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Health Law Strategist

CMS establishes self-referral disclosure protocol

By Nancy Waite

As mandated by the Affordable Care Act, on Sept. 23, 2010, the Centers for Medicare & Medicaid Services (CMS) established a voluntary self-referral disclosure protocol (SRDP) to enable health care providers to disclose actual or potential violations of the federal physician self-referral statute (the Stark Law).

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Background

The Stark Law prohibits a physician from making referrals for designated health services payable by Medicare or Medicaid to an entity with which the physician (or a member of his/her immediate family) has a financial relationship, unless an exception applies. The entity may not bill for designated health services furnished pursuant to a prohibited referral, and if an entity collects any amounts billed in violation of the Stark Law, it must refund such amounts. The Stark Law is a strict liability statute because proof of specific intent to violate the law is not required. However, for a "knowing" violation, the government can also impose civil monetary penalties of not more than $15,000 for each service and exclude the provider from participation in federal and state health care programs.

In the past, entities that discovered a Stark Law violation could utilize the Office of Inspector General's (OIG's) self disclosure protocol. However, the OIG released an Open Letter on March 24, 2009, stating that the OIG no longer would accept disclosures that only involve liability under the Stark Law in the absence of a colorable anti-kickback statute violation. CMS, in the SRDP, indicates that if conduct raises liability under both the Stark Law and the anti-kickback statute, the conduct should continue to be disclosed through the OIG's self disclosure protocol.

Overview

The SRDP is open to all health care providers and is distinct from the CMS physician self-referral advisory opinion process. The SRDP is intended to facilitate the resolution of only matters that, in the disclosing party's reasonable assessment, are

actual or potential violations of the Stark Law. Therefore, a disclosing party should make a submission to the SRDP with the intention of resolving its overpayment liability exposure for the identified conduct.

Upon receiving an SRDP submission, CMS will verify the disclosed information and must have access to all financial statements, notes, disclosures and other supporting documents without the assertion of privileges or limitations on the information produced. CMS will review the circumstances surrounding the disclosed matter to determine an appropriate resolution. Disclosing parties should be aware that CMS will coordinate with the OIG and the Department of Justice (DOJ), and CMS may conclude that the disclosed matter warrants a referral to law enforcement for consideration under its civil and/or criminal authorities.

Submission

CMS sets forth SRDP instructions on its website. The comprehensive submission must include, in part, a thorough description of the matter being disclosed, a complete legal analysis of the violation, the circumstances under which the disclosed matter was discovered, an indication of whether the disclosing party has knowledge that the matter is under current inquiry by a Government agency or contractor, and a complete financial analysis including the total amount, itemized by year, that is actually or potentially due and owing based upon the applicable "look back" period.

Factors for CMS to consider

The factors CMS may consider in reducing the amounts otherwise owed include:

- nature and extent of the improper or illegal practice;
- timeliness of the self-disclosure;
- cooperation in providing additional information related to the disclosure;
- litigation risk associated with the disclosed matter; and
- disclosing party's financial position.

CMS will determine whether a reduction is appropriate based on the specific facts and circumstances of each disclosed violation, but CMS has no obligation to reduce any amounts due and owing.

Concerns

The SRDP does not provide guidance on how CMS will weigh or analyze these factors in proposing a settlement. This uncertainty combined with the explicit acknowledgement that CMS has no obligation to reduce any amounts due and owing raises significant concerns for providers contemplating a disclosure under the SRDP.

Further, if CMS proposes a settlement the disclosing party believes is unfair, the disclosing party is in a difficult negotiating position because, in its SRDP submission, the disclosing party already admitted the Stark Law violation and provided a complete legal and financial analysis of the violation.

Conclusions

The SRDP provides a mechanism for providers to disclose Stark Law violations and, hopefully, to enter into settlements with CMS to reduce repayment obligations. However, it is unlikely that CMS will see a substantial number of submissions until CMS provides guidance on how it will analyze the factors in preparing settlements and/or CMS develops a history of proposing fair SRDP settlements. In order to make this determination, providers may need to wait until March 23, 2012, when U.S. Department of Health and Human Services must submit to Congress a report on the SRDP's implementation including the number of health care providers making disclosures, the amount collected and the types of violations reported.

