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Drug company pays $515 million to resolve FCA claims

by Valerie L. Witmer, J.D., Contributing Editor

Bristol-Myers Squibb Company (BMS) and its subsidiary have agreed to pay over $515 million to resolve allegations of fraud involving their drug marketing and pricing practices, the Department of Justice (DOJ) announced. The settlement covers a wide range of illegal marketing and pricing practices and resolves allegations made in seven *qui tam* actions brought under the federal False Claims Act (FCA) (31 U.S.C. §3729, *et seq.*).

Allegations. First, the government alleged that, from 2000 through mid-2003, BMS knowingly and willfully paid illegal remuneration in the form of consulting fees and expenses to physicians and other health care providers to induce them to purchase BMS drugs. The government also alleged that, from 1994 through 2001, BMS' subsidiary knowingly and willfully paid illegal remuneration such as stocking allowances, price protection payments, up-front rebates, market share payments, and free goods to induce retail pharmacies and wholesale customers to purchase its drugs.

Second, the government alleged that, from 2002 through 2005, BMS knowingly promoted the sale and use of Abilify®, an antipsychotic drug, for off-label uses. The Food and Drug Administration approved the drug to treat adult schizophrenia and bi-polar disorder, but not for pediatric use or to treat dementia-related psychosis in geriatric patients. Nevertheless, BMS directed its sales force to market Abilify® to child psychiatrists and other pediatric specialists and created a specialized long-term care sales force to market the drug almost exclusively to nursing homes, where dementia-related psychosis is far more prevalent than schizophrenia or bi-polar disorder.

Third, the government alleged that BMS and its subsidiary set inflated prices for various oncology and generic drugs, knowing that federal health care programs established reimbursement rates based on those prices.

Finally, the government alleged that BMS knowingly misreported its "best price," or lowest price, for an anti-depression drug by failing to include the low prices at which it sold the drug to a large commercial purchaser. BMS' failure to accurately report its best price as required under the Medicaid Drug Rebate Statute (42 U.S.C. §1396r-8) denied Medicaid the benefit of the lowest price in the marketplace, the government asserted.

Settlement. Of the $515 million total settlement, the federal government recovered approximately $328 million. Over $25 million of that amount represents disgorgement of profits resulting from BMS' illegal promotion of its antipsychotic drug for off-label uses. BMS also will pay over $187 million to the Medicaid participating states and $124,000 to certain Public Health Service entities. The

relators who brought the *qui tam* actions against BMS will receive a total of approximately $50 million as their share of the settlement.

As part of the settlement, BMS entered into a corporate integrity agreement with the Office of Inspector General that requires BMS to report accurate average sales prices and average manufacturer prices for its drugs covered by Medicare and other federal health care programs. (*See Health Care Compliance Reporter* ¶420,422).

"This settlement reflects the Justice Department's strong commitment to holding drug companies accountable for devising and implementing fraudulent marketing and pricing schemes that undermine that decision-making process at the expense of federal health care programs for the poor and the elderly," Assistant Attorney General for the Civil Division and Acting Attorney General Peter D. Keisler said.

U.S. Attorney for the District of Massachusetts, Michael J. Sullivan added, "Patients are entitled to unbiased decision-making from their physicians and should not have to worry that financial inducements or lavish entertainment have influenced their physicians' prescribing choices. Kickbacks are especially nefarious when they are used as part of a marketing effort to convince physicians to prescribe drugs for uses that the Food and Drug Administration has not determined to be safe and effective." ■

DOJ Press Release, Sept. 28, 2007.

Anti-Kickback

Experts address Stark Phase III "stand in the shoes," "physician organization" provisions

by Matthew Mann, J.D., and Susan L. Smith, J.D., M.A., Contributing Editors

The major changes to the regulations governing physician referrals, including the purpose and scope of the "stand in the shoes" provision, the amended definition of "physician in the group practice," and the changes to the physician recruitment exception and relocation requirements were the focus of an American Health Lawyers Association (AHLA) teleconference, entitled "Stark Phase III Final Regulations: Part I—Phase III Stark II: The Journey Continues," held on September 27, 2007. Speakers included CMS' Deputy Director of the Division of Technical Payment Policy, Lisa Ohrin, and the Director of the Division of Technical Payment Policy, Donald Romano, who provided background on the final rule and fielded questions about some of the rule's more substantial changes; John Brennan, Jr., Crowell & Moring LLP, Washington, D.C.; Thomas Dutton, Jones Day, Columbus, Ohio; and Albert Shay, Sonnenschein Nath & Rosenthal LLP, Washington, D.C.

