



Report



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For Hospitals, Laboratories and Physician Practices

Labs Applaud Bill To Repeal Competitive Bidding Demo

Groups representing clinical laboratories are applauding Rep. Nydia Velazquez (D-NY) for introducing legislation that would repeal the Medicare competitive bidding demonstration project for clinical laboratory services.

Rep. Velazquez introduced the bill, H.R. 3453, on August 4, just days after the Committee on Small Business, which she chairs, held a hearing on the effect of the demo on the lab industry. During the hearing, representatives from small, medium, and large labs testified that the competitive bidding would have a devastating impact on the industry.

The "Community Clinical Laboratory Fairness in Competition Act of 2007" would repeal the demonstration immediately and require the Centers for Medicare and Medicaid Services to submit a report to the committee on the impact of competitive bidding on small clinical laboratories.

Alan Mertz, president of the American Clinical Laboratory Association (ACLA), praised Rep. Velazquez for introducing the bill, saying "it's time that Congress pull the plug on this unworkable and unfixable project." ACLA was one of 32 organizations

Cont. on p. 2

Inside this issue

Bill introduced to repeal competitive bidding demo.....	1
FDA revises guidance on IVDMIs	1
House Medicare bill would avert payment cut, extend pathology TC grandfather provision.....	4
2008 Medicare physician fee schedule: Stark physician self-referral provisions & related policy changes: see <i>Perspectives</i>	5
Rule finalizes CMS's ability to exclude providers.....	10
OIG questions performance of anti-fraud contractors.....	11
News in brief	12

FDA Revises Guidance On Lab-Developed Tests

The Food and Drug Administration (FDA) on July 26 released for public comment a revised version of its draft guidance on expanded regulation of lab-developed tests (LDTs).

The FDA is requiring premarket review for new types of DNA tests that combine assays and algorithms to produce patient-specific results. These devices are known as in vitro diagnostic multivariate index assays (IVDMIs).

The revised draft clarifies several points in response to comments on the initial document issued last September. One of the major

criticisms of the first draft was that the definition of an IVDMIA was not clear, so the proposed definition has been modified. An IVDMIA is now defined as a device that:

1 Combines the values of multiple variables using an interpretation function to yield a single, patient-specific result (e.g., a "classification," "score," "index," etc.) that is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, and

Cont. on p. 9

Labs Applaud Bill, from page 1
that wrote Rep. Velazquez in support of the bill.

"The clinical laboratory fee schedule is the wrong place to be looking for cost savings given that laboratory services under Medicare have already been reduced 40% in real terms since 1984," added Mertz. "Moreover, laboratory services represent only 1.7% of Medicare spending, yet impact a staggering 70% to 80% of all medical decisions."

Mark Birenbaum, administrator for the American Association of Bioanalysts (AAB) and the National Independent Laboratory Association (NILA), also applauded the bill.

"The so-called demonstration would be nothing but a program to put small labs out of business and lessen the competition for the largest publicly traded labs," he said. "The two largest publicly traded labs that control over 65% of all independent laboratory testing would be the most likely winners under current law due to their ability to discount bids in the demonstration zone and make up that cost in other markets across the country."

CMS Moving Ahead

The legislative hearing and subsequent introduction of the repeal measure come on the heels of a recent announcement that CMS is moving forward with the competitive bidding demo. CMS in early July issued a draft bidder's package, which was followed by an open-door

Lab Bidding Demo: Tentative Timeline

Summer 2007.....	Finalize bidder's package
Summer 2007.....	Announce first Competitive Bid Area (CBA) where the demo will run
Later Summer 2007	Hold bidder's conference
Fall 2007	Bids due
Winter 2008	Labs notified of winning or non-winning status
Spring 2008	Demonstration begins

Source: CMS

forum on July 16. More than 40 people attended the forum, with more than 400 participating by phone.

