WASHINGTON G–2 REPORTS

NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 28th Year of Publication Vol. 28, No. 17, June 25, 2007

OIG Pulls The Plug On 'Substantially In Excess' Proposal

Nonetheless, the OIG asserts it still has authority to go after—and will go after—providers who charge Medicare substantially more than their private customers.

The HHS Office of Inspector General has decided to kill its long-languishing proposal to set a "bright-line" standard for when Medicare is overcharged and when healthcare providers could face sanctions for overcharges.

In the June 18 *Federal Register,* the OIG announced it was immediately withdrawing the "substantially in excess" proposal, first unveiled in 2003. Under that proposal, the OIG would have defined "substantially in excess" as any charge that is more than 120% of the usual charge for an item or service. In yanking the proposal, the OIG said it lacked sufficient information to impose the 120% standard across the board, but would rely on case-by-case scrutiny of provider charge patterns.

Most of the clinical laboratory industry welcomed the news, fearing that a fixed benchmark could threaten discount rates negotiated with physician clients and managed care plans. Lab groups opposed to the proposal also warned that it could force providers to accept less than Medicare fee schedule rates. For more on the OIG's action and its impact on the industry, see the *Focus*, pp. 4-5.

INSIDE *NIR*

List of new CPT, HCPCS codes for 2008 Medicare lab fee schedule... 2

Pathology quality measures gain key approval 3

Enforcing Medicare/Medicaid ban on overcharges, see *Focus* 4-5
— 'Substantially in excess' proposal yanked
— Impact on the lab industry
— OIG to keep scrutinizing payment disparities between Medicare, other payers

Revised blood glucose, cholesterol measures included in Medicare's final 2007 physician quality reporting program 6

Medicare Claims Advisory: Changes ahead in rules for purchased diagnostic tests ... 7

'Medically unlikely' edits continue, but without advisory panel 8

NPI update 8

CMS Posts New Lab Codes For 2008

In advance of the July 16 public meeting on pricing for new lab codes in 2008, the Centers for Medicare & Medicare Services has released the list of coding changes for clinical laboratory services payable under the Part B fee schedule as of the start of next year.

The list includes an additional code for a basic metabolic panel, two new codes in immunology, two in microbiology, and five in chemistry, including a new HCPCS code to replace two current CPT codes for hemoglobin A1c testing.

In addition to hemoglobin A1c testing for diabetes, the new codes address disease conditions that include kidney dysfunction (which can lead to higher cardiovascular risk), irritable bowel syndrome, pregnancy screening, hospital-acquired resistance to antibiotics, and acute respiratory syndrome in children.

The July 16 public forum will run from 10 a.m. to 2:00 p.m. (Eastern), at CMS headquarters with a telephone conference call *Cont. on p. 2*

New Lab Codes, *from p. 1*

dial-in (*NIR, 28, 16/Jun 11 '07, p. 1*). Its aim is to get recommendations from clinical laboratory, pathology, and other interested parties on how to price the new codes using one of two approved methods—crosswalk or gap-fill.

The crosswalk is used to match a new test code to a similar existing code and pay at that code's rate. Payment for the new test is made at the lower of the crosswalk to the local fee schedule amount or the national cap. Most lab fee schedule codes are paid at the national cap.

New Test Codes for 2008 Medicare Lab Fee Schedule

Below are coding changes (**in bold**) on which CMS invites public comment. The changes were developed by the American Medical Association's Current Procedural Terminology (CPT) Editorial Panel and will not be further discussed at the public meeting. Numbering of the codes has not yet been finalized.

Organ or Disease-Oriented Panels	
CPT 80047	Basic metabolic panel (Calcium, ionized) Calcium, ionized (82330) Carbon dioxide (82374) Chloride (82435) Creatinine (82565) Glucose (82947) Potassium (84132) Sodium (84295) Urea Nitrogen (BUN) (84520)
Chemistry	
CPT 82610	Cystatin C
CPT 83656	Unlisted antigen, each
CPT 83993	Calprotectin, fecal
CPT 84702	Gonadotropin, chorionic (hCG); quantitative
CPT 84704	Gonadotropin, chorionic (hCG); free beta chain
Immunology	
CPT 86355	B cells, total count
CPT 86356	Mononuclear cell antigen, quantitative, (eg, flow cytometry) not otherwise specified, each antigen
CPT 86485	Skin test; candida
CPT 86486	Unlisted antigen, each
Microbiology	
CPT 87470	Infectious agent detection by nucleic acid (DNA or RNA); Bartonella henselae and Bartonella Quintana, direct probe technique
CPT 87500	Vancomycin resistance (eg, enterococcus species van A, van B), amplified probe technique
87802	Infectious agent antigen detection by immunoassay with direct optical observation; Streptococcus, group B
CPT 87809	Adenovirus
New HCPCS Laboratory Code	
HCPCS Gxxxx	Hemoglobin; glycosylated (A1C). For testing at all sites of service including, but not limited to, home, office, or facility.
Deleted or Inactive Codes	
CPT 83036	Glycosylated (A1C)
CPT 83037	Glycosylated (A1C) by device cleared by FDA for home use

