



# G-2

# Compliance

# Report



Issue 09-10/October 2009

## For Hospitals, Laboratories and Physician Practices

Kimberly Scott, Senior Editor,  
kscott@ioma.com

### Inside this issue

CMS extends deadline on  
DME arrangement limits..... 1

Pfizer to pay largest  
criminal fine for illegal  
marketing scheme ..... 1

DOJ will not challenge  
joint purchasing proposal ..... 2

Stark law revisions affect  
hospitals' and clinical  
laboratories' arrangements  
with physicians:  
see *Perspectives* ..... 5

Two face jail time over  
HIPAA violations..... 11

News in brief ..... 12

[www.g2reports.com](http://www.g2reports.com)

## CMS Extends Deadline Limiting Arrangements Between DMEPOS Suppliers, Health Providers

The Centers for Medicare and Medicaid Services (CMS) on Sept. 1 said it was delaying by six months—from Sept. 8 to March 1, 2010—the effective date for imposing limits on vendors of durable medical equipment (DME), prosthetics, orthotics, and supplies (DMEPOS) that sell items at offices of health care providers.

Jana Kolarik Anderson, an attorney with the Health Care and Life Sciences Practice at Epstein Becker & Green, Washington, says the delay will allow providers and suppliers to decide whether they will restructure their arrangements or terminate them.

The delay also will give physicians and nonphysician practitioners sufficient time to obtain supplier numbers, she said.

The new directive revises the *Medicare Program Integrity Manual* to place certain conditions on DMEPOS suppliers with consignment closets in physician offices.

*Continued on page 2*

## Pfizer to Pay Largest Criminal Fine for Illegal Marketing Scheme

Drug giant Pfizer Inc. will pay a record \$1.2 billion criminal fine to the federal government for illegally marketing the anti-inflammatory drug Bextra for uses that the Food and Drug Administration (FDA) specifically had declined to approve because of safety concerns, the Department of Justice announced Sept. 2.

The criminal fine is in addition to a \$105 million forfeiture by Pfizer subsidiary Pharmacia & Upjohn Co., which manufactured Bextra and later withdrew it from the market, and a \$1 billion settlement by Pfizer to resolve federal False Claims Act allegations that the company illegally promoted Bextra and three other drugs.

The total \$2.3 billion that Pfizer has agreed to pay marks the largest health care fraud settlement ever, Associate Attorney General Tom Perrelli told reporters. The criminal fine is the largest ever imposed in the United States for any matter, he added.

As part of the deal, Pfizer pleaded guilty to a felony violation of the Food, Drug, and Cosmetic Act, which prohibits drugmakers from marketing pharmaceutical products for purposes not explicitly approved by the FDA.

*Continued on page 9*

## CMS Extends Deadline, *from page 1*

### Time to Comply

The association representing suppliers said the previous deadline did not give members sufficient time to comply with the new directive. The transmittal that announced the new restrictions with an effective date of Sept. 8 had been issued on Aug. 7.

With the half-year delay, the American Association for Homecare, which represents DMEPOS suppliers, said it was pleased that CMS recognized the need to give suppliers more time for implementation.

“The previous timeframe was inadequate given that suppliers must contact physicians and inventory the items held on consignment,” the group said in a statement. “Physician education of this process will also require more time than was allotted by the previous deadline and suppliers ran the risk of having their supplier numbers revoked if they did not comply with the policy.”

As part of the changes, CMS told suppliers that only one DMEPOS vendor will be allowed to sell items at a health care professional’s office and then only if the supplier meets several conditions.

CMS said it wants services provided to beneficiaries to be performed by individuals being paid by the treating physician or nonphysician practitioner rather than any other DMEPOS supplier. Also, the agency wants beneficiaries who have problems or questions to contact the physician or other practitioner and not the DMEPOS supplier that placed the item at the physician’s location.

In addition, the title to the DMEPOS must be transferred to the enrolled practitioner at the time the equipment is furnished to the beneficiary. The supplier must maintain a separate entrance and physical post office address from the provider.

The CMS manual revision says that most arrangements where DMEPOS suppliers are located within a provider’s office complex “do not satisfy the DMEPOS supplier standards.”