In the meantime, if a provider discovers a Stark Law violation, the provider must seek competent legal counsel to determine whether the SRDP process is appropriate.

For questions about SRDP, please contact Nancy Waite at 614.462.5015 or nwaite@szd.com or any member of SZD's Health Care Practice Group. ■

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Medical device tax enacted as part of health care reform

By Nancy Waite

On March 30, 2010, President Obama signed into law the Health Care and Education Reconciliation Act (Public Law No. 111-152) (the Reconciliation Law). This Act amended the sweeping federal health care reform bill and included a 2.3 percent excise tax on the sale of medical devices. However, certain types of devices are exempt from the tax, including eyeglasses, contact lenses, hearing aids and other devices that are generally purchased by the general public at retail for individual use. The medical device tax applies to sales after Dec. 31, 2012, and is expected to generate $20 billion over 10 years.

On March 23, 2010, President Obama signed the Affordable Care Act (ACA) which was subsequently amended by the Reconciliation Law. Media coverage of federal health care reform has primarily focused on the provisions holding insurers and providers more accountable, making health care more affordable and expanding health coverage to millions of uninsured Americans. The Congressional Budget Office estimates that these sweeping reforms come with a staggering price tag of $938 billion. The provisions that will help finance the reform and that significantly impact the life science industry have not received as much attention. One such provision is the medical device tax.

Evolution of the medical device tax

ACA. Section 9009 of the ACA would have imposed an annual "fee" on manufacturers and importers of certain medical devices. The fee would have been allocated among manufacturers and importers based upon their share of covered sales. For purposes of calculating this fee, covered sales did not include sales of (a) Class I medical devices and (b) Class II medical devices that are sold primarily to consumers at retail for not more than $100. Further, small medical device manufacturers would have been protected, because the first $5 million of receipts from a company's medical device sales were not taken into account and only 50 percent of receipts between $5 million and $25 million were taken into account. The fee was not deductible, would have first been payable in 2011 based on 2010 sales and would have raised $2 billion per year starting in 2011 and $3 billion per year starting in 2017.

Reconciliation Law. The initial version of the Reconciliation Law would have replaced the annual fee with a 2.9 percent excise tax on the sale of medical devices and included an exemption for all Class I medical devices. A House Rules Committee amendment lowered the tax rate to 2.3 percent but, in order to continue to generate $2 billion a year, the amendment also eliminated the broad exemption for Class I medical devices. The deletion of this exemption was a significant change because 47 percent of medical devices fall under Class I.

As enacted, the Reconciliation Law repealed the annual fee imposed by the ACA and instead imposed a 2.3 percent excise tax on the sale of any taxable medical device by the manufacturer, producer or importer. The medical device industry successfully lobbied to delay the tax until 2013 and for the tax to be deductible.

The term "taxable medical device" means any device (as defined in Section 201(h) of the Federal Food, Drug and Cosmetic Act) intended for humans. However, this term does not include:

- eyeglasses;
- contact lenses;
- hearing aids; and
- any other medical device determined by the Secretary of the Treasury to be of a type which is generally purchased by the general public at retail for individual use.

Under Section 201(h) of the Federal Food, Drug and Cosmetic Act, a medical device is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component, part, or accessory which is:

- **recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,**
- **intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals, or**
- **intended to affect the structure or any function of the body of man or other animals and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes."**

Taxable medical devices – Awaiting clarifying guidance

Medical devices include a diverse mix of products ranging from simple devices such as elastic bandages and bedpans to complex implantable pacemakers and joint implants. However, ambiguity exists regarding whether certain types of products will be considered "taxable medical devices." For example, combination products include products composed of a combination of (a) a drug and a device or (b) a biological and a device. Examples of combination products are devices coated or impregnated with a drug or biological (drug-eluting stent; catheter with antimicrobial coating), prefilled syringes and surgical trays with surgical instruments, drapes and lidocaine and alcohol swabs. The Secretary of the Treasury will need to determine how combination products will be treated for purposes of the medical device tax.