Source: *cms.hhs.gov/ClinicalLabFeeSched.*

The gap-fill method is used when there is no comparable existing test. In this case, local carriers set the fee for the first year, based on local pricing patterns such as charges for the test, routine discounts, resources needed for the test, and what other payers pay. CMS then taps these local amounts to set a fee cap for following years.

Public Meeting, July 16, On Fees For New Lab Codes

- **Registration:** Begins June 18 online at *www.cms.hhs.gov/ClinicalLabFeeSched*. Deadline: July 11. Individuals who wish to make a presentation on-site must register and specify the new lab codes they will be discussing.
- **Dial-in for the July 16 meeting:** 1-888-889-1954. Conference passcode: Ambulatorys. Registration not required for dial-in only.

CMS is specifically inviting comment on the gap-fill process, in response to requests, to see if changes are needed in related regulations and instructions. If a change to a regulation appears necessary, CMS will propose it in the *Federal Register* with a public comment period. The gap-fill process was codified in federal regulations last year as part of rules establishing annual lab fee-setting procedures (*NIR, 28, 4/Nov 20 '06, p. 1*).

Timetable For 2008 Lab Fee Schedule

- ❑ After the July 16 public meeting, CMS will post online (at *www.cms.hhs.gov/ClinicalLabFeeSched*) the fee recommendations for new lab codes and CMS's tentative fee determinations by September 7. CMS will accept additional comments on the posting through September 21.
- ❑ Final fee decisions will be released when CMS publishes the 2008 Part B lab fee schedule. CMS will issue instructions to local contractors on the fee schedule during or after the last week of October. Internet access to the instructions should be available at *www.cms.hhs.gov/ClinicalLabFeeSched*.
- ❑ The final lab fee schedule file should be available to the public during or after the third week of November at the same Web site, CMS said.

Pathology Quality Reporting Measures On Track For 2008

The AMA has designated the College of American Pathologists as the lead organization in developing pathology quality measures. CAP is working on additional measures to be considered for approval for 2009.

The American Medical Association's Physicians Consortium this month approved pay-for-performance measures for breast and colon cancer care developed by the College of American Pathologists, bringing pathologists a big step closer toward eligibility for Medicare's Physician Quality Reporting Initiative.

The PQRI relies mainly on Consortium-endorsed measures, with about 80% of them developed by the group, including measures for treating hypertension, asthma, and heart failure. The Consortium was founded in 2000 to help create best care practices. Members include more than 100 national medical specialty and state medical societies as well as government and medical board members.

The pathology quality reporting measures will be "included in CMS's proposed rulemaking on physician payment issues expected in August," Gretchen Schaefer, CAP's director of communications for advocacy, told the *National Intelligence Report*. "The measures, however, will need final approval from a multi-stakeholder, payer-supported organization—the AQA (formerly the Ambulatory Care Quality Alliance)—to be included in the final 2008 physician payment rule later this year."

Meantime, the PQRI is set to debut July 1 and offers a bonus to eligible doctors who voluntarily report specified quality measures on Medicare fee-for-service claims. They may earn a bonus, subject to a cap, of 1.5% of total allowed charges for services covered under the Part B physician fee schedule (*see related story*, "Final Lab Test Measures," *p. 6*). CAP's goal is to get pathologists into the bonus payment program, which is expected to continue in 2008.

focus on: Discriminatory Billing Ban

What's Next After Demise Of 'Substantially In Excess' Proposal?

Now that the HHS Office of Inspector General has thrown in the towel on its nearly four-year-old proposal to define overcharges to Medicare and Medicaid, the clinical laboratory industry and other healthcare providers are left to wonder whether it's back to business as usual. Not necessarily, say sources contacted by the *National Intelligence Report*.

