G-2 Compliance Report

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For Hospitals, Laboratories and Physician Practices

CMS Proposes Modifications, Clarifications to Anti-Markup Provisions

The Centers for Medicare & Medicaid Services (CMS) again is proposing ways to apply a provision that limits how much doctors and suppliers can bill for diagnostic testing services.

The newest changes, included in the proposed 2009 calendar year Medicare physician fee schedule, would clarify that the anti-markup provisions would not apply to certain physician arrangements that do not pose a threat of fraud or abuse to the Medicare program, CMS said. CMS also sought to clarify that the anti-markup provision would not apply to arrangements in which diagnostic testing services were performed in the same building where the billing physician or group practice was located.

The proposed Medicare physician fee schedule, announced June 30, was published in the July 7 *Federal Register*. Comments were due by August 29. CMS will publish a final rule by Nov. 1.

CMS has twice before proposed anti-markup provisions in the physician fee schedule to address concerns that certain ar-

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HHS Reaches HIPAA Privacy Settlement

In a first-of-its-kind action, the Department of Health and Human Services (HHS), on July 17, entered into an agreement with a covered entity to settle potential violations of the Health Insurance Portability and Accountability Act (HIPAA) privacy and security regulations.

HHS said the agreement with Providence Health & Services, in Seattle, settles potential violations of HIPAA privacy and security regulations arising from lost or stolen computers containing health information. Providence will pay $100,000 and implement a detailed corrective action plan to ensure that it safeguards "identifiable electronic patient information" against theft and loss, an HHS release said.

The agreement grew out of Providence's loss of electronic backup media and laptop computers containing individually identifiable health information in 2005 and 2006, HHS said.

First Such Agreement

HHS noted that its Office for Civil Rights (OCR) and Centers for Medicare & Medicaid Services (CMS) have resolved more than 6,700 privacy and security rule cases by requiring the enti-

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rangements between physicians, group practices, and other suppliers were allowing for inappropriate profits from Medicare-covered diagnostic testing services for which practitioners can bill the federal government separately for the technical and professional components of the tests. However, in the calendar year (CY) 2007 and 2008 final physician fee schedules, CMS opted to delay most of the proposals because of concerns raised during the comment periods.

In CY 2008, CMS proposed to impose an anti-markup provision on the technical and professional components of diagnostic tests. The provision would apply in cases where the billing physician or group practice purchases the technical or professional component of test services outright or where the physician or other supplier performing the technical or professional component reassigned the right to bill Medicare for the services. CMS further proposed that the anti-markup provision be applied to technical components of diagnostic testing services performed in a centralized building but requested comments on how the provision should be made effective, such as by changing the definition of centralized building.

CMS put off the proposed anti-markup provisions until January 2009, except as they applied to the technical component of purchased anatomic pathology diagnostic testing services.

> *'We believe that this proposal offers a simpler, more bright-line approach preventing potentially abusive arrangements while preserving the viability of nonabusive arrangements involving diagnostic testing facilities that might not be considered to be in the 'office of the billing physician or other supplier,' as defined under the current regulation (for example, a centralized laboratory staffed with full-time employees that is used by a physician practice with multiple office locations, sometimes referred to as a 'hub-and-spoke' arrangement).'*
>
> *—CMS*

Now CMS is seeking to modify some of those earlier proposals and clarify definitions. In particular, CMS clarified in the CY 2009 proposed fee schedule the definition of "office of the billing physician or other supplier" because it said the previous definition "may not have been entirely clear and that it could have unintended consequences."

CMS also addressed concerns raised by providers that they no longer would be able to offer diagnostic testing services to beneficiaries if the anti-markup provisions applied in cases where the providers otherwise complied with physician self-referral rules.

"That is, physician groups stated that in situations in which they are subject to the anti-markup provision and are limited to billing Medicare the net charge imposed by the performing supplier, they will not be able to continue to provide diagnostic testing services to the same extent that they are currently providing such services because they will not be able to recoup their overhead costs," CMS explained.

