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Covering Government Policy For Diagnostic Testing & Related Medical Services

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Senate-Passed Bill Blocks Physician Fee Cut Until Oct. 1

The measure also would extend the pathology "grandfather" provision for all of 2010.

The Senate on March 10 passed legislation that would extend the freeze on the Medicare fee update for pathology and other physician services until Oct. 1.

Currently, the fees are frozen at their 2009 levels through March 31, canceling a cut of 21 percent under the Sustainable Growth Rate (SGR) formula used to calculate the annual fee update. Unless Congress acts, the cut is scheduled to kick in April 1.

The Senate bill also would revive the pathology "grandfather" protection, which expired at the end of 2009, for one year, retroactive to Jan. 1, 2010. The protection allows independent clinical laboratories to bill Medicare for the technical component of pathology services to hospital inpatients and outpatients.

These and other Medicare reimbursement provisions are included in the tax extenders bill (H.R. 4213), which the Senate passed by a 62-36 vote. The measure also provides an extension of unemployment insurance, the federal tax credit for COBRA health care coverage, and increased federal Medicaid funding.

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Controversy Heats Up Over Self-Referrals for Pathology Work

The battle over physicians profiting from self-referrals for pathology services is far from over. The American Society for Clinical Pathology (ASCP) has fired the latest salvo, charging that these business arrangements result in abusive billing practices that foster overutilization of services and higher costs for patients.

In a March 1 letter to the Centers for Medicare and Medicaid Services (CMS), ASCP urged the agency to exclude pathology from the Stark in-office ancillary services exception and to fix "unintended flaws" in the anti-markup rule for diagnostic services that are being "aggressively exploited and the costs passed on to Medicare beneficiaries and taxpayers."

In the letter to CMS acting administrator Charlene M. Frizzera, ASCP president Mark H. Stoler, MD, FASCP, asked that these changes be incorporated in the 2011 Medicare physician fee schedule rule the agency will propose later this year. He said studies have consistently shown that self-referrals encourage excessive use of services and increase health care costs.

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INSIDE *NIR*

♦ Medicare Claims *Advisory*

New Medicare Codes for HIV Screening Benefit: What Your Lab Must Know to Bill and Get Paid

The CMS coverage decision is the first time the agency has used its authority to expand Medicare preventive services without first obtaining congressional approval. Since Jan. 1, 2009, CMS has had this power, if certain requisites are met, under provisions of the Medicare Improvements for Patients and Providers Act of 2008 (Public Law 110-275).

Three new G codes have been established by the Centers for Medicare and Medicaid Services (CMS) to bill for HIV screening of Medicare beneficiaries, the latest benefit to be added to the Medicare preventive services package.

The new codes are to be implemented April 5 for dates of service on and after Dec. 8, 2009, the date when CMS announced its final decision to cover this screening for beneficiaries at increased risk of HIV infection and all pregnant beneficiaries *(NIR 10, 1/Jan. 11, p. 7).*

G0432 Infectious agent antigen detection by enzyme immunoassay (EIA) technique, qualitative or semiquantitative, multiple-step method, HIV-1 or HIV-2, screening

G0433 Infectious agent antigen detection by enzyme-linked immunosorbent assay (ELISA) technique, antibody, HIV-1 or HIV-2, screening

G0435 Infectious agent antigen detection by rapid antibody test of oral mucosa transudate, HIV-1 or HIV-2, screening

Covered Testing and Frequency Limits

CMS will cover HIV screening with a Food and Drug Administration-approved EIA, ELISA, or rapid HIV antibody test, as follows:

- A maximum of once annually for Medicare beneficiaries at increased risk for HIV infection under guidelines of the U.S. Preventive Services Task Force:
  - Men who have had sex with men after 1975.
  - Men and women having unprotected sex with multiple (more than one) partners.
  - Past or present injection drug users.
  - Men and women who exchange sex for money or drugs, or have sex partners who do.
  - Individuals whose past or present sex partners were HIV-infected, bisexual, or injection drug users.
  - Persons being treated for sexually transmitted diseases.
  - Persons with a history of blood transfusion between 1978 and 1985.
  - Persons who request an HIV test despite reporting no risk factors, since this group is likely to include individuals not willing to disclose high-risk behaviors.
- A maximum of three times per term of pregnancy for pregnant beneficiaries beginning with the date of the first test when ordered by the woman's clinician.