"Stand in the shoes" provision. Phase III added a new provision at 42 C.F.R. §411.354(c), referred to as the "stand in the shoes" provision. The purpose of the new provision, according to CMS, is to close an unintended loophole in the definition of an indirect compensation arrangement (by deeming more arrangements to be direct compensation arrangements) and ease compliance by simplifying the analysis of many arrangements. Under this provision, for purposes of an arrangement between a designated health service (DHS) entity and a "physician organization," a physician who has a direct financial relationship with a physician organization will be deemed to have a direct compensation arrangement with the DHS entity if the only intervening entity between the physician and the DHS entity is the physician organization. In other words, the physician will be deemed to stand in the shoes of the physician organization with which he or she has a direct financial relationship, Shay explained. The practical effect of the provision is that physicians who have direct financial relationships with one intervening entity will be considered to have a direct compensation arrangement with the DHS entity and, therefore, will have to qualify for a direct compensation exception.

CMS officials fielded many questions related to the scope of the newly defined term "physician organization." In the final rule, physician organization is defined as "a physician (including a professional corporation of which the physician is the sole owner), a physician practice, or a group practice that complies with

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the requirements of [a group practice].” The provision applies to all physicians, whether they are owners, members, employees, or independent contractors of the physician organization, according to Ohrin.

Shay questioned the CMS officials about the meaning of the term “physician practice” within the definition of “physician organization.” Ohrin explained that the term physician practice covers a medical practice that is not a Stark qualifying group practice.

Another question raised was whether the definition of physician organization is intended to cover an academic medical center (AMC) or components of an AMC. Ohrin explained that an AMC's wholly owned faculty practice plan would be encompassed under the new definition. She also indicated that a wholly owned medical practice would be considered a physician organization for purposes of the new provision, but that the definition would not apply to: (1) a group of hospital-employed physicians who practice medicine at the hospital, or (2) a physician-owned leasing company.

Ohrin and Romano acknowledged that CMS has received a lot of comments on the question of what is or is not a physician organization, in particular with regard to AMCs, and noted that the agency is reviewing the comments and considering whether to issue clarifying guidance.

Physician in the group practice. Phase III made a small but significant change to the definition of a “physician in the group practice” found at 42 C.F.R. §411.351. The word “directly” was inserted into the definition so that it now reads: “A physician in the group practice means a member of the group practice, as well as an independent contractor physician during the time the independent contractor is furnishing patient care services (as defined in this section) for the group practice under a contractual arrangement directly with the group practice to provide services to the group practice's patients in the group practice's facilities.” Romano stated that the purpose of this provision was to create a strong and meaningful nexus between the independent contractor and the group.

The provision requires the group practice to contract directly with individual physicians, including independent contractors. Ohrin and Romano expressed CMS' concern that it does not want a contractual arrangement between the group practice and “a person to be named later.” In discussing a hypothetical example involving a radiology practice, Ohrin indicated that ideally, each individual radiologist would need to be identified and agree to the terms of the contract. She acknowledged, however, that there would be some flexibility in the mechanics of the contract, such as whether the contract would be with the group, the individual physicians, or the group and its individual members.

Romano stressed concerns that the provision of the Medicare Modernization Act (MMA) (PubLNo 108-173) that gives CMS authority to make payments to an entity that has received reassigned payments pursuant to a contractual arrangement may be subject to abuse. To address these concerns, CMS will consider an independent contractor physician a “physician in the group practice” only when he or she is performing services in the group practice's facilities.