Two Alternatives

CMS proposed two alternatives for applying the anti-markup provision, but also is seeking comments on alternative approaches that would address the government's concern about the overuse of diagnostic testing but protect legitimate arrangements.

Under the first proposal, CMS said the anti-markup provision would apply in all

cases where the professional component and the technical component of diagnostic testing services were purchased from an outside supplier or where the services were performed or supervised by a physician who does not share a practice with the billing physician or physician organization.

CMS said it would consider a physician employed by or under contract with a single physician or physician organization to share a practice for the purpose of determining whether the anti-markup provision would apply.

"We believe that when a physician provides his or her efforts for a single physician organization (whether those efforts are full-time or part-time), he or she has a sufficient nexus with that practice to justify not applying the anti-markup provision," states the proposal.

However, CMS said that a physician who is employed by or contracts with multiple billing physicians or physician organizations would not be considered as sharing a practice with those individuals or entities under the anti-markup provisions.

"We believe that this proposal offers a simpler, more bright-line approach preventing potentially abusive arrangements while preserving the viability of nonabusive arrangements involving diagnostic testing facilities that might not be considered to be in the 'office of the billing physician or other supplier,' as defined under the current regulation (for example, a centralized laboratory staffed with full-time employees that is used by a physician practice with multiple office locations, sometimes referred to as a 'hub-and-spoke' arrangement)," CMS said.

CMS did not propose specific regulatory text for the proposal and said that as an alternative, it also was proposing to maintain much of the current regulatory text proposed for CY 2008 but delayed until January 2009.

"Alternatively, we propose to maintain much of the current regulation text and its 'site-of-service' approach to determine whether a physician 'shares a practice' with the billing physician or other supplier," CMS said. "In other words, we are reproposing to apply the anti-markup provision to [technical components and professional components] of nonpurchased tests that are performed outside the 'office of the billing physician or other supplier.' We are soliciting comments on whether this is the best approach or whether we should employ a different approach."

To view the proposed rule on the Internet, please visit *federalregister.gov/OFRUpload/OFRData/2008-14949_PI.pdf*.

Fifth Circuit Remands Action to Determine Clinical Labs' Entitlement to Further Interest

On July 15, a federal appeals court reversed and remanded to a district court an action filed by two Texas clinical laboratories to determine if they were entitled to additional interest in a long-running dispute over a Medicare administrative judgment (*Texas Clinical Labs Inc. v. Leavitt*, 5th Cir., No. 07-10760, 7/15/08).

The U.S. Court of Appeals for the Fifth Circuit held that the district court erred in dismissing the action by Texas Clinical Laboratories Inc. and Texas Clinical Laboratories-Gulf Division Inc., collectively known as the Texas TCLs, on the basis that they lacked either standing or capacity to proceed. The appeals court determined it could not resolve whether the additional interest was owed because the parties had not yet presented their case to the district court.

"Even though this matter has needlessly spanned close to 20 years because of the [Department of Health and Human

Services's] repeated misrepresentations that there was evidence supporting its methodology for calculating travel allowances . . . we remand to the district court to consider whether the additional interest sought is owed," Judge Jacques L. Wiener Jr. wrote. "If, in the end, the district court is persuaded to find in favor of the [Texas TCLs] and to award them interest, . . . the government should carefully consider the situation before filing an appeal and thereby needlessly perpetuating this dispute that has already been prolonged by the government's unwarranted actions."

New Formula

Before they went out of business, the Texas TCLs provided clinical laboratory services to long-term care facilities under the Medicare program, receiving 80 percent to 90 percent of their income from Medicare. The dispute between the Texas TCLs and HHS began around 1986 when the carrier, Blue Cross/Blue Shield of Texas, implemented a new formula for calculating travel allowances.