During the forum, participants expressed multiple concerns with the demonstration and complained that CMS has paid little attention to issues they have raised repeatedly. A chief concern is a provision in the draft bidder's package that defines a "small business," which is exempt from the demo, as is any lab with less than \$100,000 in annual Medicare revenue from demo tests. Though not required to bid, they would be paid at the competitive bid price. All labs above the \$100,000 threshold would have to bid or risk getting paid nothing at all for the duration of the demo.

Labs Sound Off

At the July 25 hearing, lab representatives asked lawmakers to scrap the competitive bidding demonstration, saying it would put far too many labs out of business, ultimately diminishing patient access and stifling life-saving innovation.

Tod Schild, senior vice president of Shiel Medical Laboratory (Brooklyn, NY), told members of the House Small Business Committee that his lab, which operates at only a 5% to 7% margin, would not survive beyond a year if was required to submit a bid under the demonstration and did not win.

While the large national labs can discount their bids in the demonstration zone and compensate for these temporary discounts through their work in other parts of the country, small labs like Shiel will not have that advantage, Schild testified.

"Shiel, or a lab like us, will be the losers in the bidding process," he said. "Let me add that in no way do any labs, large or small, see any benefit to the American public coming out of this ill-conceived plan. We are all united in our objective to stop this demonstration from proceeding. The difference is that the large labs in

this demonstration are fighting for their bottom line and the small labs for their existence."

Witnesses at the hearing were almost universal in their criticism of CMS's requirement that all labs receiving at least \$100,000 in revenue from Part B Medicare reimbursement in the competitive bid area will be required to bid. Mary Jo Bonifas,

manager of laboratory services for United Clinical Laboratories (UCL; Dubuque, Iowa), testified that if Dubuque were in the competitive bid area (CBA), her lab



Witness testifying before the House Committee on Small Business, from left to right: Thomas Bejgrowicz, Mary Jo Bonifas, Tod Schild, Ronald Weiss

would be the only laboratory in the city that would have to bid.

"What concerns me is that there will be drastic consequences if I am a 'bid loser' and also significant consequences even if I am a 'bid winner,'" she said. "If I am not a bid winner and local physicians and clinics can't use my laboratory for Medicare testing, I will also lose their non-Medicare testing." The demo could also potentially hurt UCL's 30-year relationship with Mayo Medical Labs, which performs reference testing for the lab, she added.

Several witnesses expressed concern about the impact of the demo on nursing home residents, noting that small local labs often are the only ones to send phlebotomists to nursing homes to draw blood. Tom Bejgrowicz, a client account manager for Aculabs, a laboratory that primarily serves nursing homes in New Jersey, testified that there is no guarantee in the draft bidder's package that the competitive bidding "winner" will be forced to provide any level of testing to the long-term care setting.

"CMS assumes that winning laboratories are interested in servicing all Medicare beneficiaries, but this is simply not the case," he said, noting that larger labs typically have limited service to long-term care facilities and instead focus on the more lucrative physician office. Several groups had urged CMS to require bidders show evidence that they would serve nursing home patients, but the draft bidder's package released in early July did not include those recommendations.

"While we appreciate that CMS recognizes nursing home residents have special needs, the CMS bidding documents do not require labs to provide information about how or even whether the laboratory will provide services to these and other vulnerable populations," said Bejgrowicz. "So we are very skeptical that there is a way in the proposed demonstration for CMS to protect the care and services required by nursing facilities residents. It will be too late if nothing is done until after the demonstration is implemented because the smaller labs that service these facilities will not be able to survive losing their Medicare business."

Even Quest Diagnostics, the largest national lab, opposes the competitive bidding demonstration. In a statement submitted to the committee, Quest said it has "serious concerns regarding the negative impact competitive bidding will have on small businesses, including those that compete with Quest Diagnostics, such as small laboratories and hospital laboratories."

Resources

- ❖ Thomas Bejgrowicz, AHCA, 202-842-4444
- ❖ Mark Birenbaum, AAB & NILA: 314-241-1445
- ❖ Mary Jo Bonifas, United Clinical Laboratories, 563-556-2010
- ❖ Alan Mertz, ACLA: 202-637-9466
- ❖ Quest Diagnostics: 202-263-6260
- ❖ Tod Schild, Shiel Medical Laboratory: 718-552-1000

More information on the competitive bidding demonstration is available at [www.cms.hhs.gov/DemoProjects/EvalRpts/MD/.Search for "laboratory."](http://www.cms.hhs.gov/DemoProjects/EvalRpts/MD/.Search for 'laboratory.')