*The transmittal is available at [www.cms.hhs.gov/transmittals/downloads/R300PI.pdf](http://www.cms.hhs.gov/transmittals/downloads/R300PI.pdf).* 🏠

## DOJ Will Not Challenge Proposal For Joint Purchasing by Hospitals

**A**n exclusive joint purchasing agreement for the purchase of certain medical and surgical supplies “may yield volume discounts and reduced transaction costs for the hospitals and ultimately could result in lower costs and increased hospital services for consumers,” according to a Department of Justice business review letter issued Sept. 4.

Under a proposed agreement between Memorial Health Inc. and St. Joseph’s/ Candler Health System, the hospitals with which they are affiliated would enter an exclusive joint purchasing agreement with respect to the purchase of certain medical and surgical supplies.

The parties sought DOJ's current enforcement intention with respect to the agreement via the business review procedure. Assistant Attorney General Christine A. Varney, chief of DOJ's Antitrust Division, responded that the department has "no present intention to challenge the entering into or operation of the agreement."

### Parties

Memorial and St. Joseph's/Candler, two 501(c)(3) nonprofit organizations, are integrated health care systems providing health care services in Savannah, Ga., and surrounding communities in southeast Georgia and the low-country area of South Carolina.

Each is affiliated with and controls corporations that operate the only acute tertiary care hospitals in southeast Georgia. Memorial owns and operates the Memorial Health University Medical Center and has approximately a 49.9 percent share of all inpatient admissions in southeast Georgia. St. Joseph's/Candler owns and operates St. Joseph's Hospital and Candler Hospital and together they have approximately a 50.1 percent share.

### Scope of Agreement

Under the proposed agreement, the chief executive officers of Memorial and St. Joseph's/Candler will appoint members of a purchasing committee that will jointly evaluate certain medical and surgical supplies, implants, and devices to determine which of those items will be covered by the agreement.

This purchasing committee will designate one or more vendors for each covered product that initially will include spinal implants, total joint implants, cardiac rhythm management devices, drug eluting stents, and generic hospital supplies—such as bandages, antiseptics, surgical gowns, and masks.

The agreement would require Memorial and St. Joseph's/Candler to purchase covered products exclusively from the previously designated vendors and strictly in accordance with the terms and provisions agreed upon by the purchasing committee—including pricing terms, established and set forth in purchase agreements negotiated on behalf of Memorial and St. Joseph's/Candler.

*Under the proposed agreement, the chief executive officers of Memorial and St. Joseph's/Candler will appoint members of a purchasing committee that will jointly evaluate certain medical and surgical supplies, implants, and devices to determine which of those items will be covered by the agreement.*

A purchase agreement may require Memorial and St. Joseph's/Candler to commit to purchase a specified amount of a covered product in order to obtain a volume discount or other favorable contract terms with a designated vendor.

Although the agreement specifies that Memorial and St. Joseph's/Candler will not purchase any product that may reasonably serve as a substitute for a covered product from a vendor other than those deemed as a designated vendor, the agreement recognizes an exception. If a designated vendor for a covered product is not able to meet its supply commitment to Memorial or St. Joseph's/Candler due to a circumstance beyond the control or influence of the parties, a covered product may be purchased from a vendor other than a designated vendor during such period that the designated vendor is unable to meet its commitment.

The agreement also contains numerous provisions to institute procedural safeguards to confirm that the cost of all covered products accounts for less than 20

percent of the total revenue of all products sold by the parties before designating any product as a covered product.

The parties stated that they will not discuss or agree upon the price or other terms which either party intends to charge or collect for covered products or the allocation of payers and patients to whom either party intends to market covered products.

Finally, Memorial and St. Joseph's/Candler represented that since medical supplies and services are susceptible to economies of scale, the agreement has the potential to produce volume discounts and reduce transaction costs.

### Analysis

DOJ concluded that "the proposal meets the requirements of the 'antitrust safety zone' set forth in Statement 7" of the Justice Department-Federal Trade Commission *Statements of Antitrust Enforcement Policy in Health Care*.

The antitrust safety zone described in Statement 7 outlines the requirements under which, absent extraordinary circumstances, the FTC and DOJ will not challenge a joint purchasing arrangement. They include:

- ❑ "the purchases [of any product covered by the arrangement] account for less than 35 percent of the total sales of the purchased product or service in the relevant market," and
- ❑ "the cost of the products and services purchased jointly accounts for less than 20 percent of the total revenues from all products or services sold by each competing participant in the joint purchasing arrangement."