In addition, the Secretary of the Treasury has not yet issued guidance on what devices qualify for the retail exemption. The Secretary will need to define by regulation when a device is purchased by the "general public" at "retail" for "individual use." One uncertainty is how the Secretary will address types of medical devices that are sold at retail for individual use and also sold to hospitals or physician offices. It is anticipated that the Secretary will prepare a list of products that qualify for the retail exemption. Therefore, medical device companies should consider providing the Secretary with a list of their devices that they believe qualify for the retail exemption and work with their trade associations to help educate the Secretary about the appropriate scope of the retail exemption.

Will increased demand help offset tax?

Lawmakers defend the medical device tax by arguing that health care reform will result in an increase in demand for medical devices. It is true that reform initiatives should result in increased sales for certain segments of the medical device industry. For example, health care reform encourages reductions in adverse events in hospitals. Therefore, medical devices that prevent adverse events, such as catheters that are designed to reduce infections, should have increased sales.

However, the medical device industry does not believe that health care reform, particularly the coverage expansion in 2014, will result in a substantial increase in demand for medical devices overall. In fact, hospitals purchase 60 percent of medical devices and provide care to uninsured patients. By increasing the number of insured individuals, a greater percentage of hospital patients should have insurance coverage. But, the medical device industry does not believe that expanded insurance coverage will necessarily result in more hospital patients using more medical devices.

Further, older individuals utilize a disproportionally large share of medical devices and are already covered by Medicare. Therefore, while certain segments of the medical device industry may benefit from health care reform, the medical device industry as a whole does not anticipate a significant increase in demand.

Impact of the tax

While recognizing that the current health care system is not sustainable, the medical device industry is concerned about utilizing the medical device tax to finance health care reform.

The tax will negatively impact both large and small medical device companies by decreasing funds available for research, development and job growth. Small, start-up companies are an important source of innovative, breakthrough technology and are particularly vulnerable because they often have not yet achieved profitability.

Venture capital firms that provide seed capital for early stage medical device companies view the medical device tax as an additional obstacle in a highly regulated industry that incurs high research and development costs. Therefore, the tax may result in less venture capital investment for early stage companies in the medical device sector. As a result of their special concerns, start-up medical device companies are advocating for a revenue-based exemption or a phase-in of the tax for small companies.

Efforts to repeal

While some groups are challenging the constitutionality of federal health care reform and others are pursuing repeal of the health care reform in its entirety, two bills have been introduced to specifically repeal the medical device tax. In April, Representative Erik Paulsen of Minnesota introduced HR 5095, the Protect Medical Innovation Act, to remove the medical device tax from the Internal Revenue Code. In June, Representative Brian Bilbray of California introduced HR 5615, the Medical Device Repeal Bill, which would repeal the medical device tax and use unspent stimulus funds to offset the loss of revenue. Neither piece of legislation is currently moving toward enactment.

Conclusion

Because implementation of the medical device tax is delayed until 2013, the medical device industry has the opportunity to encourage the Secretary of the Treasury to provide favorable guidance regarding what devices qualify for the retail exemption and clarification of whether certain products (such as combination products) are subject to the tax. Additionally, the industry may consider pursuing legislative changes such as an exemption or phase-in for small companies. In the meantime, medical device companies should evaluate the impact of the 2.3 percent tax on their business and take appropriate steps to prepare for this possibility.

For questions about health care reform, please contact Nancy Waite at 614.462.5015 or nwaite@szd.com or any member of SZD's Health Care Practice Group. ■

Ohio Supreme Court finds dialysis clinic not entitled to property tax exemption

By Robert Cochran

On Oct. 26, 2010, the Ohio Supreme Court, in a 4-3 opinion, affirmed the Board of Tax Appeals' (BTA's) decision that a Dialysis Clinic, Inc. (DCI) facility was not entitled to a tax exemption for real property under RC §5709.121 or RC §5709.12(B). *Dialysis Clinic, Inc. v. Levin*, 2010 WL 4260620 (Ohio).

