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Medicare demonstrations show financial incentives work

Demonstration projects conducted by CMS provide strong evidence that financial incentives for delivering quality care increases quality and can reduce the growth in Medicare expenditures. CMS has announced results from three such demonstrations, one for large physician practices, one for small and solo physician practices, and one for hospitals. CMS has also announced the start of three additional value based purchasing (VBP) demonstrations.

The Hospital Quality Incentive Demonstration (HQID), entering its fifth year, shows continued quality improvement among its participating hospitals. Physician practices participating in the Physician Group Practice (PGP) Demonstration continue to improve quality for patients with chronic illnesses or requiring preventive care. More than 560 small and solo physician practices participating in the Medicare Care Management Performance (MCMP) Demonstration are being rewarded for providing high quality care in the delivery of preventive care and care for chronic disease patients.

HQID project. The HQID is sponsored by Medicare in partnership with Premier, Inc., a national hospital quality measurement organization. The demonstration, which began in 2003, was designed to see if payment incentives would improve the safety, quality, and efficiency of inpatient services. Participants raised overall quality by an average of 17 percentage points over four years, based on more than 30 nationally standardized and widely accepted care measures for patients in the clinical areas of heart attack, coronary bypass graft, heart failure, pneumonia, and hip and knee replacements. CMS is awarding incentive payments totaling $12 million in year four to 225 hospitals for top performance, top improvements, and overall achievement in these five clinical areas. Through the first four years, CMS awarded more than $36.6 million to top performers. After the first three years, CMS extended the project for three additional years to test new incentive models and ways to improve patient care.

PGP demonstration. All ten of the physician groups participating in the PGP Demonstration achieved benchmark performance on at least 28 of the 32 measures reported in year three of the demonstration. The Geisinger Clinic in Danville, Pennsylvania, and Park Nicollet Health Services in St. Louis Park, Minnesota, achieved benchmark performance on all 32 performance measures. Over the first three years, the physician groups increased their quality scores an average of 10 percentage points on ten diabetes measures, 11 points on ten congestive heart failure measures, 6 points on seven coronary artery disease measures, 10 points on two cancer screening measures, and 1 percentage point on three hypertension measures. Physician groups earn incentive payments based on the quality of care they provide and the estimated Medicare savings for their patient population. As

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a result of their efforts, five physician groups will receive performance payments totaling $25.3 million as part of their share of $32.3 million of savings generated for the Medicare Trust Funds in performance year 3.

MCMP demonstration. In the first year of the MCMP demonstration, almost all of the 610 participating small and solo physician practices are being rewarded for performance on 26 quality measures. CMS is awarding approximately $7.5 million dollars in incentive payments to over 560 practices in California, Arkansas, Massachusetts and Utah. The average payment per practice is $14,000, but some practices earned as much as $62,500. Last year, CMS paid out over $1.5 million in incentives for reporting baseline quality measures. The goal of the demonstration is to promote the use of health information technology to improve the quality of care for beneficiaries with chronic conditions. Doctors in small to medium sized practices who meet clinical performance standards on each measure are eligible to receive financial rewards. The demonstration also provides an additional bonus to practices that report the data using an electronic health record (EHR) certified by the Certification Commission for Health Information Technology. Twenty-three percent of practices were able to submit at least some of the measures from a certified EHR.

New VBP demonstrations. The VBP initiative is designed to tie Medicare payments to performance as part of an effort to transform Medicare from passive payer to active purchaser. The new VBP demonstration programs include: (1) the Nursing Home Value-Based Purchasing (NHVBP) Demonstration, (2) the Medicare Hospital Gainsharing (MHG) Demonstration, and (3) the Physician Hospital Collaboration (PHC) Demonstration. The NHVBP demonstration program will reward facilities that can improve or deliver high quality care in the areas of staffing, resident outcomes, avoidable hospitalizations and reductions in deficiency citations. The MHG and PHC demonstrations will evaluate whether gainsharing leads to improvements in quality and efficiency.