The carriers assumed that health care technicians travel at an average speed of 35 miles per hour when driving to and from the facilities they service. The Texas TCLs objected, urging that a "lower, more accurate" miles-per-hour component be used, which would result in a higher overall reimbursement for all health care providers.

After a number of actions ended in an administrative law judge's decision to rule in favor of the Texas TCLs, awarding them $581,157 plus interest, the Texas TCLs objected to HHS's calculation of interest. However, the judge held that he did not have the authority to rule on the issue and the appeals council ruled that no additional interest was owed to the Texas TCLs.

In May 2007, the district court held that the Texas TCLs lacked the requisite standing and capacity to pursue their claim for additional interest and dismissed their due process claim as well. The Texas TCLs contended that HHS deprived them of their right to due process when it flagrantly misrepresented to them and to the reviewing courts that objective evidence existed to support the 35 mile-per-hour component of its travel-allowance formula.

Personal Belief

HHS admitted in September 2002 that the 35 mile-per-hour figure was based solely on the carrier staff's personal belief regarding travel time in Texas rather than on any objective evidence. The district court, however, determined that because the Texas TCLs lacked standing and capacity to pursue their administrative claim for additional interest, they also lacked standing and capacity to pursue their constitutional claim.

On appeal, the Fifth Circuit reversed the district court's ruling that the Texas TCLs lacked capacity to maintain the action to recover additional interest under their Medicare reimbursement judgment. Nonetheless, the appeals court upheld the district court's dismissal of the Texas TCLs' due process claim—but on different grounds.

The appeals court found the district court's reasoning flawed but affirmed the dismissal because the record demonstrated that the claim was barred by the applicable statute of limitations. The statute of limitations was two years and, although the Texas TCLs first became aware of the HHS's misrepresentations in September 2002, they did not assert their claim until October 2005, the appeals court found, well after the applicable statute of limitations had expired.

COMPLIANCE PERSPECTIVES

[EDITOR'S NOTE: THIS IS THE FIRST OF TWO ARTICLES ON FINAL CHANGES TO THE STARK RULES]

Final Stark Rules Require Major Restructuring of Common Joint Venture Arrangements

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On July 31, 2008, the Centers for Medicare and Medicaid Services (CMS) posted its 2009 Final Hospital Inpatient Prospective Payment Systems rule (2009 final rule),[1] which is scheduled to be published in the Aug. 19, 2008, *Federal Register*. The rule contains final Stark rules settling many of the proposals that came out of CMS over the course of the last year and often extends far beyond the original proposals, with the intended effect of undermining many common hospital/physician joint-venture models.

Specifically, the 2009 final rule firmed up rules concerning physician "stand in the shoes," "alternative method of compliance," an exception for obstetrical malpractice insurance, provisions regarding ownership or investment interests in retirement plans, the burden of proof in appeals, and the "period of disallowance," which become effective Oct. 1, 2008.

The 2009 final rule also contains final Stark rules dealing with percentage-based compensation, per-click arrangements, and more restrictive requirements for "under arrangement" transactions, which become effective Oct. 1, 2009 due to the expectation that they will require significant restructuring of existing transactions.

The Stark-related topics covered in the 2009 final rule are as follows:

- **Percentage-based leasing arrangements:** CMS does away with all percentage-based compensation in the context of space and equipment leases.
- **Per-click leasing arrangements:** CMS severely restricts the use of per-click leasing arrangements.
- **Services provided "under arrangements":** Both the hospitals that bill for services provided under arrangements as inpatient or outpatient hospital services and the entities that provide those services will be considered to be furnishing "designated health services" (DHS) under Stark. This change will effectively eliminate referring physicians' ability to own interests in such service providers.
- **Stand-in-the-shoes provisions:** Only physicians who have an ownership or investment interest in their physician organizations will be required to stand in the shoes of those organizations. Complying with a Stark exception will now be much easier for academic medical centers, integrated tax-exempt health care delivery systems, and physician organizations that are not owned by referring physicians.
- **"Set in Advance" and amendments to agreements:** In the preamble to the new stand-in-the-shoes rules, CMS states that it is reversing its prior position and permitting multiyear agreements to be amended after the first year of their terms without violating Stark's set-in-advance requirement.
- **Period of disallowance:** CMS establishes a bright-line rule that sets the outer limit of the period during which

