

# Healthcare Law Bulletin



A summary of recent developments provided by the healthcare law firm Garfunkel, Wild & Travis, P.C.

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## NEW PhRMA CODE OF CONDUCT PUBLISHED TODAY

BY: JESSICA M. SPERLING

The Pharmaceutical Research and Manufacturers of America (“PhRMA”), the leading trade association for the pharmaceutical industry, released its revised Code on Interactions with Healthcare Professionals (the “Code”), which is substantially more restrictive than its 2002 predecessor. The Code outlines standards of conduct for pharmaceutical representatives’ relationships with healthcare professionals.

Effective January 1, 2009, the Code prohibits drug makers from distributing free “reminder” or non-educational items, such as pens and mugs, to healthcare providers. However, the representatives are permitted to distribute educational items if they are of modest value (i.e., \$100 or less) and if such items are only valuable and relevant to health care professionals within the scope of their professional duties (e.g., anatomical model).

Further, the Code states that drug manufacturers who provide funding for continuing medical education (CME) should not allow their own inter-

ests influence or impede upon the contents of the CME program, and also manufacturers should not provide meals at CME events. Additionally, the Code requires that drug companies limit the total annual compensation paid to company speakers as well as establish policies regarding the use of speakers and consultants.

While compliance with the Code is voluntary for PhRMA members, as of January 1 of next year, the Code will require chief executive officers of drug companies to certify that they have processes in place to comply with the Code. Those companies who submit such certification will be identified by PhRMA on its website.

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## SIGNIFICANT CHANGES PROPOSED TO THE MEDICARE ANTI-MARKUP RULE

BY: JACQUELINE H. FINNEGAN

On July 7, 2008, the Centers for Medicare & Medicaid Services (CMS) published proposed changes to the Medicare Physician Fee Schedule for 2009 (“2009 PFS Proposed Rule”) in the Federal Register. As in previous years, the 2009 PFS Proposed Rule includes significant proposed changes to Medicare payment policies, including proposed changes to the anti-markup rule for purchased diagnostic tests. CMS is accepting comments on the 2009 PFS Proposed Rule until August 29, 2008, and will respond to those comments in a final rule to be issued by November 1, 2008. The revised policies and payment rates will become effective January 1, 2009.

CMS offers two alternative proposals to

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clarify the anti-markup rule. Under the first proposal, CMS would remove any site-of-service requirement, thus alleviating concerns that the definition of “office of the billing physician or other supplier” contained in the anti-markup rule was more restrictive than the Stark Law’s “same building” test under the in-office ancillary services exception. Under this proposal, the anti-markup rule would apply in all cases where the technical component (TC) or professional component (PC) of a diagnostic testing service is either (i) purchased from an outside supplier, or (ii) performed or supervised by a physician who does not share a practice with the billing physician or physician organization. A physician will be considered to “share a practice” with the billing physician or physician organization if he or she is employed by or contracts only with that physician organization or physician (regardless of whether it is on a full-time or part-time basis). In contrast, a physician who is an employee of, or independent contractor with, more than one billing physician or physician organization would not be deemed to share a practice with any of the physicians or physician organizations with which he or she is affiliated, and therefore the TC or PC would be subject to the anti-markup rules.

Under the second proposal, CMS would keep the site-of-service requirement (*i.e.*, *that the anti-markup rule would apply* is the TC or PC of a non-purchased test is performed outside the “office of the billing physician or other supplier”), but the definition of “office of the billing physician” would be revised to conform certain aspects of the rule to the Stark Law by including diagnostic services furnished in the same building as the billing physician’s office, even if services are furnished on different floors (provided that applicable supervision requirements are met). CMS also proposes to clarify that, with respect to the TC, the anti-markup provision applies if the TC is either conducted or supervised outside of the office of the billing physician or other supplier. CMS takes the position that the “performance” of the TC includes both the technician’s work in conducting the test and the physician’s supervision of the technician.

CMS is also proposing to clarify that the TC of a diagnostic test would not be purchased from an

outside supplier if the TC is both conducted and supervised in the office of the billing physician or other supplier and the supervising physician is an employee or independent contractor of the billing physician or other supplier. Thus, the emphasis is on the physician supervising the test, not the technician’s employment relationship with the billing physician or supplier.

Where the anti-markup provision applies, Medicare payment to the billing physician or other supplier is limited to the lowest of the following amounts:

- The fee schedule amount for the test that would be allowed if the performing supplier billed directly
- The billing physician or other supplier’s actual charge; or
- The performing supplier’s net charge to the billing physician or other supplier.