NHVBP demonstration. Nearly 200 nursing homes in three states will participate in the NHVBP demonstration to determine if financial incentives will improve the quality of the care they provide. The demonstration will reward those facilities that improve or deliver quality care in four areas: nurse staffing, resident outcomes, avoidable hospitalizations, and reduction of the scope and severity of deficiency citations the home may have received during inspections. Nursing homes with the highest scores or greatest improvement will become eligible for a performance payment. Savings that result from improved quality and efficiency will be used to fund incentive pools in each state. CMS will conduct the demonstration in 79 nursing homes in New York, 62 in Wisconsin, and 41 in Arizona. The demonstration will run from July 2009 through June 2012, at which time its effectiveness will be evaluated.

MHG demonstration. CMS will operate two demonstrations to evaluate gainsharing as a means of aligning incentives between hospitals and physicians to improve quality of care and overall hospital efficiency. Gainsharing is normally restricted in Medicare's fee-for-service program and occurs when a hospital pays incentives to a physician who assists in saving internal hospital costs while improving quality and efficiency. The MHG demonstration began in October 2008. This demonstration consists currently of the Beth Israel Medical Center in New York City and the Charleston Area Medical Center in West Virginia. CMS will evaluate this demonstration to determine whether gainsharing leads to short-term improvements in quality and efficiency during the inpatient stay and immediately following discharge.

PHC demonstration. The PHC demonstration, comprised of a consortium of twelve hospitals administered by the New Jersey Hospital Association, began in July 2009. This demonstration is designed to track patients beyond a hospital episode to determine the impact of hospital-physician collaborations on preventing short-and longer-term complications and duplication of services. These demonstrations will allow physicians to share in the savings generated by the adoption of structural and procedural changes made to improve the quality of inpatient hospital care.

Information on value-based purchasing demonstrations is available at http://www.cms.hhs.gov/DemoProjectsEvalRpts/MD/list.asp. ■

CMS News Release, Aug. 17, 2009

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State agency subsidy of Part D copayments permissible, OIG

A proposed arrangement under which a state agency would subsidize copayments for outpatient prescription drugs owed by financially needy Medicare Part D enrollees would not constitute grounds for the imposition of civil money penalties or administrative sanctions, according to the Office of Inspector General (OIG). The state agency functions as the planning agency for alcohol, drug addiction, and mental health services.

Facts. Under the arrangement, if a patient is eligible for Medicare Part D, an independent mental health center ("center") contracting with the state agency would determine whether the individual is financially eligible for a Part D copayment subsidy. A patient would be eligible for a Part D copayment subsidy if eligible, on the basis of income and if not a Medicare beneficiary, for subsidized services from the center. If a patient is eligible, the center would inform him or her that the center would pay part or all of the copayment to the pharmacy of the patient's choice for Part D covered medications. The copayment subsidy would not be advertised. When a Medicare beneficiary enrolled in Part D takes a prescription to be filled, the pharmacy bills the beneficiary's Medicare drug plan for the cost of the prescription less the applicable copayment. The pharmacy would then bill the center for the copayment subsidy amount. Funds for the copayment subsidies would be provided by the state agency to the centers. These funds could not be used for any other purpose and at the end of the fiscal year, any amounts not used for copayment subsidies would be returned to the agency. The subsidy payment is not contingent on a beneficiary's choice of any particular Part D plan.

Analysis. Here, the state agency would provide something of value (Part D copayment) to the federal health care program beneficiary. The risk is low, however, that this remuneration would influence the beneficiary to choose any particular provider, practitioner, or supplier because: (1) the copayment subsidy would not be advertised, the beneficiary would be screened for eligibility by the center, and at that time, the beneficiary would have already selected the center as a provider; (2) while the provider may assist the beneficiary in enrolling in a Part D plan, the subsidy is not contingent upon the selection of any particular Part D plan; and (3) payment of the copayment subsidy is not contingent upon the use of any particular pharmacy.