Based on representations made by Memorial and St. Joseph's/Candler that they will abide by these limitations, the Antitrust Division concluded the proposed agreement meets the requirements of the antitrust safety zone. Varney cautioned that if "contrary to your representations, either of these conditions is not met, then the agreement may produce anticompetitive effects and violate the antitrust laws."

## G-2 Conference Alert...

### Laboratory Sales & Marketing 2009

#### Scaling New Heights in a Volatile Market

Dec. 7-9, 2009

Sheraton Wild Horse Pass Resort & Spa • Chandler, AZ

- ❖ Committing to Sales & Marketing Growth: The View from the Top
- ❖ What's Legal & What's Not: Key Compliance Issues for Sales & Marketing Staff
- ❖ Technical Sales Training for the Laboratory Professional
- ❖ Tracking Your Sales Performance: Making CRM Tools Work for You
- ❖ Selling and Marketing Specialized Tests

**Plus Much More!**

[www.g2reports.com/salesandmarketing09](http://www.g2reports.com/salesandmarketing09)

The parties mentioned that the agreement will enable them to achieve substantial savings because medical and surgical supplies, implants, and devices are especially susceptible to scale economies. To the extent that these savings generate benefits for customers, DOJ concluded that the agreement could have the pro-competitive effect of increasing output and lowering costs for consumers. 

# COMPLIANCE PERSPECTIVES

Carrie Valiant  
and Jana Kolarik  
Anderson are health  
care attorneys in the  
Washington, D.C.,  
office of Epstein  
Becker and Green, PC



Carrie Valiant, Esq.



Jana Kolarik Anderson, Esq.

## Stark Law Revisions Affect Hospitals and Clinical Laboratories' Arrangements with Physicians

**E**ffective Oct. 1, 2009, the Centers for Medicare and Medicaid Services (CMS) revised the federal physician self-referral law (commonly known as the Stark law) in a manner that will render most "under arrangements" relationships between hospitals and physician-owned, third-party service providers out of compliance with the Stark law.<sup>1</sup> Such "under arrangements" relationships include, for example, certain sleep center arrangements, cath lab arrangements, radiology service arrangements, and clinical laboratory arrangements.

Also effective Oct. 1, 2009, CMS revised the Stark law such that most arrangements involving percentage-based or per-unit of service (also known as "per-click") rental payments for office space leases and equipment leases between physicians or physician groups and clinical laboratories, hospitals, or other entities that furnish designated health services are out of compliance with the Stark law. Although there is room for certain per-click lease arrangements, described below, most percentage-based or per-click leases must be revised into flat fee or block time arrangements.

### Stark Law Basics

In brief, the Stark law (1) prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which the physician (or an immediate family member) has a direct or indirect financial relationship (ownership or compensation), unless an exception applies, and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or other third-party payer) for those DHS rendered as a result of a prohibited referral.<sup>2</sup> DHS includes inpatient and outpatient hospital services; clinical laboratory services; physical therapy, occupational therapy, and speech-language pathology services; radiology and certain other imaging services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; and outpatient prescription drugs.<sup>3</sup>

The Stark law is a strict liability statute. Therefore, a financial relationship that does not meet a relevant exception is noncompliant, regardless of whether one or both of the parties to the arrangement were unaware of, or did not intend, the defect. The Stark law establishes specific exceptions and grants the secretary of the U.S. Department of Health and Human Services the authority to create regulatory exceptions for financial relationships that pose no risk of program or patient abuse.<sup>4</sup>

<sup>1</sup> See 73 Fed. Reg. 48,434 (Aug. 19, 2008) (known as the "2009 IPPS final rule").

<sup>2</sup> 42 USC § 1395nn; 42 CFR § 411.353(a), (b).

<sup>3</sup> 42 CFR § 411.351.

<sup>4</sup> See 42 USC § 1395nn(b)-(e); 42 CFR §§ 411.352 – 411.357.

Violations of the Stark law are subject to various penalties including civil money penalties of up to \$15,000 for each service plus two times the reimbursement claimed, exclusion from the federal health care programs (including Medicare and Medicaid), and possible “boot strapped” civil penalties under the False Claims Act.<sup>5</sup>

In sum, if your financial relationship falls under the Stark law, you need to meet a Stark law exception or you will be subject to the penalties described above.

