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House subcommittee considers repeal of SGR, pay-for-performance

by John Scorza

Witnesses and lawmakers at a recent House hearing gave mixed reviews to pending legislation that would repeal the Sustainable Growth Rate (SGR) formula, which is used to adjust physician payments under Medicare. The bill – the Medicare Value-Based Purchasing Act (H.R. 3617) – was introduced on July 29 by Rep. Nancy L. Johnson (R-Conn.), chairman of the House Ways and Means Subcommittee on Health. Of the legislation, Johnson remarked at a September 29 hearing of her subcommittee, “It’s not going to be perfect. But it is a serious start."

Johnson’s bill would replace the SGR formula with an annual update based on changes in the costs of providing care. Payments to physicians would be linked to quality of care and efficiency

Differential payment. The bill, as described by Johnson, would provide a differential payment update to practitioners meeting pre-established thresholds of quality or pre-established levels of improvement, equal to the Medicare Economic Index (MEI). Practitioners not meeting these thresholds would receive an update of MEI, minus 1 percent. The Centers for Medicare and Medicaid Services (CMS) would analyze volume and spending growth and make recommendations as to regulatory or legislative changes to respond to inappropriate growth.

Like Johnson, CMS Administrator Mark B. McClellan supports pay-for-performance. “We are committed to developing reporting and payment systems that enable us to support and reward quality, to improve care without increasing overall Medicare costs,” he testified at the hearing.

But Rep. Pete Stark (R-Cal.) the subcommittee ranking Democrat is not yet sold on pay-for-performance. He warned against the “rush to embrace this latest fad.” He said Congress should wait to evaluate CMS demonstration projects on pay-for-performance for hospitals and physicians in order to know whether and how to expand the model. Stark further opposes the repeal of the SGR, as envisioned by the Johnson bill. Stark said he would not defend the SGR, but that there has been little discussion about what should replace it. Citing July testimony from McClellan, Stark said repealing the SGR would cost more than $180 billion over 10 years.

Value. Witnesses at the hearing joined Stark in questioning the ultimate value of pay-for-performance. Thomas Jevon testified that pay-for-performance would work only if financial incentives to physicians are significant. “The one percent differential in the Johnson bill would probably translate into perhaps $1,000 into the average primary care physician’s pocket, probably not enough to engage him in the effort. To really grab a physician’s attention you would need to be in the $5,000 and up range,” Jevon testified. ■

CCH Washington Bureau, Sept. 29, 2005.

FTC assesses price competition in PBM-owned service

by Gene' Stephens, J.D., Contributing Editor

A conflict of interest study to determine whether the use of mail-order pharmacies owned by pharmacy benefit managers (PBMs) that administer the Medicare prescription drug benefit would adversely affect Medicare spending as compared to the use of mail-order pharmacies not owned by a PBM found that for large PBMs, average total prices at owned mail-order pharmacies typically were lower than mail-order pharmacies not owned by large PBMs.

Additionally, the study determined that retailer-owned PBMs charged lower total average prices for generic and multi-source brand drugs at their owned mail-order pharmacies when compared to non-PBM owned mail-order pharmacies. In the Medicare Modernization Act of 2003 (PubLNo 108-173), Congress requested that the Federal Trade Commission undertake the study to examine the differences in payment amounts for pharmacy services provided to enrollees in group health plans that utilize PBMs.

Conflicts of interest. The study addressed allegations of conflicts of interest that may arise when PBMs both administer pharmacy benefits for a plan sponsor and sell drugs to a plan sponsor's members by way of the PBM's mail-order pharmacy. The potential conflict of interest could provide PBMs with opportunities to manipulate drug dispensing and enhance their profits at the expense of plan sponsors and members. The report's discussion of PBM vertically integrated pharmacies addressed concerns regarding the influence that PBMs have on which drugs are dispensed by providing advantages of vertical integration related to lower drug transaction costs and the avoidance of double markups. ■

Federal Trade Commission Report, Assessment of Competition and Prescription Drug Pricing by Mail-Order Pharmacy Services Owned by Pharmacy Benefit Managers, Aug. 1, 2005, ¶680,002.

