence of budget neutrality. Communicate regularly with the billing office. Also realize when external assistance or expertise may be needed. In this instance, select a firm with:

- Expertise in healthcare
- Expertise in coding, billing, reimbursement *and* compliance
- Experience
- No conflict of interest (not a financial auditor as well as compliance auditor for the same entity)
- Continued communication following review
- Retainer relationship

A chargemaster review should be accompanied by a review of matched patient records, requisitions for services, test results, claims, itemized bills, reimbursement advices and ABNs where appropriate. While a review of the chargemaster is both prudent and pertinent, a CDM review alone does not assess its application in billing and reimbursement as well as compliance.

The outcomes of an effective chargemaster management protocol for compliance will include coding accuracy, charges and descriptions that reflect services provided, greater accuracy in productivity reporting, predictive budgetary changes and maintenance of compliance.

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Fate Of Medicare Lab Co-Pay Still Uncertain

Beginning next year, will the laboratory industry get only 80% of the fee schedule rate for Medicare Part B testing and have to collect the remaining 20% from beneficiaries? That's a prospect the industry is lobbying aggressively to prevent. Return of the 20% co-pay, eliminated in 1984, would be required under the Senate-passed version of Medicare reform and prescription drug legislation, but not under the House-passed version.

Negotiators in the House-Senate conference committee have been laboring for months to craft a compromise Medicare reform package capable of winning approval from both chambers. For lab groups, the co-pay, approved by the Senate as one way to help fund higher Medicare payments to rural hospitals and other rural healthcare providers, has been a paramount concern.

Industry groups, including the American Clinical Laboratory Association (ACLA), maintain that the administrative cost of billing and collecting from beneficiaries would be, in many cases, as much or more than the amount collected. "These new costs would represent a sizable cut in laboratory reimbursement," ACLA president Alan Mertz told attendees at Washington G-2 Reports' Lab Institute, held Oct. 8-11 in Arlington, VA. Labs have already seen their reimbursement updates reduced or eliminated in 11 of the past 18 years, he noted.

"If this passes, it will be the second largest benefit reduction in existing Medicare benefits in the history of the program," attorney Robert Waters told Institute participants. Waters, of the law firm of Arent Fox Kintner Plotkin & Kahn (Washington, DC), is a leader in the lab coalition fighting the proposal and represents the American Association of Bioanalysts.

Mertz and Waters believe that if the lab industry keeps the pressure on lawmakers, there's a good chance the co-pay will be dropped from any final Medicare reform bill. In keynote remarks at the Lab Institute, U.S. Rep. Phil English (R-PA), a major player in the reform debate, assured the audience that he is committed to defeating the co-pay (and also to securing passage next year of a measure he has sponsored that would increase the Medicare specimen collection fee to $5.40 from the current $3).

Key "Deal-Breakers" Ahead Despite Optimistic Air

As we went to press, Medicare reform conferees were publicly confident they could strike a final compromise within the next few weeks, but whether any such accord stands a chance of passing both the House and the Senate remains very much up in the air.

As of Oct. 27, negotiators reportedly had reached agreement on many provisions in the omnibus reform legislation, but had yet to resolve the big issues that both houses and both parties acknowledge could kill prospects for final enactment. These "deal-breakers" include:

- The House-backed requirement that traditional Medicare fee-for-service compete with private health plans under a premium support system. Senate Democrats have repeatedly charged this is a House GOP conservative drive to privatize Medicare, and they appear to have enough support across the aisle to sustain a filibuster.
- Whether to means-test the Part B premium. Currently, all beneficiaries pay the same premium for the same Medicare benefits, but under means-testing, more affluent beneficiaries would pay more for these benefits.
- The amount of subsidies to help low-income beneficiaries obtain prescription drugs.

Also undecided at press time are a host of provider payment policy changes, including the lab co-pay. The Clinical Laboratory Coalition reports that conferees may no longer be considering it, but in its place may be looking at a long-term freeze on the Consumer Price Index update to lab fees.

"[S]ubstituting a long-term freeze that disproportionately harms a single industry, which already has borne more than its fair share of Medicare reduction, is not the answer," says the coalition in an Oct. 23 letter to an influential member of the Medicare conference committee, Sen. Charles Grassley (R-IA), who chairs the Senate Finance Committee and is the prime proponent of the co-pay. "We also have heard that some have suggested reducing payments to laboratories, which would be devastating to our industry."