[1] *An advance copy of the 2009 final rule is available at www.cms.hhs.gov/AcuteInpatientPPS/downloads/CMS-1390-F.pdf. The Stark-related provisions of the rule begin at page 972 of the advance copy, and a table indicating the rulemaking in which the various revised provisions were proposed is found at pages 976-77.*

referrals are prohibited as a result of a financial relationship that fails to satisfy a Stark exception. Disallowance begins when the relationship fails to satisfy an exception and ends no later than the date that it satisfies an exception and the parties have returned any overpayments or paid any underpayments of compensation.

- **Alternative method for compliance:** If a financial relationship fully complied with an applicable Stark exception, except with respect to a signature requirement, Medicare payments to the entity will be permitted if the signature requirement is complied with within 30 or 90 days after commencement of the relationship. The longer period applies only if the failure to comply with the signature requirement was inadvertent.
- **Disclosure of financial relationships report:** CMS provides additional details about this survey of physician financial relationships that it proposes to send to up to 500 hospitals.
- **Exception for obstetrical malpractice insurance subsidies:** CMS adds an exception for subsidies provided by hospitals, federally qualified health centers, and rural health clinics, that is more flexible than the current exception.
- **Ownership or investment interest in retirement plans:** CMS narrows the retirement plan exception to ensure that referring physicians cannot use it to circumvent Stark's restrictions on ownership of DHS entities by investing in those entities through their employer's retirement plans. Now, only the physician's ownership or investment interest in the employer is protected by the exception.
- **Burden of Proof:** CMS clarifies that when a DHS entity appeals a claim for payment that was denied on the basis it was furnished pursuant to a prohibited referral, the DHS entity has the burden of proving that the service was not furnished pursuant to a prohibited referral.

CMS's final rules have major implications for the industry, particularly with respect to hospital-physician joint venture arrangements. These rules were far broader in scope and impact than were originally proposed, and CMS has indicated that it will continue to enact further regulations tightening aspects of the Stark law.

The extent of these changes, coupled with CMS's repeated commentary that it has no discretion in the application of these rules and that they will be strictly applied, regardless of the ultimate financial impact to the Medicare program or the parties' intent or knowledge, is ominous.

Of potentially equal significance, the new rulemaking's delayed effective date for certain provisions should be regarded as a shot from a starter's pistol for organizations that must amend or terminate relationships in order to achieve compliance by Oct. 1, 2009. For the budget-driven health care industry, the impact of this mandate, both financially and culturally, cannot be underestimated.

Percentage-Based Compensation

Last summer, CMS proposed doing away with percentage-based compensation arrangements except in the context of services agreements where the services are personally performed. In these final rules, CMS declines, at this time, to limit percentage arrangements only to personally performed services. Instead, CMS does away with all percentage-based compensation in the context of space and equipment leases.

Specifically, the 2009 final rule amends the current Stark exceptions for the rental of office space, the rental of equipment, fair-market-value compensation arrangements, and indirect compensation arrangements to prohibit the use of compensation formulae for space or equipment leases based on a percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the leased office space or to the services performed on or business generated by the use of leased equipment.

In implementing this rule, it appears that CMS effectively ends all percent-

age-based arrangements for the lease of space or equipment, whether structured as direct or indirect financial arrangements. No doubt these types of arrangements will need to be restructured prior to the Oct.1, 2009, effective date of this rule. Failure to do so, when required, will effectively disqualify any DHS-rendered payment pursuant to a referral from physicians with whom the DHS entity has a noncomplying lease arrangement.