White House calls temporary Medicaid waiver unnecessary

by Paula Cruickshank

The Bush administration does not support a provision in legislation sponsored by the Senate Finance Committee Chairman Charles Grassley (R-Iowa) and ranking minority member Max Baucus (D-Mont.) that would provide a temporary Medicaid waiver to all hurricane victims in the Gulf Coast region. According to White House Press Secretary Scott McClellan, the administration already has taken "significant steps" to speed up Medicaid assistance to those victims of the storm who are eligible to receive benefits, but the Senate Finance Committee proposal "appears to go well beyond that."

Presumptive eligibility. McClellan said that the Grassley-Baucus proposal would allow Medicaid reimbursements to 29 states that suffered "little or no impact from the hurricanes." The existing system, once a state requests and receives a waiver, grants presumptive eligibility to evacuees who earned too much to qualify for Medicaid before the storm but no longer have the financial means to pay for health care after the hurricane hit, according to Mary Conn, a press officer at the Department of Health and Human Services (HHS).

Under the presumptive eligibility process, hurricane victims could apply for Medicaid without documentation to prove they qualify, noted Conn. The existing enrollment process for a waiver is done state-by-state as opposed to the blanket approach in the Grassley-Baucus bill.

According to Conn, the following states have applied for the temporary Medicaid waiver for all victims that seek enrollment: Texas, Mississippi, Alabama, Florida, Georgia, Idaho, the District of Columbia and Arkansas. The administration waiver lasts for five months, although the program could be extended at the discretion of the HHS Secretary, according to a Senate Finance Committee document comparing the existing and proposed programs. The Grassley-Baucus bill ends the program in five months with one possible extension of five months.

"I think we are all committed to making sure that those who depend upon vital services or benefits like Medicaid are getting the care that they need, and that they're getting it as quickly as possible," McClellan said. ■

CCH Washington Bureau, Sept. 29, 2005.

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Stock in tax-exempt practice does not create interest under Stark

by Sheila Lynch-Afryl, J.D., Contributing Editor

Stock held by the physician-shareholders of a nonprofit, tax-exempt group medical practice which employs more than 700 physicians did not constitute an ownership or investment interest in the practice and, therefore, does not constitute a financial relationship that could potentially restrict the physicians' referrals or the submission of Medicare claims under the Stark laws (see 42 U.S.C. § 1395nn(a)), according to a CMS advisory opinion. CMS regulation 42 C.F.R. § 411.354(b)(1) provides that stock ownership constitutes an ownership or investment interest, yet CMS based its determination in this case on two fact-specific reasons. First, the physicians did not receive any of the purchase and ownership rights or financial risks and benefits typically associated with stock ownership for the following reasons:

- Although the physicians nominally purchased "shares" in the practice, they did so as a formality under the terms of the state business corporation law which provided for the issuance of capital stock regardless of a corporation's non-profit status.
- The purchase and ownership rights related to the stock were restricted in such a way that a physician's financial interests could not be affected by the stock ownership - except for the initial $1,000 expenditure.
- The physicians did not have a right to distribute the net income, assets, or profits of the practice because of the practice's tax-exempt status.
- The stock did not appreciate or depreciate and was not affected by the financial performance of the practice as a whole or any of its physician-shareholders.
- Individual dividends were not paid on the stock and are not disguised as part of the physicians' salaries or compensation.
- The physician shareholders are similar to members in a nonprofit corporation because physicians may only purchase one share, which gives the physician only one vote, the shares are non-transferable and the stock was required to be returned to the practice when the physician-shareholder's employment with the practice is terminated or he or she is unable to meet practice requirements.