Physician recruitment and relocation. Phase III introduced several important changes to the physician recruitment exception. The exception was expanded to include rural health clinics, for which the geographic area served by the hospital would be the lowest number of contiguous zip code areas from which the hospital draws 90 percent of its inpatients (as opposed to 75 percent for all other hospitals).

Ohrin and Romano confirmed that with the introduction of Phase III, there is now a two-part test to meet the relocation requirement. They reiterated that a physician must indeed move his or her medical practice from outside the hospital's geographic service area to inside the geographic area, plus the recruited physician must either (1) move the practice a minimum distance of 25 miles, or (2) derive at least 75 percent of the practice revenues from professional services furnished to patients (including hospital inpatients) not seen or treated by the physician at his or her prior medical practice site during the preceding three years, measured on an annual basis (fiscal or calendar year). ■

AHLA Teleconference, Stark Phase III Final Regulations: Part I—Phase III Stark II: The Journey Continues, Sept. 27, 2007.

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On The Front Lines

A survey of new developments in tax-exemption law: What compliance officers need to know, Part II

by Paul De Muro, C.P.A, M.B.A, J.D., and Laura Gabrysch, J.D., LL.M., Contributing Editors

This article discusses and summarizes the recent developments of 2007 that apply to tax-exempt organizations, with an emphasis on health care organizations. As will become apparent, governance, transparency, and compliance are common threads among all of the developments. This two-part article provides the highlights of a more in-depth article that will be published in the November/ December 2007 issue of the Journal of Health Care Compliance.

Part I of this two-part article analyzed the Internal Revenue Service's (IRS') activities of the past year, including the impact of the Good Governance Practices, the impetus to change Form 990, the focus on political activities and executive compensation, and tax-exempt organizations' compliance with requirements related to tax-exempt bonds, specifically record retention. Part II will discuss the new draft Form 990, the IRS report on its findings related to its community benefits questionnaire sent to tax-exempt hospitals in 2006, recommendations for tax-exempt hospital reforms issued by Sen. Charles Grassley's office, IRS Acting Commissioner Kevin M. Brown's comments on top compliance issues for tax-exempt organizations, and other related developments.

New draft Form 990

The IRS' ultimate tool for governance and transparency is the new draft Form 990. The draft Form 990 was unveiled in July 2007, and the IRS hopes to finalize it in time for use for the 2008 tax year, which is just around the corner. The purpose of the new draft Form 990 is to make organizations disclose a lot of information. The thought is that the fear of negative disclosures will encourage compliance and behavior that will be viewed favorably by the public. Additionally, the advent of electronic filing will force organizations to answer all of the questions (no blanks) and make the information available to the public in real time.

When the draft Form 990 is finalized, organizations will have much more work to do in completing their return. The draft Form 990 consists of a "core" form and fifteen schedules. All organizations must complete the core form, as well as Schedules A and B. Smaller organizations may be able to get away with filing the core form and two or three schedules. More complex organizations like health care organizations, however, can look forward to filing about ten or more schedules.

The core form is ten pages, and targets hot-button issues, such as excessive compensation and loans to disqualified persons. Part one of the core form contains a summary page, which requests information about the organization's revenues, expenses, assets and liabilities, and percentage of assets expended in operations and compensation. The one-page summary is intended to give the IRS and the public a snapshot of each organization. There is some debate, however, as to the benefit of these "efficiency indicators," as all organizations are different and expend varying amounts on operations and compensation during their life cycles.

All of the schedules request detailed information and provide the format for submitting the information. A full discussion of the schedules is beyond the scope of this survey. Several schedules, however, are worth mentioning for the depth of the detail and transparency required by the new Form 990.

Schedule H is of most interest to hospitals. The trigger for filing Schedule H is very broad; an organization simply must operate or maintain a facility to provide hospital or medical care, which could include facilities such as campus student clinics and other facilities that do not have to meet the community benefits test. Schedule H itself is very short, but the worksheets for calculating the Schedule H numbers are very lengthy. Many hospitals will find that reporting charity care and community benefits according to Schedule H will require a lot of administrative costs, including training personnel and information technology updates, that may take time to implement.