State autonomy. In addition, the OIG notes that the arrangement is part of a comprehensive regulatory scheme to care for the mental health needs of the residents served by the state agency. State law requires the agency to plan and make arrangements for items and services to meet these needs. Failure on the part of financially needy Medicare beneficiaries to obtain prescription drugs from pharmacies may result in additional costs to the state agency and the state's taxpayers, which can be avoided by the copayment subsidies. States and their agencies should have sufficient flexibility to carry out their responsibilities in an efficient and economical manner. ■

OIG Advisory Opinion, No. 09-12, Aug. 7, 2009, Health Care Compliance Reporter, ¶500,217

OIG allows hospital to subsidize affiliated ambulance cooperative

A proposed arrangement under which a hospital would subsidize an affiliated ambulance cooperative to enable the cooperative to provide certain ambulance services currently provided by the hospital would not constitute grounds for the imposition of civil money penalties or administrative sanctions, according to the Office of Inspector General (OIG). The acute care hospital provides various services, including advanced life support (ALS) services, and is the only hospital in its county that has "comprehensive" emergency services capability. The hospital is part of a nonprofit health system, of which the ambulance cooperative is also a member. The cooperative provides ambulance services in the town and surrounding communities. Its members include the hospital and several local volunteer fire companies.

Facts. Under the current arrangement, when the cooperative's basic life support (BLS) ambulance is dispatched together with the hospital's paramedic squad, the cooperative bills the ALS rate, but the hospital does not bill; the cooperative bills the ALS rate when the ALS portion of the ambulance service actually is provided by the hospital paramedic squad, because the cooperative and the hospital are both

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On The Front Lines

Tightening Rules May Loosen Relationships Between Manufacturers and Physicians

by Jeff Miller, J.D.

Manufacturers and physicians around the world strive to provide the highest quality health care products and services to their patients. Relationships between these manufacturers and physicians often include financial arrangements that both facilitate and enhance the quality of medical products and devices and the delivery of high quality patient care services. While well-structured financial relationships support the best patient care, many view manufacturers' financial support suspiciously, warning that it can inappropriately influence physicians' relationships with individual manufacturers and their views of products' uses. The purpose of this article is to provide an introduction to the primary U.S. federal laws as they apply to financial relationships between manufacturers and physicians, and to provide an update on current industry initiatives designed to regulate these relationships.[1]

Legal Requirements

The primary U.S. federal law that governs physician-manufacturer financial arrangements is the federal anti-kickback statute. This statute broadly prohibits what many refer to as bribery - knowingly and willfully offering, paying, soliciting or receiving anything of value with the intent to induce the referral of patients or business. This statute ("Statute") provides criminal penalties for individuals and entities that knowingly and willfully offer, pay, solicit, or receive remuneration with the intent to induce the referral of patients or business that is reimbursed under federal health care programs.[2] "Remuneration" is defined very broadly, and includes any benefit, in any form, with no minimum value required.[3] The benefit can be presented as payments, free product or services, rebates, prebates or benefits of any other kind, made directly or indirectly, overtly or covertly, or in cash or in kind. The basic test of whether enough remuneration is involved is whether the benefit offered has materially influenced the professional clinical judgment of the other party.[4] The government need only show that one purpose of the transaction, and depending upon the jurisdiction, not necessarily its primary purpose, was to induce referrals.[5]

Violation of the Statute is a serious crime. It is classified as a felony, and is punishable for individuals by restitution plus fines of up to $250,000, and imprisonment for up to five years.[6] Corporate penalties can include up to $500,000 in fines, restitution and potentially corporate integrity agreements as conditions of probation.[7] Courtesy of the Medicare and Medicaid Patient and Program Protection Act of 1987, upon conviction, the Office of Inspector General ("OIG") is required to exclude persons or entities from participation in government-related health care programs (e.g., Medicare, Medicaid and TRICARE).[8] Under the Balanced Budget Act of 1997, the OIG also is authorized to levy additional civil monetary penalties of up to $50,000 for each violation.[9] Should the submission of claims to government programs be involved, a government claim for treble damages plus up to $11,000 per claim also could be asserted.[10]

