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CMS to Increase Medicare Travel Allowance on June 30

For a quick review of the trip fee increase and related payment policy, see the Focus, *pp. 4-5.*

In welcome news to clinical laboratories, the Centers for Medicare and Medicaid Services has instructed its contractors to implement an increase of 20 cents in the travel allowance for collecting specimens from nursing home and homebound beneficiaries as of June 30.

Payment on a per-mile basis (billing code P9603) will rise to $0.955, while payment at the flat rate (P9604) will rise to a minimum of $9.55. The current rates are $0.935 and $9.35, respectively, and have been in effect since the start of 2006.

Local contractors have the option to pay under either of the above two methods. They also may establish a higher per-mile rate in excess of $0.955 "if local conditions warrant it," CMS said.

CMS announced the trip fee hike in Change Request 5996, released May 30. Though the implementation date is June 30, the effective date is Jan. 1, 2008. However, contractors are not required "to search and adjust claims that have been already processed unless brought to their attention," CMS said.

INSIDE *NIR*

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CDC Report Takes a New Look At the Status of U.S. Lab Medicine

A new report, commissioned by the Centers for Disease Control and Prevention and released late last month, presents an overview of key factors shaping clinical laboratory medicine throughout the United States, including changes needed in Medicare reimbursement and pathology quality performance.

Citing flaws in the current Medicare payment system, the report concludes that the program needs to be redesigned in line with growing scientific, economic, and business challenges in the health care market. The fee schedule method, based on historical charges, is out of date and bears no relation to current production costs or the cost-reducing effects of technological changes, the report says. This is especially true for new molecular diagnostics and other genetic testing. "The processes for establishing reimbursement rates for [them] remain archaic and inadequate."

The report is skeptical that lab competitive bidding will produce substantial Medicare savings and says the current demo model, blocked from a San Diego launch earlier this year after local labs filed suit, is "highly exclusive and could cause significant

Continued on p. 2

The report, Laboratory Medicine: A National Status Report (May 2008)*, is posted online at www.futurelabmedicine.org and is open for comment until June 23.*

Status of U.S. Lab Medicine, *from p. 1*

detriment to labs that lose in the bidding process, since many depend on Medicare for a sizable portion of their revenues."

Redesign of Medicare lab payment would ricochet throughout the national health care system, the report points out. All public payers and approximately 67 percent of private payers use Medicare's payment methodologies as the basis for their own and as tools for negotiating discounts with providers.

The CDC requested the report "to lay the ground work for transforming lab medicine over the next decade." It discusses a wide range of issues in addition to payment, including workforce shortages, quality performance measures, lab information systems, and federal regulatory oversight, among others. The CDC intends the study to serve "as a reference point for improving quality in the future and as policy guidance for government agencies, professional groups, and others who provide, use, regulate, and pay for lab services."

The report was prepared by The Lewin Group (Falls Church, Va.), an Ingenix company, under subcontract to Battelle Memorial Institute (Columbus, Ohio) for CDC's Division of Laboratory Systems (Atlanta) as part of its *Improving Quality in Lab Medicine* initiative.

Report Calls for Pathology Changes

- ❑ Lack of uniformity and standardization of clinical pathology test values among manufacturers hinders implementation of lab-based guidelines, which require method-dependent decision limits. Heterogeneity of test values also makes it difficult for clinicians to work in an integrated health system using more than one testing method or to address the needs of special patient populations.
- ❑ Laboratorian consultations are standard practice and reimbursed for anatomic pathology, but this is not always the case in clinical and molecular pathology. The primary barriers to interpretive consultations in clinical pathology are lack of reimbursement and the shortage of subspecialty expertise.
- ❑ Digital pathology systems require further advances in high-power computation, data storage capacity, image formatting, and processing algorithms to facilitate the shift from single-field images to whole-tissue processing.