Second, the physician-shareholders did not have a right to distribute the net income, assets or profits of the group practice. Due to the practice's 501(c)(3) tax-exempt status, its assets are held in trust for the sole use of the practice toward its charitable purposes, and therefore, if the practice dissolves, 100 percent of the practice's assets must be distributed to educational, scientific, or charitable organizations. Therefore, the physician-shareholders did not have the same financial incentives as those held by purchasers of stock in for-profit corporations. ■

CMS Advisory Opinion, No. CMS-AO-2005-08-01, Aug. 5, 2005, ¶350,008.

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On The Front Lines

Practical considerations for the voluntary disclosure process - Part 2

by Ryan Meade, J.D.

While it is well settled that a health care provider must return any overpayments it receives from federal health care programs, providers often experience considerable tension between what they know they must do (self-disclose the overpayment and return the money) and the fear of not knowing where the voluntary disclosure will lead. Every voluntary disclosure is different and it is true that the government could expand its investigation beyond the issues self-disclosed, but the process of disclosing and resolving issues tends to follow some general paths. There are also actions that providers can take before they ever need to undertake a voluntary disclosure that can ease anxiety at the time of the disclosure and put the provider in a better position when it makes a voluntary disclosure. A provider should anticipate that one day it will likely need to make a voluntary disclosure and begin preparing now by instituting an active auditing and monitoring plan as a pivotal component of its compliance program.

This article discusses the actual process of voluntarily disclosing and what providers can do to prepare for the seemingly inevitable day when the provider must voluntarily disclose an overpayment. Specifically, this article covers: 1) the process of making a voluntary disclosure to the various government agencies and Medicare contractors; 2) possible outcomes to the voluntary disclosure; and 3) lessons learned as to what a provider can do before a problem occurs in order to be in the best position if an issue needs to be self-disclosed. Part 1 of this article (see the October 3, 2005, issue, pg. 4), discussed the decision making process in preparation for a voluntary disclosure.

1. The process of making a voluntary disclosure

Voluntary disclosures are typically made to one of three entities: A) the Office of Inspector General (OIG) for the Department of Health and Human Services; B) the local United States Attorney's Office (the USAO); or C) the local Medicare contractor through its voluntary refund process. The voluntary disclosure process will be different for each possible recipient of the disclosure.

A. Disclosures to the OIG

The OIG published the Provider Self-Disclosure Protocol (OIG Protocol) in 1998, which provides detailed instructions on information that the provider should assemble and report when disclosing an overpayment and compliance issue to the OIG.[1] The OIG encourages the use of the OIG Protocol and has stated that this method will expedite the review process.

The OIG Protocol requires the provider to describe the compliance issue, the cause of the issue, estimate the amount of the refund as well as to provide additional information such as how the issue was identified, the corrective action to stop the problem from recurring and "the impact on, and risks to, health, safety, or quality of care posed by the matter disclosed."[2] The OIG Protocol encourages the provider to submit a written narrative to describe the issue and the surrounding facts. Any time a provider utilizes the OIG Protocol, the provider must carefully craft its response because the information the provider supplies will be used to determine whether a violation of law occurred and whether fines and penalties should be assessed. Providers should consider having legal counsel assist the provider in preparing the self-disclosure information under the OIG Protocol.

Significantly, the OIG Protocol insists that the provider need only use the process if there is a potential violation of law.[3] If the compliance issue resulted in a straightforward overpayment in which the provider believes that no laws have been violated, the overpayment should simply be sent back to the local Medicare contractor that paid the erroneous claims.

The determination of whether there has been a violation of law is easier said than done. Factors that may not look to the provider like reckless disregard for the truth of a claim [4] may appear so to a government regulator or to the Medicare contractors. Medicare contractors may refer to the OIG or the USAO voluntary refunds.

Consequently, when in doubt whether a law has been violated, it is often wise for a provider to err on the side of caution and disclose the matter to the OIG or USAO and advance an argument as to why the provider believes that no law has been violated. If

the facts are ambiguous or they could be easily misconstrued, then the provider should disclose to the OIG or USAO rather than to the Medicare contractor because the voluntary refund might be referred back to these enforcement agencies. However, the provider should consult its own legal counsel before making such decisions and determinations of potential liability.