Patients with any known prior diagnosis of HIV-related illness are not eligible for this screening benefit.

Diagnosis Code Reporting

A claim should be submitted with one or more of the following diagnosis codes in

the header and pointed to the line item:

- When increased risk factors are reported: V73.89 as primary, V69.8 as secondary.
- When increased risk factors are *not* reported: V73.89 as primary only.
- For pregnant beneficiaries, submit the following diagnosis codes in addition to V73.89 to allow for more frequent screening than once per 12-month period:
  - V22.0 – Supervision of normal first pregnancy
  - V22.1 – Supervision of other normal pregnancy
  - V23.9 – Supervision of unspecified high-risk pregnancy

The new coverage and payment policy is presented in CMS Transmittal 113 and the related update to the National Coverage Decision (NCD) on HIV screening is presented in Transmittal 1918, Change Request 6786.

Providers Get More Time to Prevent Payment Denials

The enrollment policy and its new deadline are spelled out in CMS Transmittal 642, Change Request 6417 (Feb. 26, 2010).

The Centers for Medicare and Medicaid Services (CMS) has postponed until Jan. 3, 2011, the implementation of a policy to reject Medicare claims from Part B providers and suppliers when the ordering/referring physician or nonphysician practitioner is not enrolled in the agency's Provider Enrollment, Chain, and Ownership System (PECOS) database. The agency had intended to introduce the policy on April 5 of this year *(NIR, 09, 22/Dec. 14, p. 8).*

The delay, made in response to requests from medical groups, will give these providers "sufficient time to enroll in Medicare or take the action necessary to establish a current enrollment record in Medicare," CMS said. A current record is defined as being enrolled in the Medicare PECOS and having a National Provider Identifier (NPI).

Once the policy is implemented, claims submitted by a Part B provider or supplier who furnished the ordered/referred item or service will be rejected when the one who orders or refers does not have a current enrollment record. For now, if the ordering/referring provider is not in the PECOS database, the claim will be processed but the provider/supplier will get a warning message.

Ordering/referring providers who are enrolled in Medicare but have not updated their enrollment record since November 2003 should update it now, CMS said. Even if there are no changes to their enrollment data, providers need to submit an initial enrollment application, which will establish a current enrollment record in PECOS. Also, providers that have not billed Medicare in 12 months need to submit an application to reactivate their enrollment.

Organizations must be enrolled before individuals. Before physicians or nonphysician practitioners can reassign their benefits to a medical group or clinic other than the one they solely own, the medical group or clinic must have an approved enrollment record in PECOS.

To enroll or change an existing Medicare enrollment record, providers can use the Internet-based PECOS at *cms.hhs.gov/MedicareProviderSupEnroll/04_Internetbased-PECOS.asp#TopOfPage* or submit a paper application (CMS-855) to their Medicare contractor. The CMS-855 form is available at *cms.hhs.gov/cmsforms.*

focus on: Health Information Technology

Labs Get New CLIA Guidance on E-Health Records

The update to the interpretive guidelines applies to 215,000 laboratories nationwide that are certified under CLIA. The guidelines are used by lab inspectors to verify the facility's compliance with CLIA regulatory requirements.

In our Feb. 22 issue, we reported that release of new interpretive guidelines was imminent to help clinical laboratories align their use of health information technology, including electronic health records (EHRs), with their responsibilities under the Clinical Laboratory Improvement Amendments (CLIA).

Now, the guidelines are out. They revise CLIA regulatory standards governing test ordering, reporting of test results, and retention of test reports. They also add a new section on managing the correction of test reports for an EHR. The guidelines were released in a March 1 memo, effective immediately, to state survey agency directors from Thomas Hamilton, director of the survey and certification group at the Centers for Medicare and Medicaid Services (CMS). Below are highlights from the guidance document S&C-10-12-CLIA.

Test Request

Standard: The laboratory must have a written or electronic request for patient testing from an authorized person.

Interpretive Guidelines §493.1241(a): An "authorized person" means an individual authorized under state law to order tests or receive test results, or both. Some states expressly authorize patients to order tests or receive (or give them access to) test results regardless of who ordered the test. In these states a laboratory may release test results directly to a patient as an "authorized person" in accordance with state law. Patients may also be considered "individuals responsible for using test results" if state law does not expressly prohibit release of test results directly to patients.