DCI, a 501(c)(3) tax-exempt corporation providing dialysis services, filed an application for a property tax exemption for its West Chester facility. DCI sought exemption primarily under RC §5709.121(A)(2). To qualify for this exemption, DCI must be a "charitable institution." Because DCI's core activity involves the provision of a health care service, DCI qualifies as a "charitable institution" under RC §5709.121 only if it provides service "on a nonprofit basis to those in need, without regard to race, creed, or ability to pay." The Ohio Supreme Court determined the BTA acted reasonably and lawfully in determining that DCI is not a charitable institution.

First, the BTA found that DCI could not base its charitable institution claim on its donation of surplus revenue to kidney research. The Court agreed that DCI may not vicariously establish its own core activity as charitable by pointing to a benefit that it confers upon another entity whose activity is charitable.

Second, and most important, the BTA emphasized that DCI's indigency policy explicitly stated that it was "not a charity or gift to patients [and that] DCI retains all rights to refuse to admit and treat a patient who has no ability to pay." The Ohio Supreme Court agreed that this policy contradicts the assertion that DCI is committed to provide services on a nondiscriminatory basis, which is an essential prerequisite for a health care provider to qualify as a charitable institution.

Third, the BTA found that DCI was required to show it provided some threshold level of unreimbursed care at its facility. The Ohio Supreme Court disagreed and held that DCI did not need to show a particular percentage of unreimbursed care if it proved its commitment to providing care on a nondiscriminatory basis. Further, the Court determined that a person at DCI's West Chester facility who lacks financial means to pay is usually entitled to benefits under Medicare or Medicaid, or both. Therefore, DCI's decision to serve these patients to some extent qualifies as the provision of care to persons who otherwise lack the means to afford it.

Even though a minimum percentage of unreimbursed care is not required to be a charitable institution, the Ohio Supreme Court found that the record contained sufficient support for the BTA's ultimate finding that the property tax exemption under RC §5709.121 for DCI's West Chester facility was properly denied.

Further, the Court agreed with the BTA's finding that DCI also does not qualify for exemption under RC §5709.12(B) as an institution that uses the property exclusively for charitable purposes. Under the circumstances of this case, the Ohio Supreme Court found that the determination of DCI's exemption claim under RC §5709.12(B) does not significantly differ from the evaluation of the claim under RC §5709.121. Therefore, the Court concluded that DCI's West Chester real property also did not qualify for exemption under RC §5709.12(B).

Conclusion

In affirming that DCI's West Chester property did not qualify for property tax exemption, the majority emphasized that DCI was not a "charitable institution" because pursuant to its indigency policy DCI retains the right to refuse to treat a patient who is unable to pay.

The dissent argued that even though DCI's indigency policy reserves the right to refuse treatment to indigent patients, the evidence showed that DCI did in fact provide services to all patients irrespective of their ability to pay. Therefore, the dissent believed that DCI qualifies as a "charitable institution" and its West Chester property should be exempt.

Importantly for health care providers seeking property tax exemption under RC §5709.121 or RC §5709.12, both the dissent and majority agreed that no minimum percentage of unreimbursed care is required to qualify for property tax exemption.

For questions about charitable tax exemptions, please contact Robert Cochran at 614.462.2248 or rcochran@szd.com or any member of SZD's Health Care Practice Group. ■

OIG excludes drug company executive from federal health programs

By Robert Cochran

The Office of Inspector General (OIG), U.S. Department of Health and Human Services, recently excluded a drug company executive from participating in federal health care programs. The executive is a former member of a St. Louis-based pharmaceutical company. According to published press reports, the executive is Marc Hermelin and the pharmaceutical company is K-V Pharmaceutical Co. The exclusion is significant because Hermelin was not convicted of a crime. Instead, the exclusion was based on the company's compliance problems with the Food & Drug Administration. Hermelin is the first pharmaceutical company official who hasn't been convicted of a crime to be excluded from federal health care programs by the OIG.

Under federal law, the OIG has the authority to exclude an individual owner, officer or managing employee of a sanctioned entity (i.e. an entity that has been convicted of certain offenses or excluded from participation in federal health care programs). A "managing employee" means an individual who exercises operational or managerial control over the entity or who directly or indirectly conducts the day-to-day operations of the entity. A "managing employee" could include a general manager, business manager or administrator.