### **‘Entity’ and ‘Under Arrangements’**

Under the Medicare payment rules, certain providers, including acute care hospitals, can provide services to their patients directly or “under arrangements” with a third party and bill Medicare for those services.<sup>6</sup> As of Oct. 1, 2009, the Stark law regulations change “under arrangements” relationships from arrangements that must solely meet a Stark law compensation exception<sup>7</sup> to arrangements that must meet a Stark law compensation and ownership exception because of the change in the definition of “entity.”

Effective Oct. 1, 2009, the definition of “entity” will be expanded as follows:

Entity means . . . [a] physician’s sole practice or a practice of multiple physicians or any other person, sole proprietorship, public or private agency or trust, corporation, partnership, limited liability company, foundation, nonprofit corporation, or unincorporated association that furnishes DHS. . . . A person or entity is considered to be furnishing DHS if it:

- (i) Is the person or entity that has performed services that are billed as DHS; or
- (ii) Is the person or entity that has presented a claim to Medicare for the DHS, including the person or entity to which the right to payment for the DHS has been reassigned.<sup>8</sup>

### **Impact of the Change in Definition**

This amendment to the definition of “entity” means that the Stark law will apply not only to entities that submit claims to Medicare and receive payment for DHS but also will apply to entities that “perform” DHS, even if they do not submit claims for DHS. Whether the physician-owned service provider-hospital relationship has an issue under the revised definition of “entity” depends on whether the physician-owned service provider is “performing” the DHS.

Although CMS did not provide a specific definition of “perform” in the regulatory revisions, CMS did state, “We do not consider an entity that leases or sells space or equipment used for the performance of the service, or furnishes supplies that are not separately billable but used in the performance of the medical service, or that provides management, billing services, or personnel to the entity performing the service, to perform DHS.”<sup>9</sup> There is still an area of some uncertainty in determining whether a service provider is “performing” the DHS that are “billed as DHS.”<sup>10</sup>

<sup>5</sup> See 42 USC § 1395nn(g); 42 CFR §§ 1003.102, 1003.103, 1003.105; see also 31 USC § 3729 *et seq.*

<sup>6</sup> See, e.g., 42 USC § 1395(h)(5)(A)(iii); *id.* § 1395x(w)(1); see also, e.g., 42 CFR § 409.3; *id.* § 412.50(a), (c).

<sup>7</sup> See 42 CFR § 411.354(c) (“An ‘under arrangements’ contract between a hospital and an entity providing DHS ‘under arrangements’ to the hospital creates a compensation arrangement for purposes of these regulations.”); see also *id.* § 411.351 (Currently (and until Oct. 1, 2009), “entity” is defined by the Stark law regulations as a person or entity that “furnishes DHS,” defined as the person or entity “to which CMS makes payment for DHS.”)

<sup>8</sup> See 73 Fed. Reg. at 48,751 (revising 42 CFR § 411.351) (effective Oct. 1, 2009) (emphasis added).

<sup>9</sup> 73 Fed. Reg. at 48,726.

Therefore, as a result of the change in the definition of “entity” (in addition to the agreement between the hospital and the physician-owned third party that provides the “under arrangements” services to the hospital needing to meet a Stark law compensation exception for the physician owner to refer DHS to the hospital), effective Oct. 1, 2009, the physician’s ownership in the third-party service provider must meet a Stark law ownership exception for the physician to refer patients for inpatient or outpatient DHS performed by the third-party service provider “under arrangements” to the hospital for which the hospital bills.<sup>11</sup> Unfortunately, there are very limited exceptions for referrals from the physician owner.<sup>12</sup>

This change in the definition of “entity” is significant because many physician-owned entities provide services to hospitals. If an arrangement falls under this change, it must be examined and typically must be restructured or terminated because of the strict liability penalties of the Stark law. Restructuring could take different forms—a buyout of physician ownership in the third-party service provider, the hospital purchasing the third-party service provider, or the hospital providing the service through its own employees and leasing the equipment.