To temper the Statute's prohibition, the U.S. Congress created two categories of exemptions: (1) specific exceptions set forth in the Statute itself; and (2) regulatory safe harbors. The exceptions are specifically defined circumstances that Congress carved out of the Statute as legal, while the safe harbors are specifically defined circumstances for which the OIG has determined it will not pursue liability. Both categories of exemptions are founded upon the underlying purposes of the Statute. According to the OIG, these purposes are five-fold: (1) to ensure that medical decisions are made solely on the bases of appropriate clinical factors, and not on providers' personal financial concerns; (2) to curb over-utilization of federal health care program reimbursed services; (3) to hold down cost increases to federal health care programs; (4) to avoid interference with patients' freedom of choice; and (5) to prevent anti-competitive referral practices.[11] In effect, Congress provided two clear options when addressing arrangements that fall within the Statute's purview: (1) demonstrating that one of the basic elements of the Statute are not satisfied, potentially including that there was and is no intent to induce the referral of patients or business through the arrangement; or (2) satisfying the requirements of one of the Statute's exceptions or safe harbors. When one of these two options is satisfied, the arrangement is protected from prosecution.

Should neither an exception nor a safe harbor cleanly apply, Congress provided one additional option: obtaining formal OIG acquiescence to the arrangement through the Statute's advisory opinion process.[12] Through this process providers can present

the OIG with detailed facts on specific circumstances, obtaining the OIG's formal opinion as to the application of the Statute and the federal Civil Monetary Penalty Law.[13] It is important to note that the advisory opinion process can take nine months or more to complete. If a favorable advisory opinion is obtained, however, the proposal will be insulated from OIG prosecution. On the other hand, if an unfavorable opinion is obtained, the risk of prosecution in pursuing any similar arrangement may be increased.[14] In reviewing advisory opinion submissions the OIG considers the extent to which an exception or safe harbor can be applied, the purposes underlying the Statute, any additional safeguards that providers implement to protect against fraud or abuse and any charitable or public policy concerns. As a result, providers may discover some additional flexibility in the application of the law through this process.[15]

As a criminal statute, the anti-kickback statute requires a showing of knowing and willful behavior "beyond a reasonable doubt." This is a significant limiting factor for prosecution under the Statute. Some federal courts have construed this standard to mean that the defendant must have entered into the transaction with the specific intent to violate the Statute.[16] Others have applied lesser standards, such as knowledge that the conduct was "wrongful"[17] or a "specific criminal intent to induce referrals."[18] Whatever the mental state required, any behavior that evidences a willful blindness, reckless disregard or deliberate ignorance of the facts at issue could be used as evidence to help to satisfy the *mens rea* requirement.[19]

In the context of manufacturer relationships with physicians, value could include paying tuition for courses, funding physician expenses such as travel or lodging, or providing entertainment, meals or gifts. In reviewing these matters, enforcement authorities generally need only show that one purpose of a transaction is to induce business. Violation of the statute is a serious crime. It is classified as a felony, and is punishable by exceedingly large fines and imprisonment for up to five years. Upon conviction, the government is required to exclude persons and/or entities from participation in government-related health care programs (e.g., Medicare, Medicaid and TRICARE).

Arising Issues and Attempted Solutions

For many years manufacturer and physician relationships have been prevalent and have had the potential to result in physician-related conflicts of interest. In a recent attempt to analyze the nature, extent, and consequences of this matter, the Institute on Medicine as a Profession (IMAP) conducted a survey of a large sample of U.S. physicians.[20] Published in the *New England Journal of Medicine* in April, 2007, this survey reported that sixty percent of all physician department chairs had some form of personal financial relationships with industry.[21] Sixty-seven percent of academic-institutional departments, as administrative units, had financial relationships with industry, including sixty-five percent of all clinical departments benefiting from the support of continuing medical education. As demonstrated in this survey, the influx of industry support for continuing medical education appears to be pervasive.

The considerable support that industry has provided for physicians has not gone unnoticed by physician associations. Not surprisingly, physicians were the first to react to allegations that industry support of physician education could create conflicts of interest that would compromise patient care. As early as 1992, the American Medical Association (AMA) began issuing guidelines for its member-physicians regarding the receipt of financial support for continuing medical education.[22] While approving of the acceptance of this support as "contributing to the improvement of patient care," the AMA nevertheless warned physicians that the acceptance of any financial support personally could influence, or appear to influence, the physicians' use of industry products. As a result, physicians were advised not to personally accept financial support to attend CME events. Instead, all financial support from manufacturers should be provided to the organization providing the CME event, which may in turn use the funds to defray the costs of the event. To further guard against inappropriate influence or appearance, the AMA also advised that financial subsidies should not be accepted, directly or indirectly, to pay for the costs of physicians' travel, lodging or other personal expenses, nor for physicians' time. Subsidies for hospitality should only be accepted for modest meals or social events that are held as part of the conferences or meetings.