House Medicare Bill Would Avert Payment Cut, Extend Pathology TC Grandfather Provision

Legislation passed by the House of Representatives August 1 would avert a proposed 10% payment cut for physicians, including pathologists, and allow independent laboratories to continue billing Medicare directly for the technical component (TC) of physician pathology services provided to hospital patients for an additional two years.

Major provisions in the Children's Health and Medicare Protection Act of 2007 (H.R. 3162), which reauthorizes the State Children's Health Insurance Program (SCHIP), would change the physician reimbursement system and equalize payments between Medicare Advantage (MA) and traditional Medicare.

The Senate August 4 approved a separate SCHIP measure that does not include Medicare changes. Conferees will have to hammer out differences in the bills when Congress returns to work after Labor Day.

H.R. 3162 would also allow the Centers for Medicare and Medicaid Services (CMS) to add preventive benefits without congressional action and would eliminate cost-sharing for these benefits, as well as exclude them from the Part B deductible, a provision estimated to cost \$1.1 billion between 2008 and 2012.

SGR Formula

For physicians, the bill would switch their Medicare payment formula from one based on a single sustainable growth rate (SGR) target to one based on six SGRs: evaluation and management services for primary care and preventive services, other E&M services, imaging, major procedures, anesthesia services, and minor procedures and other physician services not described in the other categories.

Spending on so-called "incident-to" services, including office-administered drugs and clinical diagnostic laboratory tests, would not be included in the cal-

culation of allowed expenditures for any service category.

Where pathology falls in the above expenditure categories is uncertain, according to the College of American Pathologists. Potentially, certain pathology services, such as Pap smears, could logically fall within the first category of preventive care.

The bill also would eliminate a projected 10% cut for 2008 under the current single SGR by establishing a floor for updates so that the conversion factors for each service category would be no less than 0.5% in 2008 and 2009. The 10% reduction is included in Medicare's proposed 2008 physician fee schedule, announced in early July. For pathologists, the cut would be even more—12% when the negative update is combined with changes in work and practice expense relative value units (RVUs) for services.

Other Provisions

H.R. 3162 also provides a number of provisions for physicians practicing in rural areas, including two-year extensions for:

- ❖ The TC grandfather for physician pathology services;
- ❖ Medicare reasonable costs payments for certain clinical diagnostic laboratory tests for hospital patients in certain rural areas as outpatient services; and
- ❖ Continued incentive payments and extended geographic payment floor for certain rural physicians.

The bill also contains a host of provisions on MA plans, including one that would phase out payments to plans that are higher than 100% of the average fee-for-service costs over a four-year period ending in 2011.

Resource

- ❖ House Ways and Means Committee: www.waysandmeans.house.gov 

COMPLIANCE PERSPECTIVES

2008 Medicare Physician Fee Schedule: Stark Physician Self-Referral Provisions & Related Policy Changes



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Pathologists and other physician specialists—as well as hospitals, laboratories, and imaging providers—could face significant new regulatory compliance hurdles beginning Jan. 1, 2008, if certain rules under the proposed 2008 Medicare Physician Fee Schedule (MPFS) relating to the Stark physician self-referral law and reassignment and anti-markup provision are finalized (See 72 Fed. Reg. 38,122, July 12, 2007). According to the Centers for Medicare & Medicaid Services (CMS), these policy changes are necessary to close loopholes that make Medicare vulnerable to abuse. If implemented, these policy changes would require the renegotiation of thousands of existing arrangements—many of which were carefully structured to comply with CMS's previous guidance.

Comments on the proposed 2008 MPFS are due by August 31. The final 2008 MPFS is due to be published sometime this fall. Any policy changes included in the final 2008 MPFS are expected to be effective Jan. 1, 2008.