It is also noteworthy that, in connection with these rules, CMS states that it is choosing not to extend, at this time, a similar prohibition against percentage-based fees for other arrangements (e.g., non-professional, management services); however, it intends to monitor these arrangements and may similarly limit them in the future. It is also significant to note that CMS highlights the fact that this new prohibition does not affect the parties' ability to enter into flat-fee leases or use other permissible compensation methodologies, such as per-procedure compensation (if available, see below).

Per-Click Leasing Arrangements

Although in its comments relating to percentage-based leasing arrangements CMS raised the possibility of utilizing per-procedure payment formulae, under its new final rule, CMS restricts the use of per-click payment methodologies for leasing arrangements under the space and equipment lease exceptions, the fair market value exception, and the exception for indirect compensation arrangements. CMS makes clear that the limitation on per-click payments applies regardless of whether the physician is personally the lessor or whether the lessor is an entity in which the referring physician has an ownership or investment interest. This limitation applies where the lessor is a DHS entity that refers patients to a physician or a physician organization lessee.

In practical terms, this new rule, coupled with the ban on percentage-based compensation formulae, undermines current leasing joint-venture arrangements whereby referring physicians and hospitals or others have formed a joint-venture entity for the purpose of leasing space or equipment to a hospital or other DHS entity on a variable-fee basis.

Specifically, these final rules now require—to the extent there are any physician investors in the joint venture leasing entity that refer to the lessee entity—the lease payments between the lessee and the joint venture may not be based on either (1) a percentage of revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the space or through use of the equipment or (2) per-unit rental charges, to the extent that such charges reflect services provided to patients referred between the parties.

Effectively, the indirect compensation exception has been eviscerated with respect to space and equipment leasing transactions and, as CMS acknowledged, numerous joint venture transactions will need to be restructured.

In addition to these changes, CMS commented on "time-based" rental payments. While CMS is abstaining from proposing any rules addressing block leases and similar arrangements at this time, it noted that such arrangements are potentially problematic and went so far as to state that on-demand rental agreements are effectively per-use or per-click arrangements and that CMS considers them to be covered by the new final rules (i.e., they are now prohibited for leases of space and equipment). With respect to block-leasing arrangements, CMS stated that it will continue to study the ramifications and may propose rulemaking in the future.

'Under Arrangements'

The 2009 final rule changes the definition of "entity" in the Stark II regulations in a way that will have a significant effect on physician-owned entities that provide services to hospitals under arrangements. Currently, this definition provides that only the person or entity that bills for DHS is considered to be furnishing the DHS. When the 2009 final rule provision

becomes effective, the person or entity that performs services that are billed as DHS will be considered to be furnishing those services. As a practical matter, this means that referring physicians likely will not be able to hold ownership or investment interests in under-arrangements service providers.

Under the current Stark regulations, because the under-arrangements service provider is not considered a DHS entity, the Stark analysis focuses on the relationship between the hospital and the referring physicians associated with the service provider. These arrangements are analyzed as either direct financial arrangements (if a referring physician stands in the shoes of the service provider) or indirect financial arrangements (if "stand in the shoes" does not apply) and generally can be structured to fit within a direct or indirect compensation exception.

The new regulations treat an under-arrangements service provider as an additional DHS entity, which means that any financial relationships between the service provider and the physicians who refer patients to it for services billed by the hospital will need to comply with a Stark exception. Direct compensation exceptions should be available to protect referrals from the service provider's nonowner physicians. However, very few exceptions are available for referring physicians who own an interest in the service provider. In most cases, the only exception that could apply is the exception for rural providers.[2]

As a result, the change in the definition of "entity" will effectively eliminate referring physicians' ability to own interests in under-arrangements service providers. CMS provides an Oct. 1, 2009, effective date for these regulations to allow time for restructuring existing under arrangements relationships.