CMS also proposes to clarify that the “performing supplier” of the TC is the physician who supervised the TC, and the “performing supplier” of the PC is the physician who performed the PC. Therefore, where the anti-markup provision applies, the billing physician or other supplier would need to determine what it paid the physician for supervising the TC or for performing the PC. This proposed “clarification” in combination with the anti-markup rule’s requirements for calculating net charge at 42 C.F.R. § 414.50(a)(92)(ii) severely limits the amount of reimbursement the billing physician or supplier can collect from Medicare. If the amount that the purchaser can bill is limited to the amount that such purchaser paid the physician for supervising the TC or performing the PC, the purchaser would be unable to recoup payment for any other expenses related to the diagnostic test, such as the purchaser’s overhead expenses related to the equipment, space, or personnel. CMS is expressly seeking comments on whether it should allow some overhead costs to be recovered and how it should provide regulatory guidance for calculating the net charge for the PC when the anti-markup rule applies.

## OIG GIVES GREEN LIGHT FOR GIFT CARDS FOR SERVICE SHORTFALLS

BY: JESSICA M. SPERLING

In a recent advisory opinion issued on June 27, 2008 by the Department of Health and Human Services's Office of Inspector General (the "OIG"), the OIG approved of the Requestor's proposal to offer \$10 gift cards to patients dissatisfied with certain services.

The Requestor, an integrated delivery health system, proposed to establish a program to manage and resolve patient complaints. Specifically, the program would offer patients who experienced service shortfalls, such as excessive wait times, gift cards through a gift certificate service. The ten dollar (\$10) gift cards would be redeemable at certain local vendors (e.g., restaurants or movie theaters) and not at any health care vendor (e.g., a pharmacy). The program would not be advertised, and the cards would not be redeemable for cash or health care items or services. Additionally, the Requestor would have a tracking system in place to ensure that the same patient did not receive multiple cards in excess of \$50 in value in one year. The tracking system would also provide the time, location and frequency of the issuance of gift cards, enabling managing employees to respond and resolve the underlying service issues.

Because of the above cited safeguards, the card's nominal value, and the fact that the cards were not redeemable for cash or cash equivalents, the OIG determined that it would not impose civil monetary penalty sanctions, nor would it impose administrative sanctions under the Anti-Kickback Statute.

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## PROVIDENCE TO PAY \$100,000 FOR LOST LAPTOPS

BY: JESSICA M. SPERLING

In a groundbreaking enforcement action, the United States Department of Health and Human Services ("HHS") entered into a Resolution Agreement with Providence Health and Services ("Providence"), a Seattle based health system, to

settle alleged violations of the Health Insurance Portability and Accountability Act ("HIPAA") Privacy and Security Rules.

The Resolution Agreement stems from several incidents involving two entities within the Providence, Providence Home and Community Services and Providence Hospice and Home Care. Between September 2005 and March 2006, backup tapes, optical disks and laptop computers containing unencrypted protected health information ("PHI") were removed from these two Providence's facilities, left unattended and eventually lost or stolen. The electronic media and laptop computers had the PHI of over 386,000 patients. HIPAA requires Providence, as a covered entity, to safeguard these items because they contained patient information.

Providence reported the issue to HHS and also, pursuant to state notification laws, informed patients of the theft. About thirty of these patients subsequently filed complaints with HHS. Subsequently, the incidents were investigated by both HHS' Office of Civil Rights ("OCR"), which enforces the HIPAA privacy rules, and Centers for Medicare and Medicaid ("CMS"), which enforces the HIPAA security rules.

Under the terms of the Resolution Agreement, Providence has agreed to pay \$100,000 to HHS and to implement a corrective action plan, which includes revamping its policies and procedures concerning transportation of patient records outside its facilities, training employees in security procedures, and submitting compliance reports to HHS for a period of three years. Because of Providence's cooperation with the investigation, it will not face civil monetary penalties.

Winston Wilkinson, the director of OCR, stated in a press release, that "[w]e are committed to effective enforcement of health information privacy and security protections for consumers. Other covered entities that are not in compliance with the Privacy and Security Rules may face similar action." This revolutionary action should signal to healthcare providers to revisit its own policies and procedures and to review the security rule guidance released by CMS in December 2006.

## About Garfunkel, Wild & Travis, P.C.

Garfunkel, Wild & Travis, P.C. was founded in 1980 with a single purpose in mind: to become a preeminent healthcare law firm attending to the unique business and legal needs of its clients. Since then, the firm has grown to over 80 attorneys devoted to addressing the complex legal, regulatory, business and financial needs of its diverse clients.

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