Upon submission of the information under the OIG Protocol, the OIG typically assigns an OIG official to review the case and work with the provider to gather more facts. The additional information that government will ask for depends on the circumstances of the disclosure and how complete the information is that was submitted to the OIG. Common questions include clarifications of unclear facts in the narrative, the level of expertise of the people who managed the processes that produced the error, timelines related to the error and discovery of the errors, and samples of erroneously filled-out forms that could have led to the error.

The OIG may agree to hold a meeting or discuss the matter by phone and help the provider and the provider's counsel fine tune the documentation and information required by the OIG. If the provider already has a relationship with the OIG, the provider may find calling the OIG more efficient than simply following the OIG Protocol and submitting the documentation without notice.

B. Disclosures to the USAO

Providers also can choose to disclose to the local USAO. The attorneys in the USAO act as the lawyers for the United States and the various federal agencies that administer federal health care programs. The USAO is part of the federal Department of Justice and has independent authority to investigate health care fraud matters.

If a disclosure is made to the USAO, the process may proceed similarly to a disclosure to the OIG in that the prosecutor assigned to review the matter will ask for specific information and will likely have the provider or the provider's counsel put the facts surrounding the matter in writing. Both the OIG and USAO may conduct interviews of the provider's employees.

Most importantly, it is essential to cooperate with government requests. Of course, there may be times when the government officials go too far or request documents that are not relevant or germane to the issue. In such instances, legal counsel must have the appropriate discussions with the government to try to convince them to narrow the request. Requests from the government during a voluntary disclosure are reasonable, however, because the government generally realizes that the provider takes compliance seriously.

C. Disclosures to Medicare Contractors

The third option for disclosure is through the voluntary refund process that the local Medicare contractors (fiscal intermediaries or carriers) offer. This process usually requires the provider to complete forms that describe the reason for the overpayment and various other information. The voluntary refund forms typically require far less information than required through the OIG Protocol. The provider also may send a letter explaining the circumstances of the issue and how the overpayment was calculated.

Once the provider has sent the voluntary refund forms (as well as a check), it is difficult to predict the next steps that a Medicare contractor will take. The contractor will likely cash the check but the facts and the approach of the contractor determine to what extent the contractor will investigate or ask follow-up questions. Sometimes the contractor may disagree with the method used to calculate the overpayment and the provider will need to defend its approach. If an exact overpayment cannot be calculated and the provider must develop an estimate of the overpayment, it is important that the provider has thought through the estimate methodology before submitting anything to the contractor to be sure that the methodology is a defensible, reasonable approach that can be explained to the contractor should the contractor question the refund amount.

If the facts are such that the contractor believes that fines and penalties are required, the contractor could refer the matter to the OIG or USAO or to the local program safeguard contractor (PSC) for further investigation. A representative from the Medicare contractor may contact the provider directly to ask questions. There is also the possibility that the voluntary refund will ramble around the bureaucracy of the Medicare contractor for quite some time without the contractor even cashing the check until the matter is resolved.

In sum, the specific steps in the process can be unpredictable. In self-disclosing, the provider should be willing to cooperate fully with the government, be patient as to the time that it takes to investigate and resolve the issue, and prepare itself for the unexpected by aggressively auditing other areas.

2. Possible outcomes to the voluntary disclosure

There is always the risk in a voluntary disclosure that the government's investigation may move into areas not antici-

On The Front Lines

Continued from page 5

pated by the provider or expand beyond the issue self-disclosed. The facts of the matter and the approach of the official will influence how this develops. There is very little way to control this risk other than the provider being sure that it has an active auditing and monitoring program so that if the investigation is expanded, it does not stray into areas the provider has not analyzed for risk.

A. A range of outcomes

The best outcome for a provider is if a refund is approved and the straight overpayment is returned without fines, penalties or interest. This outcome happens more frequently than providers realize. Penalties associated with the voluntary disclosure can range in severity. The lightest form of a penalty is the assessment of interest.

