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HEALTH LAW NOTES

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What's Inside

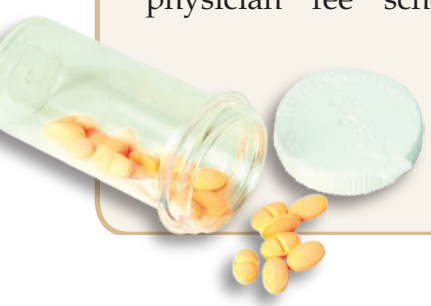
CMS COMMENTS ON RADIOLOGY SERVICE AGREEMENTS

Health care providers welcomed the changes last year to the Medicare reassignment requirements that allow independent contractor physicians to reassign payment for Medicare-covered services regardless of the site of service to another entity such as a physician group. Prior to these changes, the Medicare reassignment regulations specifically required independent contractor physicians to provide services on a group's premises if the group wanted Medicare to pay the group directly for that physician's services.

Pursuant to the changes to the reassignment requirements in the Medicare Modernization Act for independent contractor physicians, many physician group practices considered contracting with radiologists to perform the professional component of certain diagnostic services. In this arrangement, the radiologist could perform the professional interpretation of a diagnostic service at a location other than the physician group's office (e.g., via teleradiography), the group would pay a flat fee to the radiologist for the interpretation and report, and the group would bill Medicare for the diagnostic test and interpretation under a global billing code.

In the preamble to the 2005 Medicare physician fee schedule, CMS commented that the changes to the reassignment requirements did not change the requirements under other Medicare billing rules or regulations that affect billing and claims submission such as the Stark Law. CMS further commented that physician practices "should be mindful" that compliance with the physician services and in-office ancillary services exceptions to the Stark Law require a physician who is engaged by a group practice as an independent contractor may provide services subject to the Stark Law (e.g., radiology services) to the group practice's patients only in the group's facilities.

These comments by CMS were a direct reminder that the services of an independent contractor physician, such as professional services of a radiologist, must be furnished on the premises of a physician group if a physician group would like the services to meet the in-office ancillary services exception to the Stark Law. For example, if an orthopedic physician would like to refer his patient to his group for an MRI and the group would like to bill Medicare for both the MRI and as interpretation of the MRI by an independent contractor radiologist, the interpretation by the radiologist must be performed on the premises of the orthopedic group.



CMS ANNOUNCES INTENTION TO MAKE NUCLEAR MEDICINE SUBJECT TO THE STARK LAW

CMS announced on December 13, 2004 in the release of its regulatory agenda for 2005 that it plans to issue a proposed regulation around September 2005 to add nuclear medicine services and supplies to the definition of "radiology and certain other imaging services" in the Stark Law. If this proposed regulation is released and adopted in final form by CMS, nuclear medicine services such as PET imaging would be subject to the physician self-referral prohibition in the Stark Law. Physicians should be aware that this change would affect referrals of Medicare and Medicaid patients for PET imaging services to any entities in which the referring physician or a member of the physician's family has a financial relationship. CMS had included this same proposed change in its regulatory agenda for 2004; however, CMS did not issue this proposed rule during 2004.

Clay J. Countryman
225.389.3729
clay.countryman@keanmiller.com

PHARMACEUTICAL MARKET ACCESS ACT OF 2005

Senators Vitter, Salazar, Thune and Demint have proposed legislation to amend and expand the "Importation of Prescription Drugs" statute found at 21 U.S.C. §384. The Importation of Prescription Drugs statute, which became effective December 8, 2003, allows for the importation of prescription drugs from Canada to pharmacists or wholesalers in the United States. The statute calls for the Secretary to promulgate regulations under the provisions of the statute to guide such importation by pharmacists and wholesalers. Additionally, the statute allowed the Secretary of DHHS to grant by regulation or waiver a permit for individuals to import into the United States a prescription drug, approved by the Secretary under the Federal Food Drug and Cosmetic Act ("FDCA"), for personal use, in quantities that do not exceed a 90-day supply. Under this statute, individuals are granted waivers on a case-by-case basis; however, the Secretary is directed to publish guidance that accurately describes circumstances in which the Secretary will consistently grant such waivers.