This type of exclusion is derivative in nature, meaning the exclusion is based upon the individual's role or interest in the company that is excluded. The exclusion is not necessarily based on any affirmative misconduct by the individual. OIG's exclusion analysis is different depending on whether the individual is: (1) an owner or (2) an officer or managing employee.

The statute sets a higher standard for exclusion of an owner, requiring evidence that the owner knew or should have known of the conduct that formed the basis for the sanction. In general, if the evidence supports a finding that an owner knew or should have known of the conduct, OIG will operate with a presumption in favor of exclusion. This presumption may be overcome when OIG finds that significant factors weigh against exclusion.

For officers and managing employees, the statute includes no knowledge element. This means OIG has the authority to exclude every officer and managing employee of a sanctioned entity. OIG claims it does not intend to exclude all officers and managing employees, however, where there is evidence that an officer or a managing employee knew or should have known of the conduct, OIG will operate with a presumption in favor of exclusion. As with the presumption relating to owners, the presumption may be overcome if the OIG finds that significant factors weigh against exclusion.

In late October, OIG published guidance outlining the factors to be considered in implementing this exclusion authority. In general, OIG looks at (1) the circumstances of the misconduct and the seriousness of the offense; (2) the individual's role in the sanctioned entity; (3) the individual's actions in response to the misconduct; and (4) information about the entity such as the entity's compliance history. The guidelines are subject to modification at any time and are not intended to limit the OIG's authority to exclude individuals the OIG considers a risk to federal health care programs.

The published guidance followed by the exclusion of a board member may signal OIG's increased willingness and interest in excluding owners, officers and managing employees of sanctioned entities. This means compliance problems can impact not only the organization, but the people responsible for running the organization.

For questions about OIG's exclusionary authority, please contact Robert Cochran at 614.462.2248 or rcochran@szd.com or any member of SZD's Health Care Practice Group. ■

WEB EXTRAS

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No peer review privilege in federal *race discrimination* lawsuit

By Robert Cochran

On July 23, 2010, a federal court in Columbus concluded there is no peer review protection in federal court. The case, *Guinn v. Mount Carmel Health Systems*, involved a dispute between a physician (Dr. Guinn) and a hospital. Dr. Guinn claimed that some of his hospital privileges were summarily suspended without adequate investigation or discussion. The suspension was related to an alleged quality of care issue. Dr. Guinn claimed the suspension was eventually upheld by the hospital based upon unsupported accusations. Dr. Guinn further claimed that to the extent his patient care fell below the standard of care, he was treated differently than other similarly situated physicians because of his race. Accordingly, his complaint included both state law claims and federal claims for civil rights violations.

In written discovery, Dr. Guinn asked the hospital to identify all similarly situated physicians with medical privileges, whether any of those physicians had ever been disciplined, and the outcome of that discipline. Additionally, Dr. Guinn sought to discover information regarding the hospital's treatment of other similarly situated physicians in the peer review process. The hospital objected to Dr. Guinn's discovery requests based on Ohio's peer review privilege statute and physician-patient privilege statute. The hospital also claimed much of the requested discovery was irrelevant. Dr. Guinn filed a motion to compel discovery in which he sought to compel responses to all discovery requests that had been withheld on grounds of privilege or relevance.

The court granted the motion in part and denied the motion in part. The court resolved the privilege issue quickly, siding with Dr. Guinn. The court concluded that it must apply the federal law of privilege, and it is well-established that there is no federal physician-patient privilege. Similarly, the court found no peer review privilege under federal common law. Therefore, the Court granted the motion to compel and held that the hospital could not object to the discovery requests based on the physician-patient or peer review privileges.

The Court further held that Dr. Guinn failed to prove the relevance of substantially all of his discovery requests. Specifically, Dr. Guinn made no attempt to inform the Court how each request was reasonably calculated to lead to the discovery of admissible evidence or how specific requests had been narrowly tailored. Therefore, the Court denied Dr. Guinn's motion to compel, but allowed him to re-file the motion with the information the Court requested.