The OIG announced in the June 18 *Federal Register* that it is abandoning, effective immediately, its effort to establish a "bright-line" standard to determine when Medicare or Medicaid is being overcharged in violation of the statutory ban on "discriminatory billing" and when sanctions, including exclusion from these programs, would be imposed. The OIG said it lacked sufficient information to set a single, fixed benchmark that could apply across healthcare sectors.

Still, the OIG is concerned that Medicare is paying substantially more than other payers for the same Part B items and services, including lab services, and said it will address overcharges by providers on a case-by-base basis.

The Proposed Rule

Under the rule proposed in the September 15, 2003 *Federal Register*, the OIG would have had discretion to exclude from Medicare or Medicaid any provider that charges these programs "substantially in excess" (or more than 120%) of its usual charge for the same item or service. The proposal specifically exempted physicians' services, including anatomic pathology.

To many in the clinical lab industry, this could have limited a lab's ability to negotiate discounts with managed care plans or physicians for Medicare/Medicaid services. Alternatively, it could require labs to charge these programs less than the rates established under government fee schedules. But the industry was split over the proposal. Most weighed in against it, but the American Association of Bioanalysts, which represents smaller labs, said the 120% threshold would further "level the playing field." Many of its member labs are in market niches that don't allow for deep discounting, AAB said.

The proposal was the OIG's attempt to put teeth into the "discriminatory billing" prohibition. In the OIG's view, an unlawful tiered-pricing structure results when a provider's usual charge to most of its customers drops substantially below charges to Medicare/Medicaid while these programs are billed at rates equal to or higher than fee schedule amounts.

Significantly, the OIG's definition of "usual charge" would have included fee-for-service rates that a lab agrees to accept from any payer, including discounted rates negotiated with managed care plans. The OIG said that when negotiated rates make up a large part of the lab's revenues, those discounts effectively are its charges.

A "good cause" exception would have been allowed when there is justification for billing Medicare/Medicaid "substantially in excess": for example, unusual circumstances or medical complications requiring added time, effort, and expense; or the

higher costs associated with serving beneficiaries. But the burden of proof would have been on the provider; the OIG would have been the final judge of "good cause"; and there could be no review of the OIG's decision.

Impact Of Withdrawing The Proposal

Asked for comment on the scuttling of the proposal, attorney Robert Mazer, a shareholder with Ober/Kaler (Baltimore, MD), told *NIR* that the OIG generally identified two types of problems:

- First, whether the 120% benchmark could be used appropriately across the board.
- Second, whether it would increase healthcare costs—that is, would providers "comply" by raising charges or limiting discounts?

Even though the 2003 proposed rule has been withdrawn, labs should refer to it when evaluating arrangements under the Medicare/ Medicaid discriminatory billing prohibition, health law attorney Robert Mazer advises. Though the OIG expressed concern about the 120% benchmark, "there's nothing to suggest that it believes other aspects of the proposed rule—for example, its computation of 'usual charge'—is unsound," he says.

In theory, the first problem could be solved, he said. With more information, the OIG might be able to come up with benchmarks that it believes are appropriate for different types of services.

The second issue is more difficult, Mazer said. "Two goals collide. The first is to reduce health costs generally and particularly through competition. The second is to make sure that Medicare isn't paying substantially more than the rest of the market. The OIG indicates that the real problem is Medicare fee schedules that are outdated or do not reflect prevailing market rates." And the OIG refers to the discriminatory billing prohibition as "backstop protection," he noted.

Mazer suggested that the OIG may be signaling its position that Congress should fix the perceived problem through changes in the law governing fee schedules because it can't be easily resolved based on OIG interpretations and enforcement of existing law. "This could lead to intensified efforts to reduce lab payments through legislation," he observed.

As to OIG plans to review arrangements for compliance with Medicare discriminatory billing prohibitions on a case-by-case basis, Mazer said it is difficult to evaluate how much to expect. "Government priorities and enforcement policies constantly evolve," he said. "The Hanlester [shell lab] arrangement that the OIG pursued so vigorously was likely similar to many other arrangements that preceded it but were never the subject of enforcement action. And, to my knowledge, the OIG has never pursued an enforcement action based solely on the discriminatory billing prohibition. It's likely that at least one factor has been the difficulty in prevailing on such an action, given the lack of specific standards."