#### **Change in Allowed Lease Arrangements**

Effective Oct. 1, 2009, most percentage-based and per-click leases will not meet an exception under the Stark law. Specifically, the Stark law exceptions for the rental of office space, the rental of equipment, fair market value compensation, and indirect compensation arrangements have been revised to provide that charges or compensation may not be determined using a formula based on:

- (1) A percentage of the revenue raised, earned, billed collected, or otherwise attributable to the services performed on or business generated through the use of the equipment; or
- (2) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.<sup>13</sup>

In the 2009 IPPS final rule, CMS explained that it was prohibiting percentage-based and per-click leases because it had not intended that percentage-based compensation formulas be used for anything other than compensating physicians for the physician services that they personally perform.<sup>14</sup> For example, CMS saw an issue with percentage-based leases because lease payments based on a percentage of revenues earned by the lessee provide an incentive for the lessor to increase DHS referrals to the lessee so as to increase the rental payment under the lease. CMS

<sup>10</sup> Because many hospitals have physician-owned entities providing lithotripsy services, it is important to note that CMS does not consider lithotripsy to be a DHS, and as such, even “under arrangements” relationships providing lithotripsy services do not need to meet a Stark law exception. See *id.* at 48,729.

<sup>11</sup> If the physician refers DHS to an entity in which the physician has an ownership interest, then the physician ownership must meet a Stark law ownership exception, e.g., the in-office ancillary services exception. The Stark law in-office ancillary services exception could apply to services billed by the physician, physician group, or third-party service provider in which the physician has ownership; however, the in-office ancillary services exception would not apply to services billed by the hospital. See 42 CFR § 411.355(b)(3).

<sup>12</sup> For example, the Stark law rural provider exception protects ownership or investment interests in a rural provider in the case of DHS furnished in a rural area by the provider. *Id.* § 411.356(c)(1).

<sup>13</sup> See 73 Fed. Reg. at 48,752, 48,753 (revising 42 CFR §§ 411.357(a)(5)(ii), 411.357(b)(4)(ii), 411.357(l)(3), 411.357(p)(1)(ii)).

also questioned whether percentage-based lease payments, which fluctuate, could be fair market value, which would increase the risk of program or patient abuse. CMS stated its intention to continue to monitor compensation formulas between DHS entities and referring physician including arrangements for nonprofessional services (e.g., management and billing services) and, if appropriate, further restrict percentage-based formulas in a future rulemaking.<sup>15</sup>

With regard to per-click leases, the prohibition on per-click payments for space or equipment used in the treatment of a patient referred to the lessee by a physician applies regardless of whether the physician himself or herself is the lessor or whether the lessor is an entity in which the referring physician has an ownership or investment interest. The prohibition also applies where the lessor is a DHS entity that refers patients to a physician lessee or a physician organization lessee.

The exception to the per-click prohibition would be if the services are rendered to patients that were referred by others. Thus, if a physician wants to lease equipment or space to an entity and refer patients for DHS to that entity, it would be possible for the parties to structure the arrangement so the physician would receive per-click fees for services rendered to patients referred by others but would receive compensation calculated on some other basis for services that were rendered to patients who were referred by the physician.<sup>16</sup>

Under the Stark law exceptions, leases may continue to have flat fee payments or block time arrangements. Those arrangements should fit under an exception, but CMS has specifically stated that it has concerns regarding lease arrangements involving small blocks of time (e.g., once a week for four hours), or for a very extended time, which could indicate that the lessee is leasing space that it does not need or cannot use in order to compensate the lessor for referrals).<sup>17</sup> Again, CMS stated that it would continue to study the ramifications of block leases and may propose additional rulemaking in the future.

As with all physician arrangements, and as CMS reminds us, the parties to these arrangements must also take into consideration the federal anti-kickback statute when structuring their arrangements. To the extent possible, arrangements should meet a federal anti-kickback statute safe harbor.

### Next Steps

Some entities have delayed their analysis of their arrangements under the Stark law revisions with hopes that CMS would delay the effective date. However, based on our discussions with CMS regulators, the revised rules will become effective Oct. 1, 2009. As such, we recommend that entities with such arrangements review the arrangements to ensure compliance with the Stark law and, if necessary, discuss restructuring options with counsel who is familiar with the Stark law and federal anti-kickback statute.

*Carrie Valiant and Jana Kolarik Anderson can be reached at Epstein Becker and Green, PC, 1227 25th St., N.W., Washington, DC 20037. Carrie Valiant, 202-861-1857, cvaliant@ebglaw.com. Jana Kolarik Anderson, 202-861-1804, jkolarik@ebglaw.com. *

<sup>14</sup> See *id.* at 48,709.

<sup>15</sup> *Id.* at 48,710.

<sup>16</sup> See *id.* at 48,717, 48,719.

<sup>17</sup> *Id.* at 48,720.