Schedule D is interesting in that it requires disclosure of an organization's FIN 48 (Financial Accounting Standard Board's (FASB) Interpretation 48 (FIN 48), Accounting for Uncertainty in Income Taxes) positions. FIN 48, which became effective June 26, 2007, requires that all entities that file generally accepted accounting principle (GAAP) accounting reports (including nonprofit organizations) identify and mea-

sure uncertain income tax positions. For exempt organizations, these uncertain income tax positions may include whether an organization is exempt and whether certain activities are taxable. Thus, for example, incidents of private inurement or political activities may bring into question an organization's exempt status, and may require a FIN 48 disclosure on Schedule D. Joint ventures may be problematic as well, considering the lack of guidance and the fact that it is now a "no rule" area with the IRS.

Schedule J requires disclosure of both taxable and nontaxable compensation to current or former officers, directors, trustees, or key employees. Schedule J must be completed for each of these persons who receive more than $150,000 in reportable compensation or more than $250,000 in nonreportable compensation that can include deferred compensation, nontaxable fringe benefits, and expense reimbursements. Many organizations may find, when calculating the fringe benefits, that these benefits are indeed taxable. If taxable fringe benefits are not reported, the person receiving them, if a "disqualified person," is subject to automatic excess benefit penalties, regardless of whether the overall compensation paid to the person is reasonable.

Interim report on hospital project

On July 19, 2007, the IRS issued its Interim Report on the Hospital Compliance Project, which involved sending out questionnaires to over 500 tax-exempt hospitals in spring of 2006. This Interim Report summarizes the responses to the community benefits questions posed in the questionnaire. The Interim Report, however, does not contain detailed analysis of the community benefits responses, as the IRS was not able to discern the actual amount of charity care provided by the hospitals because of the disparities in measurement and reporting.[11] Additionally, the Interim Report does not address the responses to the executive compensation questions, which will be presented at a later time.

The Interim Report noted that 97 percent of the respondents had a written charity care policy and charity care accounted for 56 percent of the reported total community benefit expenditures. There was, however, a wide variation in the way hospitals defined and reported charity care, including eligibility for charity care, the treatment of bad debt and Medicaid and Medicare shortfalls, and whether costs or charges are used to measure charity care. After charity care, the range of reported community benefits included medical education and training, research, and community programs. Because of the lack of uniformity, the Interim Report recommends the adoption of the method for reporting charity care and community benefits that is contained in the draft Form 990.

As next steps, the IRS will continue analyzing the data, obtain additional data from various sources, and follow up with the respondent hospitals to verify the data and obtain additional information. A final report is expected next year.

Staff recommendations

Simultaneous with the release of the Interim Report, Sen. Charles Grassley (R-Iowa) released a discussion draft of ideas for potential tax-exempt hospital reforms. Sen. Grassley asked his staff to prepare the discussion draft after the hearings on tax-exempt hospitals concluded last September and released the discussion draft to coincide with the IRS' Interim Report. A few of the ideas are explained in further detail.

Exempt hospital classifications

Among other things, Grassley's staff recommends that hospitals be classified under either Internal Revenue Code (Code) §501(c)(3) or Code §501(c)(4). For a hospital to qualify as a 501(c)(3) hospital, it must have a charity care policy that qualifies persons at 100 percent of the federal policy level. Further, the hospital must provide annual charity care in an amount equal to at least five percent of its annual patient operating expenses or revenues, whichever is greater.[12]

Charity care would be defined as free or discounted medically necessary services performed with no expectation of payment, thus excluding bad debt. Charity care also could include medical services provided through free clinics and community clinics, as well as free medical services provided to vulnerable populations, such as school-based programs. Grants to provide these services through free clinics and to vulnerable populations also would qualify as charity care. The value of charity care would be equal to the lower of either the lowest rate paid by Medicare or Medicaid or the actual unreimbursed cost.

If a hospital does not qualify as a 501(c)(3) hospital, it may still qualify as a 501(c)(4) hospital. While still exempt from federal income taxation, a 501(c)(4) hospital would not be eligible to receive charitable contributions or use tax-exempt bond financing. For a hospital to qualify as a 501(c)(4) hospital, it would be required to conduct a community needs assessment every three years and dedicate at least five percent of its annual patient operating expenses or revenues to community benefits.[13] Community benefits would include charity care, an emergency room open to all, burn units and trauma centers, health professional education and training, health research, and activities conducted in response to the community needs assessment.