Certainly the most severe penalty that the government can impose (other than criminal sanctions and imprisonment) is exclusion from the Medicare Program. Voluntary disclosures often do not end in exclusion from Medicare if the provider cooperates and is sincere about correcting its errors. However, the OIG has the authority for permissive exclusion if it judges the circumstances to be very serious.

B. Corporate Integrity Agreement

If the government assesses penalties under the False Claims Act or the Civil Monetary Penalties Act, the most common resolution is for the provider to enter into a settlement agreement with the local USAO or Department of Justice and the OIG. In conjunction with a settlement agreement, the OIG usually requests that the provider enter into a CIA or a CCA.

When the OIG first began requiring CIAs as a condition of settlement it was in the context of using its leverage to exclude providers from the Medicare Program. As a condition for not excluding the provider from Medicare, the OIG offered a CIA as part of a settlement. CIAs have now become fairly common practice as parts of settlements and resolutions of suspected violations of the FCA. The OIG publishes the CIAs with the providers' names on its websites.

A CIA typically lasts from three to five years and involves strict timelines for bringing the provider's compliance program to a level the OIG believes is sufficient to control risk of false claims. A CIA usually will have a timeline for training employees, adopting new policies and performing audits and also usually requires independent review organizations to audit the provider at least annually and provide the report to the OIG. A CIA has severe penalties for any violations during the course of the term of the agreement. CIAs can cover the whole institution and all billing to Medicare or the CIA may be focused on the specific problem or department that gave rise to the issue.

C. Certificate of Compliance Agreement

Recently, the OIG has offered providers an alternative to a CIA. The CCA is considerably less onerous than a CIA and does not require an independent review organization to audit the institution. At its core, a CCA requires the provider to certify that the essential elements of its compliance program are maintained and that the specific problems that gave rise to the compliance issue are addressed. A CCA usually requires the compliance officer to certify the compliance program elements annually, as well as to submit an annual report that chronicles the overpayments received by the organization during the course of the year. There may also be certain material events that need to be reported to the OIG during the course of the year prior to the annual report. A CCA may also contain a declaration (by a senior administrator of the provider, such as the CEO) that the elements of the compliance program are in place at the time of the signing of the document and a commitment to maintain the current level of resources for the compliance program. Like a CIA, a CCA contains severe penalties for violating the terms. The OIG places some of its CCAs on its website. Providers with effective compliance programs should consider making the case that a CIA is not warranted and that a CCA is more suited to the situation.

3. Lessons learned: How to be prepared

When a provider needs to make a voluntary disclosure, it usually does not have time to pause and place everything in order within the organization, to do comprehensive audits and "look under every rock," so to speak. When the provider knows it has received an overpayment it must act to return the overpayment in a timely fashion. The provider usually cannot wait to be comfortable that there are no other issues that the government can find.

Consequently, it is absolutely critical that a provider have a good auditing and monitoring system in place. Instituting a comprehensive and active auditing and monitoring system not only helps to demonstrate that the provider has an effective compliance program, but provides the provider with information as to its risk exposure. Acting swiftly with a voluntary disclosure is less worrisome when the organization has been auditing and monitoring its risk and maintaining its compliance controls.

Ryan D. Meade is an attorney with the law firm of Meade & Roach, LLP in Chicago, Illinois. He focuses his practice entirely on health care regulatory issues and has facilitated several voluntary disclosures. Mr. Meade is an adjunct professor of law at Loyola University Chicago School of Law's Institute for Health Law, where he teaches Medicare law. He is also an assistant professor at Rush University's College of Health Sciences. Mr. Meade can be contacted at RMeade@MeadeRoach.com.

1 63 Fed Reg. 58399, October 30, 1999, (see ¶156,019).

2 Id. at 58401-58402.

3 Id. at 58400.

4 Reckless disregard for the truth of the claim is one of the standards available to the government to argue in support of fines and penalties for violations of the federal False Claims Act, 31 USC §3729, (see ¶10,120).