### **Pfizer to Pay Largest Criminal Fine, from page 1**

Acting U.S. Attorney for the District of Massachusetts Michael K. Loucks told reporters that Pfizer's repeated offenses in the area of off-label promotion of its drugs were a key factor in calculating the record-setting fine and settlement. Louck's office led the federal investigation that also involved the FBI and the Department of Health and Human Services. He said the latest combined criminal and civil matter is the fourth such case involving Pfizer since 2002.

Loucks said that Pfizer's "marketing machine" illegally promoted Bextra and the combination of Bextra and the drug Celebrex for uses and in dosages that the FDA did not approve in 2001 when it green-lighted the drug in certain dosages for osteoarthritis, rheumatoid arthritis, and primary dysmenorrhea.

"There is no such thing as a general approval," Loucks said, emphasizing that FDA approvals for drugs are indication-specific. That means drug manufacturers are allowed to promote drugs for only the indications approved by the FDA.

#### **'Historic' CIA**

Health and Human Services Secretary Kathleen Sebelius, also speaking to reporters, said the Pfizer deal was historic not only for the record fine and settlement but because of a broad-reaching corporate integrity agreement between the drug company and the HHS Office of Inspector General.

The five-year CIA will go further than past agreements, Sebelius said, in requiring Pfizer's audit committee to review the manufacturer's corporate compliance and certify its effectiveness. Pfizer's senior executives also will be required to certify the company's compliance program annually.

*Pfizer Senior Vice President and General Counsel Amy W. Schulman said that the company regretted "certain actions taken in the past," but that the drugmaker had improved internal controls to comply with federal and state laws and "meet the high standards that patients, physicians and the public expect from a leading worldwide company dedicated to healing and better health."*

The federal government alleged as part of the criminal investigation that between 2002 and April 2005 Pfizer made false and misleading claims about the safety and efficacy of Bextra by creating a corporate sales strategy, including marketing materials and messages, to promote the drug for acute pain, surgical pain, and other unapproved uses to doctors.

According to DOJ, Pfizer promoted Bextra directly to physicians for unapproved uses and promoted standing physician orders and hospital protocols for unapproved uses of Bextra for controlling pain.

Pfizer and its subsidiary also paid for doctors to travel to expensive resorts as part of promotional campaigns for unapproved uses and dosages of Bextra and distributed samples to prescribers for unapproved uses and dosages, DOJ said. DOJ further said that Pfizer sponsored supposed independent continuing medical education programs where Bextra was improperly promoted for acute pain and surgical pain.

Loucks said that while excluding a drug company from federal health care programs, particularly the Medicare and Medicaid programs, for criminal actions is considered as part of investigations, prosecutors generally believe that

bringing companies and their employees under corporate integrity agreements is a better way to control future problems.

HHS Inspector General Daniel R. Levinson also noted that excluding a large drugmaker from participating in federal health programs could be harmful to beneficiaries who rely on the manufacturer's products. Nevertheless, Levinson said that if Pfizer failed to meet the requirements in the CIA, penalties ranged from monetary fines to exclusion.

### Case Closed

Perrelli said that the announcement brought to a close a multiyear investigation that originated with 11 separate qui tam lawsuits. Six whistleblowers will share \$102 million in federal proceeds for their part in bringing the case against Pfizer, DOJ said.

The related civil settlement resolves False Claims Act allegations that Pfizer illegally promoted the drugs Bextra, Geodon, Zyvox, and Lyrica for uses not approved by the FDA and that were not medically accepted indications for payment by the Medicaid program. States will share \$331 million of the \$1 billion

settlement amount, DOJ said. The Medicare program will share the remainder of the settlement proceeds with the TRICARE program, the Federal Employee Health Benefits Plan, the Department of Veterans Affairs, the Department of Labor, and the Bureau of Prisons.

*The five-year CIA will go further than past agreements, Sebelius said, in requiring Pfizer's audit committee to review the manufacturer's corporate compliance and certify its effectiveness. Pfizer's senior executives also will be required to certify the company's compliance program annually.*

Although DOJ noted that Pfizer allegedly paid kickbacks to doctors as part of the

illegal marketing of Bextra and the three other drugs, Perrelli said that the federal government did not investigate any of those physicians as part of the case against Pfizer.

Pfizer will be required as part of the CIA to post on its Web site information about payments to doctors, including honoraria, travel, and lodging, according to an OIG statement on the agreement.