Robert Rabecs

OIG Sets Focus Areas, *from p. 1*

"This should alert providers that, in the areas listed, they need to be particularly sure their operations are compliant."

Along with lab billing, pharmaceutical fraud and excessive drug pricing are major target areas for the OIG in 2004. Outcomes of these reviews could lead to readjustment of how prescription drugs are reimbursed, Rabecs believes. The OIG also plans to study a number of issues related to nursing homes, hospital payments and contractor operations. Here's a rundown of what the OIG will be scrutinizing in select areas:

Laboratory Services

❖ ***Testing outside certified specialties***. Noting that Medicare currently does not compare billed testing with CLIA specialty certification before paying claims, the OIG wants to determine the extent to which Medicare is paying for any testing outside the scope of a lab's CLIA certification. In this ongoing study, the OIG will compare claims with certification records to quantify any improper payments and lost CLIA certification fees, as well as evaluate existing programmatic controls.

❖ ***ESRD payments***. Are hospitals separately billing Medicare for laboratory services already included in their ESRD (end-stage renal disease) composite rate? The OIG wants to find out, noting that under Medicare's composite rate reimbursement, ESRD facilities are paid 100% of their costs. Because lab services are paid for under the composite rate, hospitals should not separately bill for them.

❖ ***Proficiency testing***. In this area, also an ongoing study, the OIG will assess whether labs are complying with CLIA requirements to participate in PT.

Hospitals

❖ ***Consecutive inpatient stays***. To what extent do Medicare beneficiaries receive acute and post-acute care through sequential stays at different hospitals? Though Medicare allows care in different facilities according to the beneficiary's needs, payments may be denied when one or multiple stays constitute an attempt to circumvent the prospective payment system. The OIG plans to analyze claims to identify questionable patterns of inpatient and long-term care.

❖ ***Coronary artery stents***. The OIG will scrutinize inpatient and outpatient claims involving arterial stent implantation to determine whether they were medically necessary and supported by adequate documentation. The OIG will also look at claims for beneficiaries who had stent implantations during multiple surgical procedures to determine if the implantations should have been performed simultaneously.

❖ ***Outpatient cardiac rehabilitation services***. At the request of the Centers for Medicare & Medicaid Services, the OIG will determine whether cardiac rehabilitation services provided by hospital outpatient departments met Medicare coverage requirements. Medicare covers such rehabilitation under the "incident to" provisions of a physician's professional services benefit, which requires that the services of non-physician personnel be furnished under the physician's direct supervision.

Pharmaceuticals

❖ ***Physician acquisition costs*** What are physicians' acquisition costs for prescription drugs billed to the Medicaid program? Specifically, the OIG plans to determine the discount below average wholesale price at which physicians purchase drugs. Previous studies have looked at the discount for pharmacies, but not for physicians. The OIG believes the results of this review will provide states with information that will allow them to set reimbursement for physician-administered drugs at a reasonable level.

❖ ***Average manufacturer price (AMP) and average wholesale price (AWP)***. The OIG will study the relationship between the AMP and the AWP, as well as other drug rebate trends, to ascertain whether manufacturers are avoiding compliance with the intent of drug rebate pricing laws.

❖ ***Drug prices paid by Medicare***. A 2001 OIG report showed that Medicare reimbursed prescription drugs at significantly higher prices than those available to the U.S. Department of Veterans Affairs, Medicaid and the physician/supplier community. The OIG plans to again compare reimbursements.

Resources

❖ Robert Rabecs: 202-637-6842

❖ 2004 OIG work plan: *www.oig.hhs.gov/publications/workplan.html#1*

Advisory Group Urges Changes To Compliance Programs

New "Stand Alone" Guideline Recommended

The foundation of corporate compliance programs could be in for some changes if an advisory group to the U.S. Sentencing Commission has its way.

The ad hoc group in October recommended that the commission elevate the criteria that define effective compliance programs from advisory to actual guidelines. The committee also recommended changes to commentary in the Sentencing Guidelines on waiver of attorney-client privilege.

The Sentencing Commission must decide which, if any, of the panel's suggestions it wishes to embrace before submitting its next round of proposed guidelines changes to Congress

The HHS Office of Inspector General has long used the U.S. Sentencing Guidelines seven criteria for effective compliance programs as the foundation for defining effective compliance programs in voluntary guidance to health care industries.