Interpretive Guidelines §493.1241(c)(1)-(c)(8): The test requisition must provide the information necessary to identify and send test results to the individual who ordered the test (the authorized person), or where applicable, to the authorized person's agent. An authorized person may also use the test requisition to designate additional individuals/entities who will be responsible for using the test results to provide care to the subject individual.

Release of Test Results

Standard: Test results must be released only to authorized persons and, if applicable, the individual responsible for using the test results and the laboratory that initially requested the test.

Interpretive Guidelines §493.1291(f): Test results must be released to the authorized person, or if applicable, their agent. Test results must also be released to any additional individuals/entities designated on the test requisition. These entities are understood to be "responsible for using" the test results. When the authorized person and the individual responsible for using the test results receive the results, the laboratory's CLIA responsibility ends.

Transmission of Test Reports

Standard: The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to the final report destination in a timely manner.

Interpretive Guidelines §493.1291(a): The regulations apply to manual as well as automated record systems (e.g., a laboratory information system or LIS). Regardless of the means used to transmit lab results, routine checks should be conducted to verify that transmissions are being accurately and reliably conveyed to the final report destination (the authorized person or individuals/entities responsible for using the test results).

Retention of Test Reports

Standard: The laboratory must retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least two years after the date of reporting.

Interpretive Guidelines §493.1105(a)(6): A copy, either paper or electronic, of the original report includes all information sent to the individual requesting the test or using the test results, and includes the name and address of the laboratory performing the test. The copy need not be paper but may be retrieved from a computer system, microfilm, or microfiche record, as long as it contains the exact information as sent to the individual ordering the test or utilizing the test results.

The laboratory copy of the report should contain information that provides an accurate, complete, and easily understood display of previously reported data retained or retrieved from the lab's record system. For test reports from histopathology, oral pathology, or cytology that require personnel identifiers or an authorized signature (which may be electronic), the copy must include evidence of the identifiers or signatures.

Correction of Test Reports

Standard: When errors are detected in test reports, the authorized person ordering the test and, if applicable, the individual using the test results should be promptly notified.

Interpretive Guidelines §493.1291(k): Errors in test results may include incorrect patient identification, test results, reference or normal ranges, interpretive information, or other significant information. Corrected reports, either hard copy or electronic, must clearly indicate both the corrected results and the fact that the report is a corrected report.

Interpretive Guidelines §493.1291(k)(1): When determining whether the laboratory gave prompt notification of test and/or reporting errors to the authorized person(s), their agent (if applicable), and others who are identified as responsible for using the test results on the requisition, consider where contact information was provided to the laboratory, when the error was identified, when the authorized person was notified, and the extent of the error (for example, clinically significant results reported on the wrong patient). For cytology, corrected reports must be promptly sent not only to the authorized person, but also to all known recipients of the original incorrect report.

Controversy Heats Up, *from p. 1*
ASCP and other pathology groups have been highly critical of the proliferation of self-referral arrangements whereby specialty physician groups establish an in-house histology laboratory and contract with pathologists for professional services.

Their express purpose, the groups charge, is to siphon off business from pathology groups and labs and capture more Medicare revenue from pathology work. Most prominent in this market trend are gastroenterologists and urologists, and increasingly oncologists.

In the letter to CMS, ASCP pointed out, "Interestingly, there has also been a corresponding increase in the utilization of pathology services, both in terms of the number of biopsies being performed per patient and the number of patients being biopsied."

The Stark In-Office Service Exception

Removing pathology from this exception is "the most effective and appropriate means to deter abusive billing practices involving pathology services," Stoler said.

The physician self-referral law (known as the Stark law after its congressional proponent Democratic Rep. Pete Stark of California) prohibits physicians from referring Medicare or Medicaid patients for designated health services to facilities in which the physician (or an immediate family member) has a financial stake, whether as an ownership interest or compensation arrangement or both.

However, the law does allow a number of exceptions, including one that permits physicians to provide designated health services in their offices, including clinical and anatomic pathology testing and diagnostic imaging.

By its very nature, ASCP argues, pathology should not be included in the in-office services exception. "Pathology services are complex medical procedures requiring significant time, skill, and expertise to perform properly. These services cannot be performed during a patient visit—the driving rationale for including medical services or procedures in the exception."