Perrelli said two Pfizer senior managers already had been prosecuted in connection with the case. In July, former Pfizer district sales manager Thomas Farina was sentenced to three years' probation, for obstruction of justice during the investigation of the off-label marketing of Bextra. During the same month, former Pfizer regional sales manager Mary Holloway was ordered to pay \$75,000 and serve 24 months' probation for illegally marketing Bextra.

### Pfizer Statement

Pfizer Senior Vice President and General Counsel Amy W. Schulman said in a Sept. 2 news release that the company regretted "certain actions taken in the past," but that the drugmaker had improved internal controls to comply with federal and state laws and "meet the high standards that patients, physicians and the public expect from a leading worldwide company dedicated to healing and better health."

"Corporate integrity is an absolute priority for Pfizer, and we will continue

to take appropriate actions to further enhance our compliance practices and strengthen public trust in our company," Schulman said.

While Pfizer acknowledged the criminal conduct alleged by the federal government, the company said it "expressly denies" all of the civil allegations with the exception of "certain improper actions related to the promotion of Zyvox."

According to the Pfizer statement, the CIA between the company and the HHS OIG "memorializes additional voluntary initiatives" that Pfizer announced in February, including public disclosure of financial relationships with doctors, medical organizations, and patient advocacy groups. Pfizer also acknowledged it was operating under an earlier CIA with the inspector general's office. 🏛️

## Two Face Jail Time Over HIPAA Violations

**T**wo people who pleaded guilty to federal crimes involving disclosures prohibited by the Health Insurance Portability and Accountability Act (HIPAA) face maximum sentences of 10 years in prison and fines of up to \$250,000.

Isaac Earl Smith and Annetra Poole-Moore pleaded guilty in late August to HIPAA violations and aggravated identity theft. Between about September 2008 and April 2009, Smith, of Pleasant Grove, Ala., and Moore, of Midfield, Ala., engaged in a criminal conspiracy to commit health care fraud, according to separate plea agreements filed in U.S. District Court.

During that period, Moore was employed by UnitedHealthCare Inc. as a claims representative associate. In that position, Moore had access to the personal information, including the means of identification of certain persons enrolled in flexible spending accounts administered by UHC. Without authorization or approval from UHC, Smith and Moore gained access to the company's electronic database and obtained names and dates of birth of certain persons who had flexible spending accounts and were also covered by a prescription drug plan sponsored by the Federal Employees Health Benefit Plan.

The defendants and others used this information to create counterfeit and unauthorized prescriptions. Those counterfeit prescriptions were then presented to pharmacies for the purpose of illegally obtaining controlled substances. The drugs were then illegally sold to third parties. By using the stolen identities on the prescriptions, the defendants caused FEHBP's prescription drug plan to pay for the controlled substances, resulting in a loss to FEHBP of \$72,746.

Smith's plea agreement reflects he intends to plead guilty to one count of conspiracy to commit health care fraud, one count of criminally violating the HIPAA disclosure laws, and five counts of aggravated identify theft.

Moore's plea agreement reflects that she intends to plead guilty to one count of conspiracy to commit health care fraud, one count of criminally violating the HIPAA disclosure laws, and two counts of aggravated identity theft.

Smith and Moore have also agreed to pay \$72,746 in restitution to FEHBP and to criminally forfeit the same amount. In addition, they each face maximum sentences of 10 years in prison and fines of up to \$250,000. The aggravated identity theft charges carry two-year minimum prison sentences. 🏛️

**LEVY ON LABS:** Senate Finance Committee Chairman Max Baucus has proposed a \$750 million levy on clinical laboratories. The lab fee is part of a series of levies on different parts of the health care industry to help finance reform. Medical device makers would have to cough up \$4 billion a year, drug companies \$2.3 billion, and insurers \$6 billion. The fees for these sectors would be allocated by market share. The Baucus bombshell drew swift opposition from the American Clinical Laboratory Association (ACLA) and the Advanced Medical Technology Association (AdvaMed). "The plan to impose \$750 million in taxes on clinical lab services—on top of other cuts—translates into a disproportionate cut for labs, will damage efforts to enhance prevention and wellness, and raise health care costs," said ACLA president Alan Mertz in a Sept. 8 statement. The "tax unfairly targets the clinical laboratory industry among providers, which includes about 40,000 labs providing a myriad of critical health services to patients across the nation. When the \$750 million in new fees are added to other cuts in the proposal, America's clinical labs could be facing cuts several times that of other providers."