Report Profiles National Lab Market

- ❑ Spending for lab services accounts for 2.3 percent of U.S. health care expenditures and 2 percent of Medicare expenditures.
- ❑ Approximately 6.8 billion tests are performed annually.
- ❑ Lab testing revenues projected for 2007 total $52 billion.
- ❑ Clinical pathology comprises 66 percent of all lab tests and $32 billion in revenue.
- ❑ Anatomic pathology and cytology account for 23 percent of lab tests and $11 billion in revenue.
- ❑ Molecular and esoteric tests account for 8 percent of lab tests and $4 billion in revenue.
- ❑ More than 4,000 lab tests are available for clinical use. Of the 1,162 reimbursed by Medicare, about 500 are performed regularly.
- ❑ An estimated 1,430 diseases are now detectable using genetic testing. Of these, an estimated 287 are tested only in research settings.
- ❑ The number of CLIA-certified labs exceeded 200,000 in 2007. Physician office labs represent 54 percent of the total.
- ❑ Hospital-based labs account for 55 percent of total testing volume and 54 percent of total testing revenue, projected at $28.4 billion for 2007.

CMS Spells Out Policy on Assigning Providers to MACs

As part of its national rollout of a new Medicare Administrative Contractor (MAC) system for processing claims under Parts A and B, the Centers for Medicare & Medicaid Services has issued a transmittal detailing how it intends to assign clinical laboratories, pathologists, and other health care providers to these new entities.

Generally, providers will be assigned to the MAC that covers the state where the provider is located. The MAC will be the single entity to handle both Part A and Part B work, replacing the current system that splits it between carriers and intermediaries.

Under the new system, required by contracting reform provisions in the 2003 Medicare Modernization Act, CMS plans to award 15 A/B MAC contracts and, in addition, MAC contracts for durable medical equipment and other specialty providers, including histocompatibility laboratories. The agency last month announced that it had awarded its seventh A/B MAC contract and is on track to complete the transition to MACs by 2009, two years ahead of schedule (*NIR, 29, 15/May 26 '08, p. 1*).

Geographic Assignment Rule

Providers generally will be assigned to the MAC that covers the state where the provider is located (CMS Change Request 5979, effective May 18, 2008). This does not apply to the following categories: home health and hospice providers; durable medical equipment, prosthetics, orthotics, and supplies; and certain specialty providers (including histocompatibility laboratories) and demonstrations.

Exceptions

There are two exceptions to the geographic assignment rule:

1. A qualified chain provider (QCP) may request that its member providers be serviced by a single A/B MAC, specially the one that covers the state where the QCP's home office is located. The rules define a QCP as:
   - ❑ Ten or more hospitals, skilled nursing facilities, and/or critical access hospitals under common ownership or control, collectively totaling 500 or more certified Medicare beds; or
   - ❑ Five or more hospitals, skilled nursing facilities, and/or critical access hospitals under common ownership or control in three or more contiguous states, collectively totaling 300 or more certified Medicare beds.
2. Providers that meet the "provider-based" criteria of 42 CFR 413.65. Provider-based entities (other than home health and hospice providers) will be assigned to the MAC that covers the state where the main ("parent") provider is assigned.

Out-of-Jurisdiction Providers

This term refers to a provider that is not currently assigned to an A/B MAC or fiscal intermediary. For example, an individual, freestanding provider located in Oregon but currently assigned to the Florida fiscal intermediary would be an out-of-jurisdiction provider (OJP). New MACs will initially serve some OJPs until CMS finalizes reassignment of all OJPs to their destination MACs based on the geographic rule.

CMS will start the overall transfer of OJPs to their final destination MACs after two events have taken place. The first event is when all 15 A/B MACs have been awarded and implemented. The second is when all the systems and contractors at the departure and destination MACs are capable of handling the move.

focus on: *Medicare Trip Fee*

A Quick Guide to Medicare Travel Allowance Policy

The trip fee increase and related payment policy are found in CMS Change Request 5996 (May 30, 2008), an update to Pub.100-04 Medicare Claims Processing, Chapter 16, Section 60.2/Travel Allowance.

What is Medicare's travel allowance?
It is payment to cover the estimated travel costs when collecting specimens from nursing home and homebound Medicare beneficiaries as well as the expenses for trained personnel who travel to collect a sample.