OIG Scrutiny To Continue

Meantime, in its work plan for 2007, the OIG says it will continue to study Medicare test payment rates vs. the rates of other federal and state health programs and private payers. The study will build, the OIG says, on prior work in which the agency found that Medicare paid significantly higher prices than other payers for certain lab tests.

And it can't have escaped the OIG's notice that the payment disparity is growing. Many labs must negotiate large testing discounts with the nation's dominant health plans, including cuts of 40% to 50% of Medicare, to keep their business, while work for Medicare is billed at 100% of the fee schedule amount. Most recently, United HealthCare said it will lower payments to 25% of the Part B lab fee schedule as of July 1. Business on this scale could leave lawmakers wondering why Medicare should pay full freight and not use its volume purchasing power to secure similar bargains in the marketplace.

Final Lab Test Measures For 2007 Physician Quality Reporting

There is no need, CMS says, to enroll or register for the quality reporting initiative—physicians can just begin reporting the measures on claims. The agency has posted a Tool Kit to help physicians report successfully, including measure-specific worksheets to walk the user step-by-step through reporting for each measure. The kit is online at www.cms.hhs.gov/PQRI.

In advance of the July 1 launch of Medicare's new Physician Quality Reporting Initiative (PQRI), the Centers for Medicare & Medicaid Services has released the final quality measures and their specifications approved for 2007. Among the 74 measures are clinical laboratory tests for blood glucose and cholesterol in beneficiaries with diabetes, whose specifications have been revised from those issued earlier this year (*NIR, 28, 13/Apr 23 '07, p. 3*).

Under the PQRI, eligible physicians and other healthcare practitioners are entitled to a bonus payment (1.5%, subject to a cap) if they voluntarily report a designated set of quality care measures on their Medicare fee-for-service claims. The bonus period, approved in the Tax Relief & Health Care Act of 2006, runs from July 1 through December 31, 2007.

Below are the final specifications for reporting lab testing for diabetes control (additions to the previous specifications are noted in bold and deletions of previous specifications are noted in bold and strikethrough). The codes must be submitted on the same claim as the patient diagnosis and service to which they apply.

Measure: Hemoglobin A1c Poor Control in Type 1 or 2 Diabetes Mellitus
Description: Percentage of patients aged 18-75 years with diabetes, type 1 or type 2, who had most recent hemoglobin A1c greater than 9.0%. This measure is to be reported a minimum of once per reporting period (12 months) for patients seen during this period. **Add: The most recent quality code submitted will be used for performance calculation.**

Numerator Instructions & Coding
Patients with most recent hemoglobin A1c > 9.0%. A lower rate indicates better care.
Most recent hemoglobin A1c performed:
CPT II 3046F: Most recent hemoglobin A1c level > 9.0%
OR
CPT II 3044F: Most recent hemoglobin A1c level < 7.0%
OR
CPT II 3045F: Most recent hemoglobin A1c level 7.0% to 9.0%
OR
Hemoglobin A1c not performed, reason not specified. Append a reporting modifier (8P) to CPT category II code 3046F to report.

Denominator: Population & Coding
Patients aged 18-75 years with the diagnosis of diabetes.
ICD-9 diagnosis codes: 250.00-250.93 (DM), 648.00-648.04 (DM in pregnancy, not gestational)
AND
CPT E/M codes: 99201-99205, 99211-99215 (E/M); 99341-99345, 99347-99350 (home visit); 99304-99310 (nursing facility); 99324-99328, 99334-99337 (domiciliary), ~~**G0344.**~~ **Add encounter codes 97802, 97803, G0270, G0271.**

Measure: Low Density Lipoprotein Control in Type I or 2 Diabetes Mellitus
Description: Percentage of patients aged 18-75 years with diabetes (type 1 or 2) who had most recent LDL-C level in control (less than 100 mg/dl). This measure is to be reported a minimum of once per reporting period (12 months) for patients seen

during this period. **Add: The most recent quality code submitted will be used for performance calculation.**

Numerator: Population & Coding
Patients with most recent LDL-C < 100 mg/dL
~~**Most recent LDL-C performed:**~~
~~**CPT II 3048F: most recent LDL-C < 100 mg/dL**~~
~~**OR**~~
~~**CPT II 3049F: most recent LDL-C 100-129 mg/dL**~~
~~**OR**~~
~~**CPT II 3050F: most recent LDL-C > 130 mg/dL**~~
OR
LDL-C level not performed for medical reasons. Append modifier 1P to CPT Category II codes above.
OR
LDL-C level not performed, reason not specified. Append modifier 8P to CPT Category II code 3048F