The decision is part of a trend in the federal judiciary holding that a peer review privilege does not exist under federal law.

For questions about peer review law or medical staff disputes, please contact Robert Cochran at 614.462.2248 or rcochran@szd.com or any member of SZD's Health Care Practice Group. ■

CMS delays enforcing *physician certification requirements* for home health and hospice services

By Robert Cochran

In December, CMS announced a delay in the enforcement of new physician certification requirements for home health and hospice services. The new certification requirements were mandated by the Affordable Care Act (ACA). Effective January 2011, the ACA required that a physician have a face-to-face encounter with a patient for purposes of certifying eligibility for Medicare home health services or recertifying hospice eligibility. CMS announced the delay to give providers additional time to establish operational protocols necessary to comply with the law. This is a summary of the new requirements.

Home health services

Section 6407 of the ACA requires a physician to document that the physician himself or herself (or specified non-physician practitioners) has had a face-to-face encounter with the patient. This encounter may be through the use of telehealth, subject to the requirements of Section 1834(m) of the Social Security Act. The ACA does not amend the statutory requirement that a physician certify a patient's eligibility for Medicare's home health benefit. Rather, the provision allows for specific non-physician practitioners to perform the face-to-face encounter with the patient in lieu of the certifying physician, and inform the physician making the initial certification for eligibility for the Medicare home health benefit. The certifying physician must document the face-to-face encounter regardless of whether the physician himself or herself or one of the permitted non-physician practitioners performs the face-to-face encounter. CMS "believe[s] that the face-to-face statutory provision was enacted to strengthen physician accountability in certifying that home health patients meet home health eligibility requirements."

The ACA authorized CMS to prescribe a time frame for the face-to-face encounter. CMS believes the encounter needs to occur close enough to the start of care to ensure that the clinical conditions exhibited by the patient during the encounter are related to the primary reason for the patient's need for home health care. As a result, the regulations provide that the physician responsible for the certification of home health services must document that he or she (or the appropriate non-physician practitioner) has had the face-to-face encounter no more than 30 days prior to the home health start of care date.

Additionally, if this requirement is satisfied, but the patient's clinical condition changes significantly between the time of the face-to-face encounter and the home health episode of care, such that the primary reason the patient requires home care is unrelated to the patient's condition at the time of the face-to-face encounter, the original encounter will not satisfy the requirement. Instead, under this scenario, another face-to-face encounter will be required within two weeks of the start of home care. Similarly, if no encounter occurred within the 30 days prior to the start of care, the face-to-face encounter must take place within two weeks after the start of home care.

CMS has also issued regulations governing the documentation of the face-to-face encounter. The documentation must clearly state that either the certifying physician himself or herself (or the applicable non-physician practitioner) has had a face-to-face encounter with the patient and include the date of the encounter. The documentation also needs to describe how the clinical findings of the encounter support the patient's eligibility for home health benefits. Specifically, the physician has to document how the clinical findings of the encounter support findings that the patient is homebound and in need of intermittent skilled nursing or therapy services. Moreover, the certifying physician is required to sign and date the certification, and document the face-to-face encounter in his or her practice's medical record. As such, the physician's medical record keeping for that patient must be consistent with and supportive of the required documentation of the face-to-face encounter as part of the certification.

Hospice services

For hospice services, the ACA requires a hospice physician or nurse practitioner to have a face-to-face encounter with every hospice patient to determine the continued eligibility of the patient prior to the 180-day recertification, and prior to each subsequent recertification. The ACA also requires that each hospice physician or nurse practitioner attest that the encounter took place. Recertification visits by physicians or nurse practitioners must be made not sooner than 15 calendar days prior to the recertification and subsequent recertifications, and the visit findings must be used by the certifying physician to determine continued eligibility for hospice care.

Conclusion

CMS expects full compliance with the certification requirements beginning with the second quarter of calendar year 2011. During the first quarter of 2011, CMS expects that providers will collaborate and establish internal processes to ensure compliance.

For questions about home health and hospice care, contact Robert Cochran at 614.462.2248 or rcochran@szd.com or any member of SZD's Health Care Practice Group.

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