Antitrust

PHO ordered to notify FTC of messenger role

by Andra Popa, J.D., LL.M

A physician-hospital organization (PHO) has been ordered to notify the Secretary of the Federal Trade Commission (FTC) in writing 60 days before entering into any agreement with physician or medical goup practices under which the PHO would act as a messenger due to alleged collective negotiations with payors. The PHO allegedly engaged in repeated instances of collective negotiations with insurance companies that allegedly effected and restrained trade unreasonably and hindered competition in the county in which the PHO is located, resulting in the possible violation of Section 5 of the FTC Act, 15 U.S.C. § 45.

The PHO stated that its contracting method was based on the "messenger model," under which an insurer is permitted to submit a contract offer to a messenger who delivers the offer to a group of physicians who in turn submit individual offers or counteroffers to the messenger as to the price of their services. The messenger may inform the insurer as to the number of physicians in each speciality who accepted the offer or made a counteroffer, but is strictly prohibited from coordinating the physicians' offers or counteroffers into a collective response to the insurance company.

The PHO, however, allegedly polled its physician members to determine the fee amount that they expect from insurance contracts. In several contract negotiations, the PHO allegedly did not transmit the offers to their members for the required individual acceptance or rejection. In a specific instance, the PHO allegedly included a single fee schedule labled "members aggregated fee expectations" in response to an insurer's offers to the PHO. Given the alleged dominant position of the PHO in its county, the negotiation methods of the PHO have allegedly raised the prices insurance companies paid to its physician members. The consent order expires on September 19, 2025. ■

In the Matter of Partners Health Network, Inc., Docket No. C-4149, September 19, 2005, ¶650,027.

Trends

Gainsharing implicates fraud and abuse, official testifies

by John Scorza

Gainsharing arrangements can result in hospital savings, but without changes to current law the arrangements by their nature implicate fraud and abuse, the Health and Human Services Department's Chief Counsel to the Office of Inspector General (OIG) testified at a recent congressional hearing.

Gainsharing, as described by Chief Counsel Lewis Morris, typically refers to procedures in which hospitals give doctors a share of reductions in the hospitals' costs attributable in part to the doctors' efforts. Morris, testifying on October 7 before the House Ways and Means Health Subcommittee, offered examples of gainsharing arrangements. These include narrowly targeted arrangements that give doctors financial incentives to reduce the use of specific medical devices and supplies or to adopt clinical practices that reduce costs. Other more problematic arrangements, Morris testified, offer physician payments to reduce total average costs per case below target amounts.

There are systemic impediments to full cooperation between doctors and hospitals, including separate Medicare payment systems for hospitals and doctors. Also, Morris noted, the OIG's office has historically been wary of gainsharing arrangements because they implicate the Civil Monetary Penalty (CMPs) and the federal Anti-kickback Statute. Additionally, there may be physician self-referral implications under Stark laws, an area regulated by the Centers for Medicare and Medicaid Services.

The CMP Act prohibits hospitals from encouraging doctors, through direct or indirect payments, to reduce or limit clinical services. Ahospitals' payment, Morris explained, does not have to be tied to an actual reduction in services if the hospital knew the payment could induce doctors to reduce services. Gainsharing arrangements also may violate anti-kickback prohibitions if a purpose of the cost-savings payments is to influence referrals of federal health care program business, such as sending healthier patients to hospitals that offer gainsharing while sending sicker, more costly patients to hospitals without gainsharing arrangements, Morris said.

Morris said that when evaluating a particular gainsharing program, his office generally focuses on three aspects: accountability, quality controls and safeguards against payments for referrals. Transparent arrangements that clearly identify the actions that will result in cost-savings promote accountability. On quality of care, Morris said, for instance, it is important to have a qualified, outside and independent party perform a review of each cost-savings measure to assess potential impact on patient care. Regarding safeguards against payments for referrals in violation of anti-kickback statutes, Morris said regulators will focus on how payments are calculated and distributed to doctors. Every evaluation of a gainsharing arrangement, Morris stressed, is fact-specific. ■

CCH Washington Bureau, October 7, 2005.