"...The Importation of Prescription Drugs statute... ...allows for the importation of prescription drugs from Canada to pharmacists or wholesalers in the United States."

One of the major expansions of the current statute proposed by Senator Vitter, et al, is to allow importation of prescription drugs from not only Canada but from any "permitted countries". The term "permitted country" means a country, union, or economic area listed as an eligible country for export. In other words, any country listed, i.e., Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa or in the European Union, as an approved country for export purposes with the United

States would qualify to import prescription drugs into the United States under this new legislation. Moreover, the new legislation grants the Secretary the authority to add or delete a country from this list if he determines that they do or do not have a "substantially equivalent or superior pharmaceutical infrastructure" to the United States.

The proposed legislation also changes the language in the statute and in the Food Drug and Cosmetic Act ("FDCA") from "prescription drugs" to "qualifying drugs". Qualifying drugs under the proposed legislation include those prescription drugs approved under the FDCA's new drug application and approval regulations minus those drugs requiring refrigeration or those that are photoreactive or are manufactured through a biotechnology process. The proposed legislation also removes the requirement for individuals to obtain waivers by the Secretary in order to import prescriptions for personal use. Instead, the new legislation permits individuals to import a drug from a permitted country to the U.S., as long as "it is a qualifying drug; imported from a licensed pharmacy or qualifying internet pharmacy; for personal use by an individual or family member; in a quantity not to exceed a 90-day supply during a 90-day period; and accompanied by a copy of a valid prescription for the drug issued by a practitioner authorized to administer prescription drugs". The proposed legislation also allows individuals to import a drug from a country that is not a permitted country if it was dispensed to the individual while the individual was in that country and it was dispensed according to the laws and regulations of such country, as long as the drug is approved for commercial distribution in the country in which the drug was obtained. The drug cannot appear to be adulterated and the quantity of the drug cannot exceed a 14-day supply.

"The drug cannot appear to be adulterated and the quantity of the drug cannot exceed a 14-day supply."

In order to accomplish the goals of the proposed legislation, the government, would have to create an entire infrastructure for inspections and registrations of importing countries to maintain the public safety. Additionally, the internet would be used as a primary source for individuals wishing to import drugs for personal use. This would greatly impact local pharmacies and pharmacists and create further concerns of internet privacy and consumer safety.

Jennifer F. DeCuir
225.389.3748
jennifer.decuir@keanmiller.com

SPECIALTY HOSPITAL UPDATE

The regulatory debate over Specialty Hospitals continues as the moratorium on referrals of Medicare patients by physician-investors expired on June 8, 2005. The moratorium was an 18-month period in which Congress provided that physician ownership and investment in "specialty hospitals" would not qualify for the "whole hospital" and "rural provider" exceptions in the Stark Law. Thus, during this period, a physician-investor in a "specialty hospital" was prohibited by the Stark Law from referring Medicare patients to a specialty hospital in which the physician had an ownership interest unless the specialty hospital was under development on the date the moratorium began.

The road ahead still may be uneasy for many specialty hospitals. CMS has instructed state survey and certification agencies to stop processing new provider enrollment applications for specialty hospitals until CMS completes a review of its procedures for examining specialty hospitals. CMS has also announced that it will pursue the following four initiatives related to specialty hospitals: (1) reform payment rates for inpatient hospital services through changes to the DRG; (2) reform payment rates for ASCs; (3) scrutinize whether specialty hospitals meet the definition of a hospital; and (4) review criteria for approving and paying new specialty hospitals. CMS commented that it hopes to complete this process by January 2006.

Clay J. Countryman
225.389.3729
clay.countryman@keanmiller.com

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