Purchased Diagnostic Test Rule

CMS has proposed changes to the text of previously proposed rules relating to the purchased diagnostics testing rule. In the proposed 2007 MPFS (71 Fed. Reg. 48982, Aug. 22, 2006), CMS solicited comments on (1) amending the reassignment rules to eliminate the distinction between the purchased diagnostic test rules and the reassignment rules, (2) redefining the term "centralized building," and (3) imposing an anti-markup provision on the professional component of purchased

diagnostic tests. CMS did not finalize those provisions in the final 2007 MPFS, but has now revisited the issue in the proposed 2008 MPFS.

The proposed 2008 MPFS would impose an anti-markup provision on the interpretation portion of purchased diagnostic tests to match the anti-markup provision already imposed on the technical component of such tests. The anti-markup provision would apply whether the billing entity purchases the technical or professional component outright or receives a reassignment of the right to bill. The only exception to the anti-markup provision is where the individual performing the test is a full-time employee of the billing entity. To try to avoid efforts to "game" these rules by inflating the physician's net charge, CMS would define the performing physician's "net charge" to exclude costs of equipment and space leased to the performing physician.

CMS has also raised concerns that the current anti-markup provision applicable to the technical component does not address overutilization of diagnostic tests performed in centralized locations where the technician performing the test is a part-time or leased employee of the group. CMS is seeking comments on whether it should include a specific anti-markup provision to address this situation. Additionally, CMS has indicated that it would add an exception to the anti-markup provision for professional components ordered by independent laboratories because it does not view such arrangements as posing a significant

risk. Finally, CMS has indicated that the proposed anti-markup provisions make several aspects of the proposed 2007 MPFS unnecessary, such as a change in the definition of "centralized building."

Per-Click Payments

The Stark statutory and regulatory space and equipment exceptions permit physicians to refer to entities with which they have a lease arrangement provided the arrangements meet certain criteria. Among the criteria, rental payments must be set in advance, consistent with fair market value, and not determined in a manner that is related to the volume or value of the physician's referrals.

CMS initially prohibited "per-click" arrangements in the 1998 proposed Stark II, Phase I regulation as reflecting the volume or value of a physician lessor's own referrals. In the final Stark II, Phase I regulation, CMS reversed itself and permitted time-based or unit-of-service based payments, even when the physician receiving the payment generated the payment through a designated health service (DHS) referral.

In the proposed 2008 MPFS, CMS has again reconsidered its position and seems to be resurrecting the position taken in the 1998 proposed rule. CMS has proposed that the exception for space and equipment leases not include "per-click" lease payments for services rendered by the DHS entity lessee to a patient referred by the physician lessor. CMS is concerned that such lease arrangements provide incentives for physician lessors to refer a higher volume of patients to the DHS entity lessee. If this proposed rule is finalized, physician space and equipment leases involving per-click fees that relied on the equipment or space lease exception, as opposed to the indirect compensation exception, will be prohibited.

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Definition Of "Set In Advance"

Currently, the Stark regulation states that "compensation will be considered 'set in advance' if the aggregate compensation, a time-based or per-unit-of-service based amount, or a specific formula for calculating the compensation, is set forth in an agreement between the parties before the furnishing of the items or services for which the compensation is paid." In the Stark II, Phase I regulation, CMS took the position that percentage compensation arrangements were not set in advance. CMS subsequently became aware of numerous arrangements under which payment to a physician was based on a percentage of the revenue generated by a physician's own services. CMS delayed the effective date of this

sentence in an effort to avoid unnecessary disruption of such arrangements.

In the Stark II, Phase II interim final rule, CMS found its position on percentage compensation overly restrictive and revised it. In the proposed 2008 MPFS, CMS indicates that its intent in allowing percentage compensation was only to allow it where the compensation is to physicians for their own professional services, not in the context of equipment and space leases. Without explaining why, CMS stated that use of percentage-based compensation within equipment and space leases is potentially abusive.