When is it payable?
The travel allowance is payable *only* when a specimen collection fee would be payable. *No* travel allowance is made when the technician merely performs a messenger service to pick up a specimen drawn by a physician or by nursing home personnel. Further, the travel allowance may *not* be paid to a physician unless the trip to the patient was solely for the purpose of drawing a specimen.

What codes are used to bill Medicare for the travel allowance?
The HCPCS codes below:

P9603 Travel allowance: one way, in connection with medically necessary laboratory specimen collection drawn from homebound or nursing home patient; prorated miles actually traveled (carrier allowance on per-mile basis); or

P9604 Travel allowance: one way, in connection with medically necessary laboratory specimen collection drawn from homebound or nursing home patient; prorated trip charge (carrier allowance on flat-fee basis).

To indicate round-trip travel, use the modifier LR.

In using P9604, the lab should determine whether it is appropriate to bill on an average round-trip basis for all trips during a one-year time period, CMS has previously cautioned. Thus, payment for travel under this code is made to reasonably pay on average for a varying range of trip miles, so the lab should not also require payment on another basis (for example, code P9603).

What trip fee increase is due to be implemented June 30?
The per-mile travel allowance (P9603) will rise to $0.955. The total is computed using the federal mileage rate of $0.505 per mile, plus an additional $0.45 per mile to cover the technician's time and travel costs. Contractors have the option to set a higher per-mile rate in excess of the minimum $0.955 "if local conditions warrant it," CMS said.

The travel allowance paid on a flat-rate trip basis (P9604) will rise to $9.55.

Current codes for the allowance pay $0.935 and $9.35, respectively.

Will claims from clinical laboratories be automatically adjusted?
The effective date of the trip fee increase is Jan. 1 of this year, according to CMS. In response to the above question raised by *NIR*, CMS responded, "The contractors will not automatically make retroactive corrections, but labs should probably check

their contracts for information on how to resubmit if they want a correction made (just a precaution against accusations of double billing)."

How does Medicare pay on a per-mile basis?

The minimum per-mile travel allowance is $0.955. It should be used when the average trip to patients' homes is *longer than 20 miles round trip*, and is to be prorated where specimens are drawn or picked up from non-Medicare patients during the same trip.

Example 1: A laboratory technician travels 60 miles round trip from a lab in a city to a remote rural location and back to the lab after drawing a single Medicare patient's blood. The total reimbursement would be $57.30 (60 miles x $0.955 cents a mile), plus the specimen collection fee.

Example 2: A laboratory technician travels 40 miles from the lab to a Medicare patient's home to draw blood, then travels an additional 10 miles to a non-Medicare patient's home, and in returning to the lab, travels 30 miles. The total miles traveled would be 80 miles. The claim submitted would be for one half of the miles traveled (because only one of the two patients was a Medicare beneficiary) or a total of $38.20 (40 miles x $0.955), plus the specimen collection fee.

How Does Medicare Pay on a Flat-Rate Trip Basis?

The minimum travel allowance is $9.55 one way (P9604). This code should be used in areas where average trips are *less than 20 miles round trip*. When billing P9604, identify round trip travel by use of the LR modifier.

Example 3: A laboratory technician travels from the lab to a single Medicare patient's home and returns to the lab without making any other stops. The flat rate would be $19.10 (2 x $9.55), plus the specimen collection fee.

Example 4: A laboratory technician travels from the lab to the homes of five patients to draw blood. Four of the patients are Medicare beneficiaries, and one is not. The flat rate would be calculated based on the five stops plus the return to the lab, for a total amount of $57.30 (6 x $9.55). Each of the claims submitted would be for $11.46 ($57.30/5). Since one of the patients is non-Medicare, four claims would be submitted for $11.46 each, plus the specimen collection fee for each.

Example 5: A laboratory technicians travels from the lab to a nursing home and draws blood from five patients and returns to the lab. Four of the patients are Medicare beneficiaries and one is not. The $9.55 flat rate is multiplied by two to cover the return trip to the lab (2 x $9.55 = $19.10) and then divided by five ($19.10/5 = $3.82). Since one of the patients is non-Medicare, four claims would be submitted for $3.82 each, plus the specimen collection fee.