If a hospital failed to meet the quantitative requirements for exemption, averaged over a three-year period, then an excise tax would be imposed on the hospital equal to twice the amount of the shortfall. The IRS would have the discretion to reduce the excise tax to the amount of the shortfall for 501(c)(3) hospitals that demonstrate that they met the

requirement over a longer period of time and the shortfall was due to a lack of demand.

Joint ventures

Joint ventures involving 501(c)(3) hospitals also would be required to adopt a charity care policy. The charity care from the joint venture attributable to the 501(c)(3) hospital would be equal to the hospital's investment percentage divided by the total 501(c)(3) investment percentages. For instance, if a 501(c)(3) hospital owned 10 percent of an ancillary joint venture, and another 501(c)(3) organization owned 20 percent of the same joint venture, then the 501(c)(3) hospital would be able to count one-third of the joint venture charity care toward its total charity care.

Governance requirements

The staff also recommended various governance requirements. First, the staff recommended that hospitals have a community board that is controlled by persons who represent the public interest, such as persons with special health care knowledge, public officials, community leaders, and representatives of low-income beneficiaries. Participation by conflicted persons (such as management employees) and physicians would be limited to 25 percent each. Second, the hospital would be required to adopt a conflicts of interest policy that, among other things, would address arrangements with for-profit parties in joint ventures. The community board would be responsible for all charity care policy matters, reviewing the Form 990, and reviewing and approving the community needs assessment.[14]

The Staff Recommendations are just that — recommendations from the staff of the minority party.

Letter from the commissioner

Perhaps a better indicator of the future is the letter that IRS Acting Commissioner Kevin M. Brown wrote to Sen. Grassley on June 28, 2007. In releasing the letter to the public, Sen. Grassley hinted that the letter may serve as a blueprint for future legislation. While major charitable reform legislation may not be likely immediately before an election year, Sen. Grassley and others will continue to push for reforms in the next several years.

In the letter, Commissioner Brown described the top compliance issues for exempt organizations as follows:

(1) abusive tax transactions and the use of tax-exempt organizations as accommodation parties;
(2) various issues involving overvaluing charitable contributions; and
(3) issues with tax filing and transparency.

With respect to tax filing and transparency, Commissioner Brown noted that the Executive Compensation Project revealed that the Form 990 did not request complete information, was difficult to understand, and was in need of revision. The IRS has attempted to address these issues in the draft Form 990, which is discussed above.

Other compliance issues for exempt organizations include:

(1) charities established to benefit the donor, such as abusive donor-advised funds and supporting organizations;
(2) the blurring of the line between the tax-exempt and commercial sectors;
(3) executive compensation and private inurement; and
(4) political activities.

The Commissioner also noted the following issues with tax-exempt bonds:

(1) transactions designed to earn and divert illegal arbitrage; and
(2) record retention issues.

In addition to identifying the top compliance issues, the Commissioner identified three broad areas of discussion for possible reform.

First, the Commissioner considered whether there were gaps in the legal framework created by wide-scale changes in the tax-exempt industry over the past few decades. Commissioner Brown noted that the last major overhaul of tax-exemption law occurred in 1969, and that the current laws may not be enough to address the current commercial drift for tax-exempt organizations. This may be a hint that the IRS may be pushing for changes to the community benefit standard.

Second, the Commissioner contemplated whether the IRS had the flexibility to respond adequately to compliance issues. The letter opined that the revocation of tax-exemption may in many instances be harsh and punish innocent charitable beneficiaries, while intermediate sanctions may not work as intended. He also noted that the increasing complexity of many exempt organizations, mainly health care organizations, has made tax administration more difficult and fact intensive.

Third, Commissioner Brown pondered whether more should be done to promote transparency, good governance, and the efficient delivery of public benefits. While applauding the initiatives taken by many exempt organizations, Commissioner Brown wondered whether exempt organizations should be legally required to adopt good governance practices to obtain and retain tax-exempt status.