Finally, CMS expressed concerns about percentage compensation based on factors that are not directly or indirectly related to physician services. As an example, CMS cited savings by a hospital department, which could limit many common gainsharing arrangements. To address these potential abuses, CMS has proposed limiting the use of percentage compensation to arrangements for personally performed physician services based on the revenues directly resulting from the physician services.

Definition Of "Entity" For Services Furnished Under Arrangement

In the proposed 2008 MPFS, CMS notes its continuing concern with overutilization of services provided "under arrangement." CMS specifically cites its unease with arrangements for hospital outpatient services paid on a per-service basis and physician and hospital joint ventures that provide hospital imaging services. CMS claims that there is no legitimate reason for these arranged for services, especially when the hospital could furnish such services itself. CMS also expressed concern with services provided under arrangement that are furnished in less medically intensive settings, but billed at the higher outpatient rate. CMS cautioned that such arrangements may be little more than a method to share hospital revenues with referring physicians.

In a 2005 report to Congress, MedPAC warned that physician ownership of entities that provide services and equipment to imaging centers and other providers creates financial incentives for physicians to refer patients to these providers, which could lead to overutilization. To address this issue, MedPAC recommended expanding the definition of entity to include entities that "derive a substantial proportion of its revenue" from a provider of DHS.

In the proposed 2008 MPFS, CMS suggests revising its definition of "entity" to include persons or entities that perform the DHS, as well as the person or entity that submits claims, or causes claims to be submitted, to Medicare for DHS. CMS suggests that this approach is more "straightforward" than MedPAC's approach.

In-Office Ancillary Services

While not yet proposing specific regulatory changes, CMS is soliciting comments on whether any restrictions to the in-office ancillary services exception are appropriate. Specifically, CMS expresses concern that the types of services now being protected under this exception have expanded beyond what Congress originally intended. CMS states that the

exception was intended to allow for the provision of certain services "necessary to the diagnosis or treatment of the medical condition" for which the patient is seeing the physician. CMS suggests that a good example is a clinical laboratory owned by physicians and located in the physicians' office that permits the physicians to obtain diagnostic results while a patient waits.

CMS seeks comments on the following:

- ❖ Whether certain services should even qualify for the exception (e.g., therapy services not provided on an incident-to basis, services not needed at the time of the office visit, complex laboratory services)?
- ❖ Whether the definition of the terms "centralized building" and "same building" should be changed, and if so, how?
- ❖ Whether nonspecialists should be allowed to use the exception to refer patients for specialized services?

Although CMS's discussion of the in-office ancillary services exception lacks details, the nature of the questions suggests that CMS is inclined to narrow the exception. Any such narrowing could have far-reaching repercussions.

Burden Of Proof As To Whether Prohibited Referral Occurred

The Stark law is currently silent as to who bears the burden of proof that a prohibited referral has occurred in the context of appealing a Medicare payment denial. CMS proposes adding a new section to clarify that the entity submitting the claim has the burden of proof to establish that the service was not furnished pursuant to a prohibited referral.

OB Malpractice Insurance Subsidies

Due to concern that the current exception for obstetrical malpractice insurance subsidies may be "unnecessarily restrictive," CMS is seeking comments on various potential changes to the exception to address problems of patient access to

care without creating increased risk of program abuse.

Period Of Disallowance

For Noncompliant Relationships

CMS is soliciting comments on how to establish a “period of disallowance” during which an entity could not bill Medicare for referrals from a physician with whom the entity has a financial relationship that failed to meet an exception. This question has been difficult for arrangements where it is unclear when the arrangement ended or came into compliance with an exception (e.g., an isolated transaction that did not satisfy an exception).

Innocent And Technical Violations:

Alternative Method For Satisfying Exception

In response to comments that even “innocent and trivial” violations of the Stark law could result in huge penalties, CMS is soliciting comments on establishing a new “alternative method for compliance” provision. The alternative method for compliance provision would be designed to address arrangements that fail to meet certain exceptions because of technical violations resulting from innocent mistakes (e.g., failure to obtain a necessary signature on a written agreement). This new provision is intended to “complement, and not replace,” the temporary noncompliance exception at 42 C.F.R. § 411.353(f). The ultimate usefulness of this proposed exception is unclear given some of the proposed terms of the exception.