Changes in the Medicare Trip Fee, 2002—June 30, 2008

	Per mile	*Flat trip rate*
2002—2003	$0.810	$8.10
2004	$0.825	$8.25
2005	$0.855	$8.55
2006—June 29, 2008	$0.935	$9.35
2008—June 30	$0.955	$9.55

Can contractors establish a flat rate above the minimum $9.55?

Yes, they have the option to do so if local conditions warrant it.

Can an additional payment be made for travel due to emergencies?

Yes. Medicare payment may be made to cover travel expenses to collect a specimen from a nursing home or homebound beneficiary when diagnostic lab tests are needed on an emergency basis outside a lab's general operating hours.

CMS Takes Another Look at Stark 'Stand in the Shoes' Rules

Robert E. Mazer

Editor's Note: The Centers for Medicare & Medicaid Services is proposing to revisit the controversial "stand in the shoes" provisions that apply to direct and indirect compensation arrangements under the Stark physician self-referral rules. The agency called for comment, to June 13, on this and several other Stark modifications in its proposed rule for the fiscal 2009 inpatient prospective payment system, issued April 30. For an analysis of the "stand in the shoes" proposal, NIR *turned to attorney Robert E. Mazer, with Ober/Kaler in Baltimore, Md., who commented as follows:*

The proposed rule addresses both the *physician* and the *entity* applications of the so-called "stand in the shoes" principle that CMS has developed in connection with the Stark statute.

First, under the *physician* "stand in the shoes" provisions included in existing Stark regulations, when a group practice or other "physician organization" has a contract with a provider of a designated health service (DHS), physicians practicing as part of the physician organization are deemed to be parties to the contract for purposes of determining whether they have a compensation arrangement with a DHS entity and whether that relationship is considered a direct or indirect compensation arrangement.

Second, under the *entity* "stand in the shoes" provisions included in a previously proposed rule, one entity furnishing DHS would be deemed to have the same contract relationship with referring physicians as another entity that it owned or controlled.

CMS has proposed to limit the application of the *physician* "stand in the shoes" principle. Under existing regulations, when a hospital or a laboratory has a contract arrangement with a physician organization, each physician who practices as part of that organization is deemed to have a direct financial interest with the hospital or laboratory. Therefore, one of the exceptions applicable to direct compensation requirements must be satisfied.

Under one alternative approach included in the proposed rule, physicians would not be deemed to "stand in the shoes" of their physician organization if their only financial arrangement with the organization was protected by the exception for *bona fide* employment relationships, personal service arrangements, or fair market value compensation. As a result, under the Stark regulations, any financial relationship between such a physician and a DHS entity with a contract with the physician organization would be considered to be, at most, an indirect compensation arrangement.

While this proposal would provide some relief to integrated health care delivery systems, it is unlikely to have a significant impact on relationships that a laboratory or hospital might have with a traditional medical group. In those situations, physicians' ownership interests in the physician organization would continue to subject them to the "stand in the shoes" principle.

Under the *entity* "stand in the shoes" provisions included in the proposed rule, any financial relationship that an entity had with referring physicians would be imputed

to any other entity that had a 100 percent ownership interest in the entity that was party to the contract with the physicians. Although this rule may not apply to nonprofit entities that control, rather than own, another entity, CMS is considering application of the "stand in the shoes" principle to those types of relationships.

CMS also addressed the time period during which physicians could not refer DHS to an entity and during which the entity could not bill Medicare, where a financial relationship between a physician and the DHS entity failed to satisfy an applicable exception. Under the proposed rule, when the reason that a financial relationship between a physician and a DHS entity was noncompliant was *unrelated* to compensation, Medicare payments for services resulting from the physician's referrals could be made once the arrangement was brought into compliance. This would be the case, for example, when an unexecuted contract was signed. However, when the arrangement was noncompliant because the compensation being paid was excessive or inadequate, Medicare would pay for services resulting from the physician's referrals only after any excess compensation was returned or additional required compensation was paid.