Denominator: Population & Coding
Patients aged 18-75 years with the diagnosis of diabetes
ICD-9 diagnosis codes: 250.00-250.93 (DM), 648.00-648.04 (DM in pregnancy, not gestational)
AND
CPT E/M codes: 99201-99205, 99211-99215 (E/M); 99341-99345, 99347-99350 (home visit); 99304-99310 (nursing facility); 99324-99328, 99334-99337 (domiciliary), ~~**G0344.**~~ **Add encounter codes 97802, 97803, G0270, G0271.**

♦ MEDICARE CLAIMS *Advisory*

Changes Coming In Payment Rules For Purchased Diagnostic Tests

Currently, a physician, laboratory, or other supplier billing Medicare for a purchased diagnostic test/service, including pathology services, can be paid at the local rate established for a carrier/MAC contractor under the Part B physician fee schedule. The physician, lab, or other supplier still gets the local rate even when the purchased test/service is rendered outside the carrier/MAC's jurisdiction.

That will change this fall, the Centers for Medicare & Medicaid Services has told contractors (Change Request 5543). For dates of service on or after October 1, 2007, carriers/MACs are to pay at the rate applicable to the ZIP code where the test/service was rendered. The current policy has been a temporary fix, CMS said, until a potential problem in the data files for physician payment localities was resolved.

Also on or after October 1, physicians, labs, and other suppliers are to begin reporting the rendering physician/supplier's information and the location where the service was rendered on all claims for purchased tests/interpretations, including those for tests/interpretations outside the local carrier/MAC's jurisdiction. They are not to report the National Provider Identifier of the out-of-jurisdiction performing physician/supplier when submitting a claim for a diagnostic service purchased outside their local carrier/MAC's jurisdiction. (Physicians/suppliers must maintain this information on file and provide it upon request to their local carrier/MAC).

MUEs Moving Ahead, But Without Advisory Panel

The MUEs are limits on the units of service that a healthcare provider can bill a particular CPT/HCPCS code per Medicare beneficiary per day. Claims for services exceeding these limits are automatically rejected. Providers may not bill the beneficiary for MUE-denied claims.

Medicare is set to implement Phase III of its controversial "medically unlikely" edits (MUEs) of Part B claims, including claims for pathology and laboratory services, on July 1 and has already gotten comments on Phase IV to begin October 1. But the Centers for Medicare & Medicaid Services has turned down a request to establish an advisory committee on the MUE process.

The College of American Pathologists and other national pathology groups had called for such a panel to add broader clinical expertise to the MUE process and make its rationale, criteria, and methodology more transparent (*NIR, 28, 11/Mar 26 '07, p. 3*). CMS said an advisory panel would not be "an effective use of resources," but added it would "make every effort" to keep providers involved.

In comments on Phase IV proposed edits, the American Clinical Laboratory Association and CAP noted that certain methodology CPT codes, not analyte-specific, and pathology consultation codes should not be subject to any MUE. Many of these codes are used to detect antibodies of infectious agents, and as ACLA noted, CPT guidelines specify: "When multiple tests are done to detect antibodies to organisms classified more precisely than the specificity allowed by available codes, it is appropriate to code each as a separate service."

✦ NPI Update ✦

NPPES Data Retrieval, Sorting: Technical Support Advised

When you're ready to search for the National Provider Identifiers (NPIs) of your trading partners via a database to be made available by the Centers for Medicare & Medicaid Services, you should get expert IT technical assistance to download the initial data file and sort it to find one or more providers by NPI or name.

That's the advice CMS officials delivered during the June 14 roundtable conference call on the data to be made available from the National Plan & Provider Enumeration System (NPPES). Neither CMS staff nor the NPI project contractor can help with searches or sorts.

CMS urges providers to check their data on file so that the information is accurate when the initial downloadable file is rolled out. If you have a problem checking your data, contact the NPI project enumerator at 1-800-465-3203.

 NATIONAL INTELLIGENCE REPORT (ISSN 0270-6768) is published twice monthly (except August and December, which are one-issue months) by Washington G-2 Reports, 3 Park Avenue, 30th Floor, New York, NY 10016-5902. Telephone: (212) 244-0360. Fax: (212) 564-0465. Web site: www.g2reports.com. Order Line: (212) 629-3679.

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