Following or consistent with the AMA's lead, many other physician professional associations adopted ethical standards governing relationships between manufacturers and physicians. These associations and ethics standards include:

- the American Academy of Facial Plastic and Reconstructive Surgery ("AAFPRS") Code of Ethics,[23]
- the American Academy of Orthopaedic Surgeons ("AAOS") Opinions on Ethics and Professionalism,
- the Orthopaedic Surgeons Relationship with Industry, Issues Raised,[24]
- the American College of Emergency Physicians ("ACEP") Code of Ethics for Emergency Physicians,[25]
- the American College of Healthcare Executives ("ACHE") Considerations for Healthcare-Executive Supplier Interactions,[26]
- the American College of Obstetricians and Gynecologists ("ACOG") Code of Professional Ethics,[27]
- the American College of Rhuemetology ("ACR") Code of Ethics,[28]
- the American Osteopathic Association ("AOS") Code of Ethics,[29]
- the North American Spine Society ("NASS") Code of Ethics,[30] among others.

On the manufacturer side, industry associations have also worked to develop guidelines for their members. In 2002, the Pharmaceutical Research and Manufacturers Association of America (PhRMA)

developed and published a code of conduct governing academic-institution industry relationships.[31] Entitled the "Code of Interactions with Healthcare Professionals" ("PhRMA Code"), this code supports pharmaceutical companies in their efforts to provide financial support for CME events, proffering that such support "contributes to the improvement of patient care."[32] Reflecting its continuing commitment to compliance with the law and to policies and practices that best serve the needs of patients and its members, PhRMA updated and enhanced the PhRMA Code effective January 1, 2009.

Similarly recognizing that "adherence to ethical standards and compliance with applicable laws are critical to the medical device industry's ability to continue its collaboration with health care professionals,"[33] the medical device industry entered the fray as well. On January 1, 2004, the Advanced Medical Technology Association ("AdvaMed") created its own set of guidelines specifically designed for medical device manufacturers.[34] These guidelines, known as the Code of Ethics on Interactions with Health Care Professionals ("AdvaMed Code"), were generated to help to ensure that medical device company financial support for physician education served the goals of quality patient care and patient safety.

On December 18, 2008, following the PhRMA's update to its Code, AdvaMed approved a significant update to the AdvaMed Code that became effective July 1, 2009. The AdvaMed Code update helped to further clarify and distinguish between appropriate and inappropriate activity between physicians and other health care professionals and representatives of AdvaMed member companies, among other goals.

Similar in their intent and content, these industry codes generally provide a series of limitations and safeguards related to manufacturer and physician financial relationships.

Congressional Inquiry and Reports

Despite the voluntary promulgation of guidelines and limitations by these organizations, this issue has been and appears to be headed towards a boiling point in the halls of the United States Congress. In June, 2005 Senators Max Baucus (D-Mont.) and Charles Grassley (R-Iowa), Chairman and Ranking Member of the Senate Committee on Finance, began formal inquiries of the twenty-three largest drug manufacturers in the U.S. following allegations that they were utilizing educational grants to promote off-label uses for their medications.

This past April, the U.S. Senate Committee on Finance released a committee staff report to the Chairman and Ranking Member on the use of educational grants by pharmaceutical manufacturers. In the report, the committee staff concluded that while the pharmaceutical industry is paying increased attention to its compliance with federal law, some CME events, and their associated physicians, are still improperly influenced by industry sponsors. Supporting its conclusions, the report cited several specific instances of improper influence, including a 2004 instance in which Warner-Lambert paid $430 million to settle allegations that it funded purportedly independent educational events to promote its anti-epilepsy drug, Neurotin, for off-label uses, and a 2005 instance in which Serono Laboratories paid $704 million to settle allegations that it engaged in the same improprieties related to its drug, Serostim. Both pharmaceutical and medical device investigations, prosecutions and settlements continue to this day.