CMS appears to have generally abandoned the idea that payments could continue to be disallowed even after the noncompliant arrangement was cured, a concept introduced in a previous proposed rule. However, CMS proposed no firm rule regarding the period of disallowance when the noncompliant arrangement ended without ever having been brought into compliance.

If the proposed rule becomes a final rule, there are sure to be disputes between parties to contract arrangements regarding whether their arrangements are Stark-compliant and whether one party is required to make a financial payment to the other before Medicare claims for DHS referred by a physician participating in the arrangement may be submitted and properly paid.

Physician Self-Referral Prohibitions and Designated Health Services

The physician self-referral prohibitions (popularly known as the Stark ban after their chief congressional sponsor, Rep. Pete Stark, D-Calif.) bar physicians from making referrals for 11 types of designated health services furnished in facilities with which the physician or an immediate family member has an ownership interest or compensation arrangement, unless the financial relationship qualifies under exceptions to the ban. The rules also prohibit the entity from billing Medicare or any other entity for services referred in violation of the ban.

The designated health services include:

- Clinical laboratory services
- Physical therapy, occupational therapy, and speech-language pathology services
- Radiology and other imaging services (including nuclear medicine)
- Radiation therapy services and supplies
- Durable medical equipment and supplies
- Prosthetics, orthotics, and prosthetic devices and supplies
- Home health services
- Outpatient prescription drugs
- Inpatient hospital services
- Outpatient hospital services
- Parental and enteral nutrients, associated equipment and supplies

The original Stark statute (Stark I, 1992) prohibited self-referrals for clinical lab services payable by Medicare. A subsequent statute (Stark II, 1995) prohibited such referrals for the other above designated services as well as Medicaid referrals. CMS concluded a nine-year rulemaking on the Stark statute when it published Phase III rules on Sept. 5, 2007 (*NIR, 28, 21/Sep 10 '07, p. 1*). It has since proposed changes to certain of these rules, including the "stand in the shoes" provisions discussed in this article.

Senate to Soon Take Up Medicare Physician Fee Fix

Scheduled cuts in Medicare payments to physicians would be blocked for 18 months, and physicians would get a 0.5 percent increase in 2009, under provisions likely to be part of Medicare legislation being developed by Senate Finance Committee Democrats, according to a June 2 outline of the bill. Chairman Max Baucus (D-Mont.) said he aims to bring the measure to the Senate floor in a week or so. Unless Congress acts, Medicare physician fees are slated to be cut by 10.6 percent under the program's Sustainable Growth Rate formula, starting July 1.

For laboratory and pathology organizations, the Senate Medicare bill is their best hope for now to get their other key legislative priorities enacted. They continue to lobby to get related pending measures attached to the bill, including:

- ❑ Extending the pathology "grandfather" protection for independent lab billings. It expires June 30. The House passed a two-year reprieve, through 2009. Bipartisan bills H.R. 1105 and S. 458 would make the protection permanent.
- ❑ Repeal of the lab competitive bidding demonstration (bipartisan bills H.R. 3453 and S. 2099).
- ❑ Overhaul of cytology proficiency testing by replacing the current CLIA program with a lab CME oversight program (bipartisan bills H.R. 1237 and S. 2510).

NPI Update

The Medicare fee-for-service switch to National Provider Identifier-only transactions, required as of May 23, has gone pretty well, CMS reported June 2. More than 90 percent of claims are NPI-compliant, while some Medicare contractors report 100 percent compliance.

Rejections did spike on May 23, CMS noted, largely because legacy numbers were put in the secondary provider identifier field. But the agency said it is seeing rapid improvement as more and more providers realize the need for NPI-only in this field.

To assist providers who, after reasonable effort, are still unable to obtain NPIs for secondary providers, Medicare has temporarily allowed them to bill using their own NPI in secondary identifier fields.

CMS said it would consider, in limited circumstances, accelerated or advance payments in financial hardship cases. Providers having cash flow problems related to NPI claims processing issues should contact their Medicare contractor to see if they are eligible.

For more on the NPI, go to *www.cms.hhs.gov/NationalProvIdentStand*

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