**BAD HOSPICE CLAIMS:** Medicare paid about \$1.8 billion for hospice care claims that did not meet at least one coverage requirement, the Department of Health and Human Services Office of Inspector General (OIG) estimated. In a report issued Sept. 9, the OIG examined a sample of claims from 2006 for hospice care in nursing facilities. The report, *Medicare Hospice Care for Beneficiaries in Nursing Facilities: Compliance with Medicare Coverage Requirements*, found that 81 percent of claims did not meet at least one coverage requirement in regard to election statements, plans of care, services, or certifications of terminal illness, the report said. Additionally, 1 percent of claims were undocumented. The OIG's recommendations for the Medicare program included stronger monitoring practices regarding hospice claims and more frequent certification surveys of hospices as a way to enforce the Medicare requirements for such claims. The report found that not-for-profit hospices were less likely to meet coverage requirements than for-profit hospices: 89 percent of claims from not-for-profit hospices did not meet the requirements, compared with 74 percent of claims from for-profit hospices. 🏛️

### G-2 Compliance Report Subscription Order or Renewal Form

- YES**, enter my one-year subscription to the **G-2 Compliance Report (GCR)** at the rate of \$487/yr. Subscription includes the **GCR** newsletter, The G-2 Compliance Resource Guide, the Quarterly Compliance Tips on Video, and electronic access to the current and all back issues at [www.ioma.com/g2reports/issues/GCR](http://www.ioma.com/g2reports/issues/GCR). Subscribers outside the U.S. add \$100 postal.\*
- I would like to save \$292 with a 2-year subscription to **GCR** for \$682\*
- YES!** Please send me \_\_\_ copies of **Medicare Reimbursement Manual for Laboratory & Pathology Services 2009** for just \$499, (Washington G-2 subscribers pay only \$449) and your state's sales tax. The price includes shipping/handling. (Report Code # 3438C)

#### Please Choose One:

- Check Enclosed (payable to Washington G-2 Reports)
- American Express     VISA     MasterCard
- Card # \_\_\_\_\_ Exp. Date \_\_\_\_\_
- Cardholder's Signature \_\_\_\_\_
- Name As Appears On Card \_\_\_\_\_

#### Ordered by:

Name \_\_\_\_\_  
 Title \_\_\_\_\_  
 Company/Institution \_\_\_\_\_  
 Address \_\_\_\_\_  
 City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_  
 Phone \_\_\_\_\_ Fax \_\_\_\_\_  
 E-mail address \_\_\_\_\_

\*By purchasing an individual subscription, you expressly agree not to reproduce or redistribute our content without permission, including by making the content available to non-subscribers within your company or elsewhere.

**MAIL TO:** Washington G-2 Reports, 1 Washington Park, Suite 1300, Newark, NJ 07102-3130. Or call 973-718-4700 and order via credit card or fax order to 973-622-0595 GCR 10/09

©2009 Institute of Management and Administration, a division of BNA Subsidiaries, LLC. All rights reserved. Copyright and licensing information: It is a violation of federal copyright law to reproduce all or part of this publication or its contents by any means. The Copyright Act imposes liability of up to \$150,000 per issue for such infringement. Information concerning illicit duplication will be gratefully received. To ensure compliance with all copyright regulations or to acquire a license for multi-subscriber distribution within a company or for permission to republish, please contact IOMA's corporate licensing department at 973-718-4703, or e-mail [jping@ioma.com](mailto:jping@ioma.com). Reporting on commercial products herein is to inform readers only and does not constitute an endorsement. *G-2 Compliance Report* (ISSN 1524-0304) is published by Washington G-2 Reports, 1 Washington Park, Suite 1300, Newark, NJ 07102-3130. Tel: 973-718-4700. Fax: 973-622-0595. Web site: [www.g2reports.com](http://www.g2reports.com).

Kimberly Scott, Senior Editor; Dennis Weissman, Executive Editor; Janice Prescott, Sr. Production Editor; Perry Patterson, Vice President and Publisher; Joe Bremner, President. **Receiving duplicate issues? Have a billing question? Need to have your renewal dates coordinated? We'd be glad to help you. Call customer service at 973-718-4700.**