Finally, the Commissioner concluded the letter by requesting an increase in the IRS' enforcement budget. If granted, the IRS would use the additional funds to study reporting compliance by exempt organizations and increase the number of agents for its examinations and determinations programs.

House Ways and Means hearing

These days, no news is good news for tax-exempt organizations, particularly hospitals, when it comes to congressional involvement. The 90-minute hearing before the Oversight Subcommittee of the House Ways and Means Committee on July 24, 2007,[15] was a pleasant departure for exempt organizations.

During this hearing, the participating legislators went out of their way to praise the exempt community, and participants generally acknowledged that the overwhelming majority of tax-exempt organizations were tax compliant. The Commissioner of the IRS Tax-Exempt and Governmental Entities Division echoed many of the comments made above in Commissioner Brown's letter.

Other miscellaneous IRS developments

On May 11, 2007, the IRS issued a memorandum to clarify under which circumstances an exempt hospital could provide financial assistance to physicians to implement electronic health record (EHR) software without running afoul of the excess benefit and private inurement rules.[16] The memorandum provided that there would be no excess benefit if the provision of the software complied with final HHS regulations. Thus, the software should be provided to all staff physicians on the same basis and by applying criteria designed to ensure that the health care needs of the community are met. The memorandum does not address income tax issues regarding EHRs, and does not address whether software can be provided to nonmedical staff physicians or physician groups. The IRS subsequently issued Questions and Answers on its website on June 21, 2007,[17] which noted that the memorandum provided a safe harbor, and that other arrangements may be permissible as well. The extent of these other permissible arrangements remains unknown. Hospitals should not assume, however, that this informal guidance provides authority for a wide range of information technology assistance to physicians, as these authorities only apply to EHRs.

In early August, the IRS released a notice of proposed rulemaking for Type III supporting organizations.[18] These supporting organizations are subject to onerous requirements under the Pension Protection Act of 2006 (PubLNo 109-280) unless they are "functionally integrated." Many parent organizations in health care systems are Type III supporting organizations, although it is generally acknowledged that health care parents are not the abusive organizations targeted by the Act. In the notice, the IRS proposed that the Type III parent may be subject to a lesser test to be functionally integrated.

Conclusion

Exempt health care organizations will face many challenges in coming years in complying with new standards, both legal and *de facto*, for tax exemption. When the draft Form 990 is adopted, for example, many organizations will need to recalibrate how they determine and track charity care and community benefits, and possible executive compensation. The draft Form 990 also will encourage organizations to operate in a manner that makes the various required disclosures less painful. Continuing public and congressional pressure will push organizations toward adopting recommended governance practices and closely monitoring political activities. The IRS bond initiative may encourage organizations to pull the bond documents out of storage and closely examine the uses of the bond proceeds and bond-financed facilities. Hopefully these moves toward transparency and good governance will be enough to forestall the trend toward further legislation.

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11 A December 2006 Ernst & Young report concludes that surveyed tax-exempt hospitals are meeting the community benefit standard set forth under Revenue Ruling 69-545. At the request of the American Hospital Association, Ernst & Young reviewed the submissions of 132 of the over 500 hospitals who received the IRS Compliance Check Questionnaire in May and June of 2006. Ernst & Young concluded that all of the non-specialty hospitals provided emergency rooms that were available to all regardless of ability to pay. Further, all of the hospitals charged patients the same price for the same services, regardless of insurance or ability to pay. The report made several suggestions to encourage more accurate and complete responses from hospitals. The full report is available on the American Hospital Association website at www.aha.org.

12 Critical access hospitals would be exempt from this requirement.

13 Critical access hospitals would need to comply with the first requirement but would be exempt from the second.

14 The IRS person in charge of overseeing the drafting of the draft Form 990 was at one point a member of Sen. Grassley's staff. Thus, some of the concepts of the staff recommendations may have found their way into the draft Form 990.

15 *Available at* http://waysandmeans.house.gov/hearings.asp?formmode=detail&hearing=577.

16 *Available at* http://www.irs.gov/pub/irs-tege/ehrdirective.pdf.