Recent developments in gainsharing

by Paul Danello, J.D.

ASPEN PUBLISHERS

In a series of three excerpts from the *2006 Health Law and Compliance Update*, published by Aspen Publishers, Mr. Danello provides a detailed analysis of gainsharing. In Part II of the series, Mr. Danello focuses on recent developments.

In its March 2005 recommendations to Congress the Medicare Payment Advisory Commission (MedPAC) called for pay-for-performance quality incentives in Medicare payments to hospitals, physicians, and home health agencies. In 2003, MedPAC released similar recommendations for Medicare managed care plans and dialysis facilities. MedPAC said Medicare pay-for-performance quality incentives across all sectors should include: (1) availability of well-accepted measures; (2) ability of most providers or plans to improve; (3) incorporation of risk-based adjustment; and (4) reasonable burden on CMS and providers. MedPAC says CMS should earmark between 1% and 2% of Medicare payments to pay bonuses to providers that meet specific quality measures. The quality incentives would take into account the severity of patients' illnesses. Many expect that the pay-for-performance payments will eventually total 20%-25% of Medicare payments.

"MedPAC says CMS should earmark between 1% and 2% of Medicare payments to pay bonuses to providers that meet specific quality measures."

The current Medicare physician payment system - called the sustainable growth rate (SGR) formula - resulted in recent reductions in Part B payments, some of which were averted by Congress. CMS is positioning pay-for-performance as a means to cover the emerging gap. Payments declined by 5.4% in 2002. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 replaced cuts of 4.5% in 2004 and 3.3% in 2005 with 1.5% hikes and made other adjustments to the payment system. Without additional actions, a cut of about 5% is predicted for 2006.

The American Medical Association (AMA) recently released a new "white paper" to get physicians ready for pay-for-performance. The report says pay-for-performance is a "tsunami building offshore in a sea of stakeholder unrest, threatening those who are not prepared." The AMA is concerned that, by expecting quality improvement initiatives to be budget neutral, payments would be improved to some physicians but reduced to those who cannot afford the investments since quality improvement programs require investments in new technology and personnel. On February 10, 2005, an AMA representative told the House Ways and Means Subcommittee on Health Programs that financial incentives to physicians for improvements in quality of care should not be undertaken until the SGR formula is changed.

MedPAC agreed that the SGR formula, which compares actual spending to target spending and adjusts the update on that basis, is flawed but recommends that Congress change it "in a major, thoughtful way toward pay-for-performance":

- Adjust payments based on physicians' ability to collect and use types of information that could improve quality of care, such as identifying and coordinating care for chronically ill patients.
- Pay physicians based on their use of clinical standards or evidence-based standards of care.

On May 11, 2005, Senators Chuck Grassley, the chairman of the U.S. Senate Committee on Finance, and Max Baucus, the ranking member of the Committee, introduced new legislation, captioned as the "Hospital Fair Competition Act of 2005," that would grant authority to the Secretary of HHS to regulate and approve gainsharing arrangements, known in the legislation as "coordinated care incentive arrangements." The legislation would direct the Secretary of HHS to establish criteria under which hospitals and physicians could align incentives and benefit from hospital cost-containment measures, as long as financial incentives affecting physician referrals are minimized and such arrangements do not compromise quality of care. It would also amend the Stark Law, the Anti-Kickback Statute, the Civil Monetary Penalties Law to create special legislative exemptions and safe harbors for gainsharing "coordinated care incentive arrangements" that have been approved by the Secretary of HHS. ■

Paul F. Danello, Ch. 10, "Analysis of Gainsharing in OIG Advisory Opinions 05-1 to 05-6 and Other Recent OIF and CMS Guidance," 2006 Health Law and Compliance Update, J. Steiner, ed. (Aspen Publishers 2005). Aspen's Health Law and Compliance Update brings you the latest information on emerging issues in health law every year. Each article is authored by an expert in the area and includes analysis of the latest cases and statutes.

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