Ownership In Retirement Plans

Currently, the Stark regulations carve out “an interest in a retirement plan” from the definition of ownership or investment interests. CMS expressed concern that some physicians may be exploiting this language to use their retirement plans to purchase interests in DHS entities to which they refer patients for DHS. CMS is proposing to revise the language to provide that an ownership or investment interest does not include: “an interest in a retirement plan offered by the entity to the physician or immediate family member as a result of the physician’s or

immediate family member’s employment with the entity.” (emphasis added).

‘Stand In The Shoes’

CMS has again expressed concerns about the scope of protection afforded indirect financial relationships. While not proposing specific regulatory language, CMS is suggesting treating a DHS entity, like a hospital that owns or controls another DHS entity, as “standing in the shoes” of that owned or controlled entity. Essentially, CMS is proposing to collapse relationships between DHS entities and their owned or controlled entities, thereby turning what are currently indirect financial relationships between DHS entities and physicians into direct financial relationships between the DHS entities and the physicians.

CMS suggests that this “stand in the shoes” approach may be necessary to protect against abuse by parties who may insert an entity or contract amid other financial relationships linking a DHS entity and a referring physician to avoid scrutiny under the Stark statute. In soliciting comments, CMS hints that it may apply the “stand in the shoes” approach to physicians and their group practices in the Stark II, Phase III regulation.

Conclusion

The policy changes in the proposed 2008 MPFS could have significant impacts on pathologists and other physician specialists as well as hospitals, laboratories, and imaging providers beginning as early as January 1. Unfortunately, we will not know the full extent of these changes until the final 2008 MPFS is published sometime this fall. In addition, CMS is required to publish Phase III of the Stark II implementing regulations by March 28, 2008. Some reports suggest Phase III may be published as early as this fall.

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FDA Issues Revised Guidance, from page 1

2 Provides a result whose derivation is nontransparent and cannot be independently derived or verified by the end user.

According to the law firm of Hyman, Phelps & McNamara, P.C., which writes an FDA law blog (www.fdalawblog.net), the second prong of the definition is likely to attract the most attention since it will not always be clear whether a result is "non-transparent" or how the phrase "cannot be independently derived or verified" will be applied. The FDA has given some examples of tests that are IVDMIA and some that are not. These illustrations provide some greater clarity, writes attorney Jeffrey Gibbs in the blog, but even so there will almost certainly be controversy over whether a particular test falls inside or outside the IVDMIA definition.

Scope of Device

Another area of concern for commenters related to the scope of the IVDMIA "device," notes Gibbs. "Was the device the algorithm; the algorithm and the software; the algorithm, software, and laboratory tests; or something else? FDA has definitely answered that question, although not in a way that will satisfy those who proposed a narrow definition." The new draft guidance states:

"FDA believes that any safety and effectiveness determinations that are part of the premarket review process should include review of the performance of the entire system, including the accurate measurement of the input variables, directions for use, and expected analytical or clinical performance, rather than a review of only certain subcomponents of the test."

"The impact of that broad definition may be partially softened (at least in the short term) by FDA's acknowledgement that the Clinical Laboratory Improvement

Amendments (CLIA) 'requirements may partially fulfill corresponding' Quality System (QS) requirements," writes Gibbs. "FDA states that it will issue guidance to help laboratories comply with QS requirements. Furthermore, FDA will 'exercise enforcement discretion' (i.e., presumably not apply QS requirements until the final guidance has been issued). How FDA will ultimately minimize the overlapping requirements of CLIA and the QS regulations is not discussed in the document."

FDA also adopted the suggestion offered by many commenters that there be a transition period.

The grace period will be 12 months from the date of the final guidance document "for currently marketed" IVDMIA, and then six more months if a 510(k)

or premarket approval application is submitted.