In the preamble, CMS makes clear that even if a service provider (such as a cardiac-catheterization or sleep lab) performs services that would not be DHS if they were provided and billed by the service provider in a freestanding setting, the services become DHS and the service provider becomes a DHS entity when a hospital bills for those services as inpatient or outpatient hospital services.[3]

CMS declines to define in the regulations when an entity is considered to be "performing" DHS, saying that the common meaning of the term should apply. CMS comments in the preamble that it considers a physician or physician organization to have performed DHS "if the physician or physician organization does the medical work for the service and could bill for the service but the physician or physician organization has contracted with a hospital and the hospital bills for the service instead."[4]

CMS states that it would not consider a lessor of equipment or space; a provider of management, billing services, or personnel; or an entity that furnishes supplies that are not separately billable but are used in the performance of medical services to be performing DHS.[5] This language fails to clarify whether a turnkey management service provider will be considered to be performing DHS, and this lack of clarity may well have a chilling effect on a number of business arrangements.

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[2]*The Stark II regulations provide an exception for ownership or investment interests for DHS furnished in a rural area by a rural provider. To qualify as a rural provider, the entity must furnish at least 75 percent of its DHS to residents of a rural area.*

[3]*Lithotripsy appears to be the only exception to this rule. CMS states in the preamble that lithotripsy will not be considered a DHS, whether it is billed by the service provider or by a hospital under arrangements.*

[4]*CMS cautions that a service provider may not avoid the regulations simply by arranging for the billing entity or some third party to complete a medical service that the provider has substantially completed.*

[5]*CMS declines to treat physician-owned medical device companies as DHS entities at this time, but notes that it may propose rules to address this issue in the future.*

HIPAA Privacy Settlement, *from page 1*

ties involved to make "systemic changes" to their health information privacy and security practices.

The Providence action, however, is the first time that HHS has required a resolution agreement from a HIPAA-covered entity, the department said. OCR handles HIPAA privacy rule civil enforcement, while CMS handles the security rule under HIPAA.

The Department of Justice investigates and prosecutes criminal violations of the privacy rule. Privacy advocates have criticized OCR for never having assessed a civil money penalty for a privacy rule violation in the more than five years since the regulations went into effect.

HHS noted that Providence's cooperation with OCR and CMS allowed the department to resolve the case without a need for imposing a civil money penalty.

The corrective action plan requires Providence to:

- revise its policies and procedures regarding physical and technical safeguards (e.g., encryption) governing offsite transport and storage of electronic media containing patient information, subject to HHS's approval;
- train workforce members on the safeguards;
- conduct audits and site visits of facilities; and
- submit compliance reports to HHS for three years.

The HHS statement included comment from Providence's chief information security officer, Eric Cowperthwaite: "The protection of patient information is a top priority for Providence Health & Services."

Cowperthwaite added, "Since these incidents occurred, we have reinforced our security protocols and implemented new data protection measures. Under the terms of the agreement, we will continue to implement appropriate policies, procedures, and training."

The company's Web site said it is a nonprofit health system operating in Alaska, Washington, Montana, Oregon, and California. Providence Health & Services includes 26 hospitals as well as physician clinics and a health plan.

Missing Records

HHS said in its announcement that the incidents leading to the agreement involved two entities within the Providence health system: Providence Home and Community Services and Providence Hospice and Home Care.

"On several occasions between September 2005 and March 2006, backup tapes, optical disks, and laptops, all containing unencrypted electronic protected health information, were removed from the Providence premises and left unattended," HHS said. The media and laptops were lost or stolen, according to HHS, "compromising the protected health information of over 386,000 patients."

The department said it received more than 30 complaints about the stolen tapes, disks, and laptops, submitted after Providence—as required by state notification laws—informed patients of the theft. "Providence also reported the stolen media to HHS," the department said.

Attorneys Comment

Reece Hirsch, an attorney with Sonnenschein Nath & Rosenthal in San Francisco, says the announcement about Providence is a "landmark" event and a sign that regulators may be taking a more proactive enforcement approach to protecting health care data. He noted that the type of breach in question in the Providence case "is not that uncommon these days," so there could be more such enforcement actions in the future.