Conclusion

Manufacturers and physicians around the world strive to provide the highest quality health care products and services to their patients. Relationships between these manufacturers and physicians often include financial arrangements that both facilitate and enhance the quality of medical products and devices, and the delivery of high quality patient care services. The U.S. Government, professional associations and industry groups continue to focus on these important relationships to ensure that they facilitate the best quality patient care.

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1 This article is not intended to provide legal advice, and should not be used for that purpose.

2 42 U.S.C. § 1320a-7b(b).

3 See 56 FR 35952 (July 29, 1991) (describing the applicable standard as "to lead or move by influence or persuasion").

4 See letter dated May 20, 1991 from Richard P. Kusserow, Inspector General to Paul C. Rettig, Executive Vice President of the American Hospital Association (asserting that case law "makes it clear that the Statute's prescriptions apply to those who can materially influence the flow of Medicare and Medicaid business").

5 See *United States v. Greber*, 760 F.2d 68 (3rd Cir.), *cert. denied*, 474 U.S. 988, 106 S.Ct. 396 (1985) (the intent standard is satisfied if the payment made is at least in part for the purpose of inducing referrals); *compare United States v. Bay State Ambulance*, 874 F. 2d 20 (1st Cir. 1989) (the intent standard is satisfied only if the primary purpose of the payment is to induce referrals).

6 42 U.S.C. § 1320a-7b(b); 18 U.S.C. § 3571. Actual sentences are set in accordance with the Federal Sentencing Guidelines. United States Sentencing Commission, *Guidelines Manual*, § 3E1.1 (Nov. 2003).

7 42 U.S.C. § 1320a-7b(b)(2)(A); 18 U.S.C. § 3571.

8 42 U.S.C. § 1320a-7(a).

9 42 U.S.C. § 1320a-7a.

10 Citing providers' general certifications that all claims are "in compliance with the law," the government has alleged (and some jurisdictions have agreed) that violations of the Statute could result in liability under the federal False Claims Act on the theory that the satisfaction of the Statute's requirements is material for program reimbursement. 31 U.S.C. § 3729(a). See *Thompson v. Columbia/HCA*, 125 F.3d 899 (5th Cir. 1997).

11 See "Briefing: Safe Harbor Regulations," Office of Inspector General, Department of Health and Human Services, August 6, 1991.

12 42 C.F.R. § 1008.47. Requestors are required to pay a $250.00 filing fee and reimburse the OIG for all of its costs incurred in issuing an opinion.

13 42 U.S.C. § 1320a-7a.

14 The failure to seek an advisory opinion cannot, by regulation, be used by the government as evidence to prove wrongful intent. 42 C.F.R. § 1008.55(a).

15 An analysis of OIG Advisory Opinions appears to reveal that the OIG exempts some arrangements based primarily upon certain charitable, public policy factors, often centered on supporting the continued provision

of historically provided charitable care. See OIG Advisory Opinion 02-11; OIG Advisory Opinion 02-1. Additionally, while the OIG may not specifically address these same concerns in its analyses of each Anti-kickback Statute exception and safe harbor, it also appears that it does weigh these factors when determining whether or not an exception or a safe harbor is satisfied. See "Briefing: Safe Harbor Regulations," Office of Inspector General, Department of Health and Human Services, August 6, 1991.

16 *Hanlester v. Shalala*, 51 F.3d 1390 (9th Cir. 1995).

17 *United States v. Jain*, 93 F.3d 436 (8th Cir. 1996).

18 *United States v. LaHue and Anderson*, 261 F.3d 993 (10th Cir. 2001). See also *United States v. McClatchey*, 217 F.3d 823 (10th Cir. 2000) ("purposely intending to violate the law").

19 *United States v. Wert-Ruiz*, 228 F.3d 250 (3rd Cir. 2000).