**Comments on the revised
draft guidance are due
August 27.**

"These transition periods are certainly better than requiring immediate compliance, but they are significantly shorter than some commenters had proposed," writes Gibbs.

While FDA did adopt the concept of a transition period, it rejected the many comments that requested the agency to proceed through notice and comment rule making. FDA's decision to use the guidance document process instead of rule making may result in a legal challenge over whether FDA violated the Administrative Procedure Act, says Gibbs.

"Even more fundamentally, FDA continued to assert that IVDMIA are devices that are subject to FDA regulation. This position, too, has been sharply questioned," he adds. Comments on the revised draft guidance are due August 27.

Resource

- ❖ Revised IVDMIA guidance: www.fda.gov/cdrh/oivd/guidance/1610.pdf.

Rule Finalizes CMS's Ability To Exclude Providers

The Centers for Medicare and Medicaid Services (CMS) cleared the way in a July 20 final rule to exercise its authority to exclude providers from federal health programs for consistently failing to comply with regulatory requirements. The rule becomes effective August 20.

The regulation also gives CMS the ability to advocate for providers facing program exclusion under the Department of Health and Human Services Office of Inspector General's authority to exclude providers for fraud reasons.

CMS's exclusion authority is reserved solely for instances when providers egregiously fail to comply with programmatic requirements and cause unnecessary and costly expense for the government, according to CMS Director of Program Integrity Kimberly A. Brandt.

For example, she said, CMS could seek program exclusion in cases where providers do not comply with technical billing and coding requirements and for whom other interim sanctions have not worked.

Rule Provides Flexibility

The rule provides for a great deal of discretion in excluding providers, meaning CMS would seek to remedy compliance problems every other way possible before seeking to exclude a provider, Brandt said.

"It has the attention of enforcement for the very few providers that refuse to come into compliance," she said, adding that CMS would use its exclusion authority as a last resort in oversight of providers.

The rule finalizes a July 23, 2004, proposed rule in which CMS said it planned to exercise its statutory exclusion authority in much the same way the OIG does under its civil monetary penalty authority.

The OIG can exclude providers in cases

of fraud, abuse, misrepresentation, or falsification. In some criminal cases, exclusion under the OIG's authority is mandatory.

"It has the attention of enforcement for the very few providers that refuse to come into compliance."
— Kimberly Brandt, CMS

Brandt said the agency would not hesitate to use its exclusion authority where necessary, but that exclusions would be reserved for providers costing the program the most money and for

those least willing to correct compliance problems, adding that generally providers want to operate in the right way.

CMS Advocacy

The rule also gives CMS the ability to act on behalf of providers who face program exclusion for fraud reasons and advocate for nonexclusion where the loss of a provider could result in access problems for beneficiaries.

Brandt said that while the agency rarely would be called on to exercise its advocacy authority, it was an important tool for underserved and rural areas where exclusion of a provider would be detrimental to beneficiaries.

The rule specifically finalizes a CMS proposed rule published Aug. 4, 2005, in which the agency, under authority provided for in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, defined provisions allowing it to seek waivers of program exclusions in certain cases where excluding a provider would restrict access to care.

Attorney Kathleen McGuane, Reed Smith LLP in Washington, said the OIG already considers potential hardships for beneficiaries that exclusions could create, including in cases where criminal convictions would mandate exclusion. McGuane has served as chief counsel at CMS.

McGuane said Congress was wise to give CMS the authority to act on behalf of

providers that might be integral to the healthcare delivery in certain areas be-

cause it is in the best position to make those determinations. 

OIG Questions Performance Of Anti-Fraud Contractors

A report released July 20 by the Health and Human Services Office of Inspector General (OIG) raises concerns that some contractors responsible for investigating potential fraud and abuse in the Medicare Part A and Part B programs may be underperforming and not effectively using data tools to develop cases.

The OIG found that while some program safeguard contractors (PSCs) initiated several new investigations, others had few or no new investigations or law enforcement referrals in 2005, the year it reviewed.