Hirsch said that the theft or loss of patients' information has been an area of sensitivity in recent years, adding that CMS issued a guidance document in

late 2006, the *HIPAA Security Guidance for Remote Use of and Access to Electronic Protected Health Information*.

Kirk J. Nahra, an attorney with Wiley Rein LLP in Washington, D.C., says that the Providence action is "the first time a monetary sanction has been imposed, and it's a big amount." HHS seems to have avoided its normal enforcement rule approach by having a monetary payment that is what HHS calls a "resolution amount" and not an actual penalty, he said. Nahra said the $100,000 paid by Providence "is a big dollar amount," noting that under the HIPAA enforcement rule, the maximum penalty would be $25,000.

The resolution agreement is available via *www.hhs.gov/ocr/privacy/enforcement/*.

Labs Score Big Under New Medicare Law

Congress in July overrode President Bush's veto of Medicare legislation and enacted major program changes advocated by clinical laboratory and pathology organizations. The changes include a physician fee fix and extension of the "grandfather" protection through next year, plus a repeal of the lab competitive bidding demonstration.

The Medicare Improvement for Patients and Providers Act of 2008 became law July 15. The votes to override the veto were well above the two-thirds required. (President Bush has vetoed bills nine times but has been overridden only three times before.) The president said he did not oppose the physician fee increase but rejected paying for it in part by reductions in Medicare managed care funding. The reductions target Medicare Advantage indirect medical education payments and include new provider network requirements for private fee-for-service plans, saving $12 billion over five years, according to Senate Finance Committee estimates.

Competitive Bidding

Competitive bidding has been touted by the Bush administration as a fee-for-service alternative intended to inject more market forces into the Medicare program. For clinical laboratory services, this effort is now at a dead end. The new Medicare law repeals the authority of the Centers for Medicare and Medicaid Services (CMS) to conduct a Part B lab-bidding demonstration, as was required under the 2003 Medicare reform law passed by the GOP-controlled Congress.

The law also puts a halt on the national rollout of competitive bidding for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), which CMS began July 1. It imposes an 18-month delay in Round 1 involving 10 communities throughout the country and required a corresponding 18-to-24 month delay in subsequent rounds. National competitive bidding for DMEPOS was mandated by Congress, following reports of savings that this payment method achieved in two pilot projects in Texas and Florida.

Pathologist/Physician Fees

Congress has replaced the 10.6 percent cut in Medicare physician fees that took effect July 1, under the Sustainable Growth Rate (SGR) update formula, with a 0.5 percent increase, retroactive to July 1 and effective through Dec. 31. For 2009, fees will rise an additional 1.1 percent.

The new law also extends through Dec. 31, 2010, the Physician Quality Reporting Initiative (PQRI), which authorizes bonus payments for reporting on CMS-approved quality performance measures. Moreover, the bonus increases to 2 percent in 2009 and 2010.

Laboratory Services Reimbursement

For the first time in five years, the Part B lab fee schedule will get a positive update starting Jan. 1, 2009, though it will not be the full Consumer Price Index (CPI) update currently projected to be 5 percent. Congress reduced the CPI update to the lab fee schedule by 0.5 percent, for a net gain of 4.5 percent.

Also, critical-access hospitals serving rural areas will receive 101 percent of reasonable costs for clinical lab services to beneficiaries, regardless of whether the lab specimen was taken in the hospital or offsite at another facility operated by the hospital.

Pathology TC 'Grandfather' Protection

The new law extends for 18 months, from July 1, 2008, through Dec. 31, 2009, the "grandfather" provision that allows qualified independent clinical laboratories to bill Medicare Part B separately for the technical component (TC) of anatomic pathology services to hospital inpatients and outpatients. The protection affects hospital-lab arrangements in effect as of July 22, 1999, the date when CMS first proposed to end such billings on grounds that the TC is reimbursed as part of Medicare's Part A inpatient payment and that labs should seek TC payment from the hospital, not Part B.

