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HEALTH LAW NOTES

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INSPECTOR GENERAL RELEASES OPEN LETTER

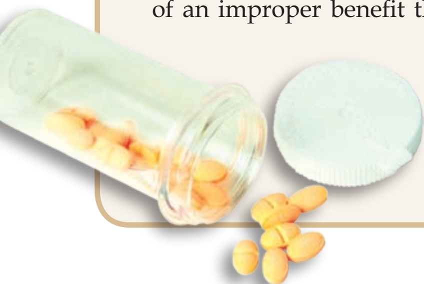
On April 24, 2006, the Inspector General of the U.S. Department of Health and Human Services (the "IG"), Daniel R. Levinson, issued an open letter to health care providers, focusing specifically on physicians and hospital providers. This letter focuses on potential violations of the Stark and anti-kickback statutes in the context of the hospital-physician relationship. The letter states that several hospital providers are discovering, through their compliance programs, improper financial arrangements under the Stark law, which is a strict liability statute. Stark prohibits the referral of Medicare or Medicaid patients to a hospital by any physician who has a "financial relationship" with the hospital. The financial relationship can take the form of either an ownership interest or a compensation arrangement. There are numerous exceptions to the Stark law's prohibition, but each element of an exception must be met to avoid the strict liability of the Stark law.

> *"Violations of the anti-kickback law....can result in the imposition of civil monetary penalties against both parties to the transaction as well as possible exclusion from federal health care programs..."*

The IG points out in his letter that physicians and hospitals that have these problematic arrangements may also be at risk of violating the federal anti-kickback statute. This statute is a criminal statute, the violation of which is a felony. It requires proof of intent to violate the law for a conviction to result. Violations of the anti-kickback law, as well as knowing violations of the Stark law, can result in the imposition of civil monetary penalties against both parties to the transaction, as well as possible exclusion from participation in federal health care programs, including the Medicare and Medicaid Programs.

The IG's letter encourages hospital and physician providers to utilize the OIG's Self-Disclosure Protocol ("SDP") to deal with "conduct that may result in liability under the OIG's CMP authorities for physician self-referral and anti-kickback violations." He refers to his letter as a "new initiative" for seeking to make providers aware of how to resolve this kind of issue. He suggests that the initiative supplements the SDP, and that under it, the IG will confer with the Department of Justice ("DOJ") before accepting a provider into the Protocol. He also states that the OIG's agreement to resolve a SDP matter is not binding on the DOJ, the federal criminal enforcement agency.

Unfortunately, the IG's letter gives only one example of an improper benefit that may be conferred by a hospital to a physician—an arrangement whereby the physician pays the hospital less than fair market value for a good or service, such as the lease of office space. He does reiterate, however, that the focus of the enforcement effort is on situations involving a financial benefit being knowingly conferred. At the same time, he stresses the importance of health care providers implementing an appropriate compliance program.



A compliance program, if effective and adequately implemented, should include a review of all hospital-physician relationships. Such a review arguably would place hospital and physician providers on notice of whether they have exposure to liability for a knowing violation of the Stark law or for a violation of the anti-kickback statute. Once they have such knowledge, they would need to assess the risks, if any, of their arrangements and then make an informed decision of whether and how to act on that information. A provider who is considering the use of the SDP should do so carefully and with the assistance of health law counsel, and, potentially, other experts. Anyone, whether hospital and physicians or otherwise, who discloses under the SDP is subject to involvement of the DOJ, and there is no guarantee that resolution via the SDP will end the matter as to all enforcers. Additionally, disclosing providers can expect to enter into either a corporate integrity agreement, which is basically a federal-government imposed compliance program, or a "certificate of compliance agreement", which is a less onerous agreement by which the provider agrees to continue an existing compliance program for a set number of years.

The potential good news (if there is any) in IG Levinson's letter is that resolution of improper remuneration cases is generally reached through the payment of a multiple of the value of the financial benefit conferred. He gives the ever-present disclaimer, however, by qualifying his statement with the phrase "subject to the facts and circumstances of the case." Nevertheless, any SDP resolution for such an amount would allow a provider to potentially avoid the payment of triple damages, civil monetary penalties or both. As always, however, there are no guarantees as to how a SDP matter will be resolved or as to whether further action will be taken by DOJ.

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LEGISLATION PENDING TO ESTABLISH A PRESCRIPTION MONITORING PROGRAM IN LOUISIANA

Representative Ronnie Johns has introduced House Bill No. 153 for consideration during the 2006 Regular Session of the Louisiana Legislature. This Bill, if enacted, would authorize the Louisiana Board of Pharmacy to develop and run a prescription monitoring program. The purpose of the program is to monitor the prescribing and dispensing of controlled substances in order to identify and inhibit the diversion of controlled substances. The Bill requires all dispensers, including dispensing physicians and pharmacies, to report information to the Louisiana Board of Pharmacy whenever a controlled substance and other "drugs of concern" identified by the board, is dispensed in the state of Louisiana. As the Bill currently reads, the information to be submitted to the Board includes: prescriber information, patient information, prescription information, controlled substance or drug information, and dispenser information. The Board will maintain the information in an electronic database.

The information submitted to the database will not be public record, but may be made available to law enforcement and professional licensing agencies to utilize in the course of an investigation and subsequent criminal and administrative proceedings. The Bill would allow access to the database, upon successful completion of educational courses, by the following persons: prescribers and dispensers for the purpose of providing medical care to their patients; representatives from licensing agencies; representatives of the Medicaid program; and representatives of any contractor maintaining the monitoring program. An individual may also request his personal information maintained by the board. The information will not be available for civil subpoena and will not be discoverable in any civil proceeding. Kean Miller assisted with drafting amendments to the Bill to ensure that the program will comply with HIPAA.

The Bill provides that any person required to report information shall not be liable for any claim of damages as a result of reporting the information and no lawsuit may be predicated thereon. In addition, any person who in good faith submits information that is not subject to the prescription monitoring program shall not be liable for any claim of damages and no lawsuit may be predicated thereon. However, a dispenser who fails to report prescription information shall be referred to the appropriate licensing agency.

The Bill also provides for penalties. Any person who knowingly discloses information in violation of the Act shall be referred to the appropriate licensing agency for administrative sanctions and may, upon criminal conviction, be imprisoned, with or without hard labor, for not more than five years, and in addition, may be fined not more than $5,000.00. Also, any person who uses such information for a purpose in violation of the Act shall be referred to the appropriate licensing agency for administrative sanctions and may, upon criminal conviction, be imprisoned, with or without hard labor, for not more than five years, and in addition, may be fined not more than $5,000.00.

In order to generate funds for the program, the Bill provides the Board of Pharmacy the authority to levy and collect an annual fee of $25.00 from each of the following practitioners in possession of authority to prescribe or dispense controlled dangerous substances: physicians, podiatrists, dentists, optometrists, advanced practice registered nurses, physician assistants, medical psychologists, or any other person subsequently authorized by law to prescribe controlled dangerous substances with the exception of veterinarians. The annual fee can also be levied on each pharmacy.

House Bill 153, if passed, would go into effect on July 1, 2006. The Board of Pharmacy has indicated that it anticipates a start-up date for reporting by January 1, 2007, and may open the database to full access by July 1, 2007. House Bill 153 has already been approved by the House of Representatives and is pending approval by the Senate.

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