17 *Available at* http://www.irs.gov/pub/irs-tege/ehr_qa_062007.pdf.

18 *Available at* http://www.irs.gov/charities/charitable/article/0,,id=172714,00.html.

Anti-Kickback

FQHC arrangements protected under new safe harbor

by Valerie L. Witmer, J.D., Contributing Editor

Certain arrangements involving federally qualified health centers (FQHCs) will be protected pursuant to a new safe harbor provision under the anti-kickback statute issued by the Office of Inspector General in a final rule on October 4, 2007.

The safe harbor protects remuneration in the form of goods, items, services, donations, or loans, in cash or in-kind, provided by a donor to a qualifying health center as defined in §1905(l)(2)(B)(i) or §1905(l)(2)(B)(ii) of the Social Security Act. The remuneration must be medical or clinical in nature or relate directly to services provided by the FQHC within the scope of the FQHC's §330 grant.

To be protected under the safe harbor, an arrangement must contribute to the ability of the FQHC to maintain or increase the availability of, or enhance the quality of, services provided to a medically underserved population. Health centers must reasonably expect before entering into an agreement that the arrangement will yield such a benefit and must document the basis for that determination.

Protected arrangements must be in writing and signed by the parties. The amount of the remuneration must be specified and may not be conditioned on the volume or value of federal health care program business generated between the parties. Further, health centers must not be required to refer patients to a particular provider or supplier under the arrangement, but rather must be free to refer patients to any provider or supplier. Donors that offer to furnish goods, items, or services to FQHC patients must furnish those goods, items, or services to all FQHC patients who clinically qualify for them, regardless of their payor status or ability to pay.

The FQHC safe harbor regulations will be effective December 3, 2007. ■

Final rule, 72 FR 56632, Oct. 4, 2007, Health Care Compliance Reporter ¶700,051.

In the News

Medicaid prescription pad requirement delayed

The implementation date for all paper Medicaid prescriptions to be written on tamper-resistant paper has been delayed from October 1, 2007, until April 1, 2008. Under §7002(b) of the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act, which was signed into law on May 25, 2007, for outpatient drugs to be reimbursable by Medicaid, all written, nonelectronic prescriptions must be executed on tamper-resistant pads. To be considered tamper-resistant, a prescription pad must have one or more industry-recognized features designed to prevent (1) unauthorized copying of a completed or blank prescription form; (2) erasure or modification of information written on the prescription form by the prescriber; or (3) use of counterfeit prescription forms. President George W. Bush signed the "Extenders Law" on September 29, 2007.

Low Access Open Door Forum, Oct. 1, 2007; CMS Letter to State Medicaid Directors, No. 07-012, Aug. 17, 2007.

Mental health parity bill advancing in House

The House Ways and Means Health Committee passed a bill designed to improve the overall health of all Americans by providing greater access to mental health and addiction treatments. Under the bill – the Paul Wellstone Mental Health and Addiction Equity Act (H.R. 1424) – group health plans that provide mental health benefits would be required to do so on the same terms as care for physical ailments. The bill would prohibit employer group health plans from imposing higher copayments, steeper deductibles, maximum out-of-pocket limits and lower visit limits unless comparable terms are imposed on benefits for physical health problems. The committee approved the legislation by a 27-13 vote on September 26.

CCH Washington Bureau, Sept. 27, 2007.

Company pays $160 million for drug misrepresentations

The makers of OxyContin and several of their executives paid $160 million to federal and state government agencies for misrepresenting the dangers of the drug. The payment comes as a consequence of a federal prosecution that charged the companies with misrepresenting the narcotic painkiller's potential for abuse and addiction, and an accompanying civil settlement. In a federal case prosecuted in the Western District of Virginia, the companies and executives pleaded guilty to charges of knowingly and fraudulently misbranding OxyContin as being less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal problems than other pain medications. The Attorney General's Medicaid Fraud Control Unit headed the team charged with negotiating on behalf of the states and distributing the funds to the participant states, including New York, which received $7.26 million in damages.

New York Attorney General Press Release, Sept. 13, 2007.