The OIG noted in its report, Medicare's PSCs: Activities to Detect and Deter Fraud and Abuse, that PSCs are charged with conducting initial fraud and abuse investigations and that the Centers for Medicare and Medicaid Services (CMS) expects a "significant" portion of PSC work to encompass proactive data analysis, in which contractors look for potential cases or patterns of fraud and abuse through claims and other data reviews.

Of the PSCs performing CMS work in 2005, four had between five and 19 new Part A investigations for the year, while at least one had 479 for the same period, the OIG said. Similarly, three of the PSCs had fewer than 80 new Part B investigations, while at least one had more than 3,700.

"Although PSCs might be expected to differ from one another in workload activity levels, neither the size of a PSC's budget nor its oversight responsibility was strongly correlated with the number of new investigations or the number of new case referrals to law enforcement produced in 2005," the OIG said.

Furthermore, the OIG said more than three-quarters of the PSCs reported that 18% or fewer of new investigations were the result of proactive data analysis, and two said they had no new investigations from such work.

The OIG said CMS should evaluate more closely the work done by PSCs with the lowest levels of investigative and case referral activity to ensure they appropriately sought out instances of fraud and abuse. Furthermore, the OIG said CMS should consider remedies, including termination, under the PSC contracts in cases where PSCs did not perform as expected.

The OIG also said CMS should require PSCs to provide more detailed information in monthly reports to the Medicare agency about investigations, case referrals, and proactive data analysis.

In a written response to the OIG on the report, CMS said that it was difficult to compare performances among PSCs, but noted it was matching up PSC jurisdictions to payment contractor jurisdictions to better evaluate PSC work and compare PSCs to one another. In addition, CMS said it had begun paying PSCs based on performance, workload, and program vulnerabilities.

Resource

- ❖ OIG report, "Medicare's PSCs: Activities to Detect and Deter Fraud and Abuse" (OEI-03-06-00010): www.oig.hhs.gov/oei/reports/oei-03-06-00010.pdf. 



Join Washington G-2 Reports at **Lab Institute** on October 11 for a special session on the competitive bidding demonstration for clinical laboratory services.

The session will feature Linda Lebovic, CMS project officer; Alan Mertz from ACLA; and Robert Waters, Esq., a partner with Gardner Carton & Douglas, LLP. For more information, go to www.g2reports.com/labinstitute25.

Medicare Advantage Plan Terminated: The Centers for Medicare and Medicaid Services (CMS) July 20 terminated a Medicare Advantage (MA) plan in the first termination of a plan due to quality-of-care issues, an agency spokesman said. America's Health Choice Medical Plans Inc. (AHC), of Vero Beach, Florida, operated a health maintenance organization under MA and operated a prescription drug plan. The HMO was eliminated from the MA program because of doctor access problems experienced by members and some mishandling of medications. The allegations date back to 2005. The drug plan from AHC is still in operation. The 12,000 HMO members in seven counties will be moved to a plan called SecureHorizons, run by UnitedHealthcare.

Financial Relationship Disclosure: Beginning in September 2007, CMS will require hospitals to report on their relationships with physicians and their immediate family members. Initially, 500 hospitals will be required to make disclosure. Later, reporting will be mandated for "all Medicare participating hospitals."

The purpose of the disclosure is to allow CMS to scrutinize physician/hospital arrangements for compliance with the Stark law. CMS's action to put hospital/physician relationships under a magnifying glass resulted from a congressional directive to the Department of Health and Human Services in the Deficit Reduction Act to address issues related to physician investment in specialty hospitals.

Aetna Hit With Fine: New Jersey insurance regulators on July 25 announced fines totaling \$9.5 million against Aetna Health Inc., alleging that the insurer's reimbursement practices with regard to certain services provided by out-of-network providers violate state law. In a seven-page administrative order, issued July 23, the New Jersey Department of Banking and Insurance said it received complaints about a June 1 letter in which Aetna informed out-of-network providers of its payment policy for certain services. The department said its regulations obligate Aetna to pay nonparticipating providers a benefit large enough to ensure HMO members are not billed for the difference between the provider's charge and the insurer's payment. 

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