The advisory group recommended that the commissioners enhance the status of compliance program provisions by adopting a "stand alone guideline" to supplement existing criteria. Within that guideline, the panel suggested adding new provisions that would:

- Stress the importance of having a compliance-oriented culture
- Define compliance standards and procedures
- Specify the responsibilities of a company's governing authority and leadership for compliance
- Emphasize the importance of providing sufficient resources and authority for those in charge of compliance
- Define what an organization should do to ascertain whether someone is apt to engage in misconduct
- Include training and dissemination of training materials within the definition of an effective program
- Require periodic evaluation of the effectiveness of the compliance program
- Mandate a means for anonymous reporting of misconduct
- Require ongoing risk assessments

Waiver Of Privilege

The advisory group also recommended changes to commentary in the Sentencing Guidelines dealing with waiver of attorney-client privilege and work product protections. Historically, waivers of privilege have been considered key to cooperating with government investigations.

The advisory group, however, suggested adding clarifying language to the guidelines stating that the absence of such waivers would not necessarily prohibit reductions in sentencing scores.

"If the defendant has satisfied the requirements for cooperation set forth in this note, waiver of the attorney-client privilege and of work product protections is not a prerequisite to a reduction in culpability score under subsection (g)," the recommended language reads. "However, in some circumstances waiver of the attorney-client privilege and of work-product protections may be required in order to satisfy the requirements of cooperation."

Resources

Advisory group report on corporate compliance: *www.ussc.gov/corp/advgrprpt/advgrprpt.htm*

CMS Drops Proposed Pathology Edit

At the urging of the American College of Pathologists (CAP), the Centers for Medicare & Medicaid Services has agreed to drop a proposed edit under the National Correct Coding Initiative that would have precluded payment for cytopathology codes CPT 88160 and 88161 when billed with code 88329, pathology consultation during surgery.

In an Oct. 2 letter to AdminaStar, CMS's NCCI contractor, CAP argued that the edit would have prevented intraoperative cytologic evaluation from guiding surgical intervention, forcing slower and less accurate frozen section analysis by pathologists during surgeries. CAP said intraoperative cytologic evaluation is a relatively new process that the CPT Editorial Panel never considered as part of the intraoperative consultative service code and offered to seek a CPT code for it if CMS would drop the edit. CMS agreed and gave a nod to the idea of establishing a new code for it.

Bringing Home The Bacon: Federal enforcers collected $1.4 billion through healthcare anti-fraud and abuse efforts in fiscal 2002, according to a new report touting work of the U.S. Departments of Justice and Health & Human Services. The money came primarily from judgments, settlements and administrative impositions. Altogether, the enforcement agencies filed 361 criminal indictments and 221 civil healthcare fraud cases. To view the report, go to *http://oig.hhs.gov/publications.html*. Click on "HCFAC."

Coding Fecal Leukocyte Exams: Beginning Jan. 1, 2004, laboratories that are CLIA-certified for provider-performed microscopy (PPM) procedures must use CPT/HCPCS code 89055 (leukocyte assessment, fecal, qualitative or semiquantitative) when submitting claims for the fecal leukocyte exam. The coding requirement is contained in an Oct. 25 transmittal from the Centers for Medicare & Medicaid Services, posted online at *www.cms.gov/manuals/transmittals*.

Paying The Right Amount: The General Accounting Office has urged the Centers for Medicare & Medicaid Services to take steps to prevent Medicare beneficiaries from paying too much or too little in co-payments for outpatient hospital care. In findings addressed to CMS administrator Thomas Scully, the GAO said the methodology used to calculate beneficiary co-payment amounts in hospitals for 2003 under the outpatient prospective payment system resulted in inaccurate payments in 75 APCs (ambulatory payment classifications). This could lead to continued inaccurate beneficiary costs in 2004, the agency warned. The GAO report is online at *www.gao.gov/new.items/d04103r.pdf*.

Pleading The Fifth: Former HealthSouth Chairman and Chief Executive Officer Richard Scrushy refused to answer questions about his involvement in accounting fraud at the company during a congressional hearing Oct. 15. Committee members lambasted Scrushy for appearing on *60 Minutes* Oct. 12 and answering similar questions while invoking the Fifth Amendment in the hearing only days later. Scrushy has denied he had any knowledge about top officials at the Birmingham, AL-based company falsely inflating earnings to meet Wall Street Expectations, resulting in at least $1.4 billion in overstatements. At last count, 15 former HealthSouth executives have pleaded guilty to federal accounting fraud charges, all pointing fingers at Scrushy as the one who directed the scheme.

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