The "grandfather" protection applies to the hospital, not the lab, CMS has noted. Hospitals may switch labs without losing the protection; however, independent labs cannot switch hospitals and still be protected. CMS also has defined the TC of pathology services to include not only anatomic services but also cytopathology and surgical pathology.

Pathologist Agrees to Pay $457,379 for Allegedly Defrauding Medicare, FEHBP

A Maryland pathologist agreed to pay the government just over $457,000 to resolve allegations that she fraudulently billed Medicare and the Federal Employees Health Benefits Program (FEHBP), Rod J. Rosenstein, U.S. attorney for the District of Maryland, announced July 9.

The government alleged that Shahla Moshiri, who owns and operates Chesapeake Diagnostics Laboratory Inc., a cytopathology testing facility in Cockeysville, Md., violated the False Claims Act from Jan. 1, 2002, through July 31, 2005, by billing Medicare and the FEHBP for unnecessary physician interpretation of Pap smears, the settlement agreement said.

Further, during the same period, Moshiri allegedly billed the health care programs for consultation and preparation of reports on slides prepared and referred for examination without any documentation supporting such claims for reimbursement, the settlement agreement added.

Promoting Compliance

"The resolution of this matter underscores our commitment to ensure that the critical resources of federal health care programs are not improperly diverted to reimburse claims that should not be paid," Rosenstein said. "The settlement provides for the recovery of monetary damages and the protection of health care programs that taxpayers depend upon through the use of a monitored integrity agreement that promotes compliance with federal health care program regulations."

Moshiri and Chesapeake also agreed to enter into a five-year integrity agreement with the Department of Health and Human Services's Office of Inspector General, the press release said. The integrity agreement requires Moshiri and Chesapeake to have written procedures related to billing and medical record documentation, an employee training program, and review of claims submitted to federal health care programs, the release added.

According to the settlement agreement, Moshiri denied and disputed the claims and stipulated that the agreement should not be construed as an admission of liability or wrongdoing. Nevertheless, the United States noted that the agreement was not a concession by the government that its claims were not well-founded, the settlement agreement said.

OIG Clears Cost-Savings Arrangement: The Department of Health and Human Services's Office of Inspector General (OIG) will not impose sanctions against a medical center and surgeons over an arrangement between them to share cost savings from the surgeons' cost-reduction measure for certain procedures, the OIG said in an advisory opinion (No. 08-09) posted Aug. 7. Under the arrangement, the medical center agreed to pay the orthopedic surgery groups and the neurosurgery group a share of the first-year cost savings directly attributable to specific changes made in the groups' operating room practices. The advisory opinion is available at *www.oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-09B.pdf*.

OIG Issues Guidance on Waivers: Medicare providers and suppliers will not risk administrative sanctions if they do not collect retroactive fee increases from beneficiaries because of changes to Medicare payment rates in the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), the OIG said in a July 23 policy statement. Under MIPPA, certain payment rate increases apply retroactively to July 1 and the Centers for Medicare and Medicaid Services (CMS) has said that beneficiary liability for cost-sharing also could retroactively be increased. However, the OIG said that providers who choose to waive retroactive beneficiary liability for services between July 1, 2008, and the date on which CMS implements the changes under MIPAA would not be subject to OIG administrative sanctions for waiving those beneficiary cost-sharing amounts.

New AO Payment Structure: Requestors seeking advisory opinions from the OIG no longer will be required to pay a $250 down payment, although the final rule making the change requires that requestors still pay a fee equal to the cost of preparing an advisory opinion. The final rule became effective July 17, the same day it appeared in the *Federal Register*. Besides eliminating down payments for advisory opinions, the rule requires requestors to make payments for advisory opinions directly to the Treasury Department through wire or other electronic funds transfer.

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