The College of American Pathologists (CAP) also is lobbying to have anatomic pathology tests removed from the Stark exception. CAP contends that self-referral arrangements can only be controlled by removing the economic self-interest of ordering physicians, either by tightening the exception or prohibiting reassignment for such services under Medicare.

Anti-Markup Rule for Diagnostic Services

Currently, the markup of these tests is allowed only when the tests are performed by a physician who "shares a practice" with the billing physician (the ordering physician). There is a two-test approach to determine whether the physician performing the service meets this requirement.

The first test requires that the performing physician—either the physician performing the professional component (PC) or supervising the technical component (TC)—furnish at least 75 percent of his or her services through the billing physician or group practice. Alternatively, the TC and/or PC may be marked up if the service is performed in the office of the billing physician.

"While the first of these two tests may help deter self-referral arrangements, the latter test is weak and ineffectual," ASCP said. "This test can easily be satisfied by any physician who is part of the billing group practice."

One of the problems with these arrangements, Stoler said in the letter to CMS, is that the TC is often supervised by a physician who has little or no training or experience supervising (or performing) histology (the TC of the pathology service).

"This is because neither the Clinical Laboratory Improvement Amendments of 1988 (CLIA) nor Medicare requires that the physician supervising the processing of the biopsied specimen have any training or experience in pathology," he noted. "This major oversight essentially allows the highly skilled, near art form field of histopathology—the key step in taking a tissue sample and preparing it for diagnosis—to be equated with in-office laboratory tests waived under CLIA. … Given the often irreplaceable nature of anatomic pathology specimens and the highly complex multistep process of properly making a biopsy into a slide, the improper supervision of this process can potentially have dire consequences for patient care."

To fix these flaws with the anti-markup rule, ASCP recommends that CMS:

- ❑ Prohibit the use of independent contractors by referring physicians or group practices billing for the performance of the PC and the TC of a pathology service.
- ❑ Require that supervision of the TC be provided by a physician (preferably an anatomic pathologist) meeting the high-complexity laboratory director requirements enumerated in CLIA. ❑ Past or present injection drug users.
- ❑ Require that the supervision be provided on site during the performance of the TC.
- ❑ Alternatively, delete the "second test" that allows the markup of diagnostic tests performed in a physician's office. Most of the flaws in the anti-markup rule are traceable to this part of the two-test approach, ASCP said. ❑ Require that supervision of the TC be provided by a physician (preferably an anatomic pathologist) meeting the high-complexity laboratory director requirements enumerated in CLIA.
- ❑ Reinstate the purchased test rules to prohibit physicians from marking up tests purchased from outside suppliers.

MedPAC Weighs In Too

The Medicare Payment Advisory Commission (MedPAC), which reports to Congress, is also looking at three options to tighten the Stark in-office services exception, including excluding certain services such as diagnostic tests that are not usually provided at the same time as the office visit.

The other options are creation of new payment tools (for example, bundling of services) to reduce the incentive for using such services and establishment of a prior-authorization system for physicians who are self-referring for advanced imaging.

In-office ancillary services are growing at a rapid pace, and the increased utilization may require narrowing the exception for such services under the physician self-referral law, as well as altering the payment system, MedPAC officials noted at a public meeting held earlier this year to invite comments.

Senate-Passed Bill Blocks Physician Pay Cut, *from p. 1*

Because the Senate bill adds provisions to the underlying House bill, the legislation goes back to the House to reconcile the differences. The outstanding issue between the two chambers is not the health extenders but the offsets to pay for the bill, said Alan Mertz, president of the American Clinical Laboratory Association, adding that this could delay final passage of the legislation.

If no agreement is reached by March 31, another short-term extension of the physician fee freeze is likely. Congress is scheduled to be in recess for the first two weeks of April.

The American Medical Association remains opposed to short-term fixes to the SGR system "of any duration" and is urging the Congress to use the month of March to replace the SGR with a new payment update system that does not trigger ever-steeper cuts. The House has already passed a bill that would repeal the SGR in 2010 and establish a new update formula tied to growth in the gross domestic product at an estimated net cost of $210 billion over 10 years. But the change is not paid for, a sticking point with some senators who worry about the effect on the federal deficit. The Senate previously rejected an unpaid-for bid to repeal the SGR.

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