20 More information on IMAP can be found on its website at www.imapny.org.

21 Campbell EG et. al., *A National Survey of Physician-Industry Relationships*, New England Journal of Medicine, vol. 356 pgs. 1742-50 (April 26, 2007).

22 AMA Ethical Opinions/Guidelines, E-8.061, Gifts to Physicians from Industry, *available at* http://www.ama-assn.org/ama/pub/category/4001.html.

23 http://www.aafprs.org/Code_Of_Ethics.pdf.

24 http://www.aaos.org/about/papers/ethics/1204eth.asp.

25 http://www.acep.org/practres.aspx?id=29144.

26 http://www.ache.org/policy/execsuppliers.cfm.

27 http://www.acog.org/from_home/acogcode.pdf.

28 http://www.rheumatology.org/about/codeofethics/index.asp?aud=mem.

29 http://www.osteopathic.org/index.cfm?PageID=aoa_ethics.

30 http://www.spine.org/Pages/PracticePolicy/Default.aspx.

31 More information on PhRMA can be obtained from its website at www.phrma.org.

32 PhRMA Code of Interactions with Health Care Professionals, Introduction (July 1, 2002), *available at* http://www.phrma.org/files/PhRMA%20Code.pdf.

33 Code of Ethics on Interactions with Health Care Professionals, Section 1 (January 1, 2004), *available at* http://www.advamed.org/NR/rdonlyres/FA437A5F-4C75-43B2-A900-C9470BA8DFA7/0/coe_with_faqs_41505.pdf.

34 More information on AdvaMed can be obtained from its website at www.advamed.org.

members of the health system and subject to the health system's global budget. As a result of this and other billing practices, the hospital recoups only half of the cost of providing ALS services through Medicare and other payers. In contrast, under the proposed arrangement, responsibility for providing the ALS services provided by the hospital and the BLS services provided by the cooperative would be consolidated in the cooperative.

Analysis. The proposed arrangement would continue an essential service to the community—ALS ambulance services—currently provided by the hospital at a financial loss. The risk of kickback abuse from the proposed arrangement is low because: (1) the cooperative and its members would receive no benefit from the proposed arrangement; (2) the hospital's donations to the cooperative would not vary with the volume or value of referrals to the hospital by the cooperative; (3) the cooperative and the volunteer fire companies are not in a position to affect referrals in a significant way; and (4) any risk posed by the proposed arrangement is offset by the fact that there are no for-profit ambulance services in the county, given the expense of operating an ambulance service in a sparsely-populated area, and the fact that ALS ambulance services cannot be provided unless subsidized by the hospital. ■

OIG Advisory Opinion, No. 09-13, Aug. 11, 2009, Health Care Compliance Reporter, ¶500,218

CMS offers guidelines regarding electronic health records

HHS and CMS support the use of electronic health records (EHR), and their goal is that by 2014 most Americans will have access to health care providers who use EHRs. The benefits of EHRs include better patient care, and reduced costs to providers, Medicare and Medicaid. Presently, providers are permitted to use any system of medical records that best suit their needs, including paper and/or electronic systems.

State survey agencies are responsible for enforcing various conditions of participation (CoPs), conditions for coverage, or conditions for certification (CfCs). Toward that end, providers must grant access to any medical record when requested by a surveyor. Surveyors must establish with the facility the process they will follow to have unrestricted access to the medical records. If a surveyor requests access to an EHR, the facility must, among other things, provide the surveyor with a tutorial on how to use its particular electronic system, and designate an individual who will, upon request, assist the surveyor in accessing the electronic information. The facility must also be able to provide a paper copy of any record, regardless of whether the records are stored in paper or electronic form. In turn, surveyors should make reasonable efforts to avoid the printing of entire records, and should request paper copies of only those records that are necessary to verify noncompliance, unless protocols require otherwise. Refusing access to any medical record is a basis for terminating the facility's Medicare agreement.

While providers are required to maintain the content and confidentiality of the medical records, surveyors are not expected to review whether the facility has fulfilled its obligations under the Health Insurance Portability and Accountability Act. Rather, they should review how the EHR system is being used, and whether that use is consistent with the Medicare CoPs or CfCs. ■

CMS Letter to State Survey Agency Directors, No. S&C-09-53, Health Care Compliance Reporter, ¶350,173

Health IT

$1.2 billion in grants for use of electronic health records

Vice President Joe Biden announced on August 20, 2009, that nearly $1.2 billion in grants will be available to (1) help hospitals and health care providers implement and use electronic health records (EHRs), and (2) help health care providers qualify for new incentives that will be made available in 2010 for doctors and hospitals that meaningfully use EHRs. According to HHS Secretary Kathleen Sebelius, "[EHRs] can help reduce medical errors, make health care more efficient and improve the quality of medical care for all Americans."

The grants, which would be funded by the American Recovery and Reinvestment Act of 2009, include: $598 million to establish approximately 70 Health Information Technology Regional Extension Centers, which will provide hospitals and clinicians with hands-on technical assistance in the selection, acquisition, implementation, and meaningful use of certified EHR systems; and $564 million to states and Qualified State Designated Entities to support the development of mechanisms for information sharing within a nationwide system of networks.

The grants for the Regional Extension Centers will be awarded on a rolling basis, with the first awards being issued in fiscal year 2010. The grants for states will be issued in fiscal year 2010. Interested grant applicants can visit http://HealthIT.HHS.gov for more information.

HHS will also provide additional assistance to health care providers through the Health Information Technology Research Center, which will gather relevant information on effective practices from a wide variety of sources across the country, and help the Regional Extension Centers collaborate with one another and with relevant stakeholders to identify and share best practices in EHR adoption, effective use, and provider support. ■

CCH Chicago Bureau, Aug. 20, 2009

In the News

Breach notification rule for unsecured PHI issued

In response to the American Recovery and Reinvestment Act of 2009 requirement that covered entities under the Health Insurance Portability and Accountability Act (HIPAA) and their business associates provide notification when there is a breach of unsecured protected health information (PHI), effective September 23, 2009, vendors of personal health records and other related entities must notify individuals, the media and the Secretary when the security of electronic health information has been breached. The HHS final rule differentiates between entities operating as HIPAA covered entities and business associates subject to the HHS breach notification rule, as opposed to the FTC version. In the rare instance where an entity may be subject to both rules, the regulations now reflect the same or similar requirements, within the parameters of the statutory language. Comments on the provisions of the final rule are required on or before October 23, 2009.

Final rule, 74 FR 42740, Aug. 24, 2009, Health Care Compliance Reporter, ¶700,229

New ASC survey process to prevent HAIs

The reduction of healthcare-associated infections (HAIs) in ambulatory surgical centers (ASCs) through better survey processes are the focus of $10 million of the $50 million appropriated to reducing HAIs by the American Recovery and Reinvestment Act of 2009 (PubLNo 111-5) (ARRA). The 2008 Hepatitis C outbreak in Nevada stemmed from ASCs, and follow-up surveys in Nevada found serious deficiencies in 64 percent of the ASCs surveyed. The ARRA funds are intended to be used for (1) executing and implementing HAI reduction strategies, (2) state prevention activities, and (3) improving state oversight. The improved survey process would improve inspection by survey agencies and the frequency of surveys, implement a new survey tool, improve the survey process through use of CMS tracer methodology, and even use multi-person teams when surveying ASCs.

CMS Announcement, Aug. 19, 2009, Health Care Compliance Reporter, ¶350,175

EMTALA clarified for H1N1 flu outbreak

A fact sheet has been released regarding Emergency Medical Treatment and Labor Act (EMTALA) requirements for emergency departments (EDs) in anticipation of an increase in demand for services stemming from the H1N1 influenza outbreak. State survey agencies (SAs) are asked to distribute the fact sheet to providers and public health officials charged with emergency preparedness, to address the concerns raised in the community regarding the ability to comply with EMTALA requirements during an outbreak and to inform them that there is flexibility under the EMTALA requirements. Among the other options available to EDs described in the fact sheet, the medical screening examination, for example, may take place outside the ED and does not require an extensive work-up in every case.

CMS Memo to State Survey and Certification Agencies, Aug. 14, 2009, Health Care Compliance Reporter, ¶350,172