



A summary of recent developments provided by the health care law firm **Garfunkel, Wild & Travis, P.C.**

Changes Regarding Medicare Reimbursement for Diagnostic Tests Included in 2008 Physician Fee Schedule

Medicare has issued new regulations, to be effective January 1, 2008, that expand significantly the Medicare anti-mark up rule for diagnostic tests. This expanded rule will have a drastic effect on a provider's ability to bill Medicare for more than the cost of diagnostic tests which are either "purchased" by the provider or performed in certain offices of a provider. Moreover, the expanded anti-mark up rule applies to both the technical component and the professional component of a test.

In commenting on the new rule, Medicare has stressed that the rule is designed to take the profit out of billing for certain tests and to ensure that a profit motive is not driving a provider's decision of where to send a patient for a diagnostic test.

This new expansion of the anti-mark up regulations is included in the 2008 Physician Fee Schedule. Specifically, Medicare will prohibit a physician or practice from billing in excess of its costs for either the technical or professional component of a diagnostic test, ordered by the billing physician or other supplier, when the billing physician or supplier either (a) outright "purchases" the components, or (b) the component

is performed at a site other than the office of the billing physician or other supplier. For purposes of this new rule, office of a billing physician or other supplier is limited to space in which the physician organization provides substantially the full range of patient care

services that a physician organization provides generally. It is important to note that the definition does not refer to an office in the "same buildings" as set forth in the in-office ancillary service exception under the Stark provisions.

Continued on page 2

Claims Rejections Because of Mismatched Identification Numbers

The Center for Medicare and Medicaid Services ("CMS") announced that effective March 1, 2008, all Medicare fee-for-service claims must contain the National Provider Identifier ("NPI") and claims with only the legacy identifier will not be accepted. To date, the Medicare NPI crosswalk is successfully linking all NPIs to legacy numbers for most claims.

Until this implementation date or further notice, providers may continue to include legacy identifiers, but only in the secondary fields. CMS encourages all providers to use the NPI.

Since October 15, 2007, providers and suppliers who bill carriers and Medicare Administrative Contractors

(MACs) using the ASC X12 837P or CMS-1500 will receive informational warnings called "Provider Identification Code Qualifier Invalid Value" messages that indicate no NPI was used in the primary provider fields on the claim(s). Medicare is including these informational warnings on the providers' pre-pass reject reports provided. However, if a provider receives one of these messages and is certain that the claim was submitted with an NPI, the provider should contact its clearinghouse or billing agent to ascertain the reason behind the message. It is possible that the clearinghouse or billing agent removed the NPI prior to submitting the claim to Medicare. A provider may also want to call its carrier/MAC to inquire about the message and how it can correct future claims. Furthermore, if a provider continues to receive rejections despite the correct use of the NPI, re-enrollment with Medicare may be required. ■

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CMS Proposes Measures Against Fraud in Medicare Advantage, Part D Drug Plans

The Centers for Medicare and Medicaid Services (“CMS”) proposed new federal guidelines aimed at preventing fraud in the Medicare Advantage program and Part D prescription drug plans. The proposal seeks to expose fraud by requiring mandatory self-reporting. The guidelines also clarify the imposition of

intermediate sanctions and civil penalties for specified violations. Finally, the proposal would also require Medicare Advantage organizations to develop strategies for addressing fraud and abuse as part of Medicare Advantage compliance plans. ■

IRS Releases Draft of Revised Form 990

The Internal Revenue Service (“IRS”) released a draft of its revised Form 990. Form 990 is used by nonprofit hospitals to report tax information. The revised Form 990 seeks transparency by requiring hospitals to publicly report sensitive information.

The revised Form 990 requires hospitals to publicly report information regarding their financial information,

including compensation. The Form also requires hospitals to report information regarding fundraising and charitable contributions. One of the main revisions to Form 990 is the new emphasis on governance. The revised Form requires hospitals to report various governance-related data, including the composition of their boards of trustees. ■

Changes Regarding Reimbursement for Diagnostic Tests

Continued from page 1

Effectively, this means that if a practice maintains a separate office for the provision of diagnostic tests and does not provide substantially the full range of its services at such office, the practice may be prohibited from marking up the professional and/or technical component of services ordered by such practice and performed at such location. This prohibition will apply even if such location is (i) in the same building as another full service office of the practice, or (ii) a centralized location, as such term is defined in the Stark provisions. The limitation also applies when the component is “purchased” by the practice.

In essence, when read together with the existing Stark regulations, this

means that a practice may, if it meets the requirements of applicable Stark exception, be permitted to order, perform and bill for a test; but, based upon the new provisions, it may not be able to charge in excess of its costs. Further, the commentaries accompanying the new rule make it clear that overhead is not to be included in the determination of cost.

Providers are encouraged to review their existing ancillary activities. To the extent the practice provides services which may fall within this anti-markup provision, we strongly suggest that the service be reviewed as well as the applicability of these billing limitations. ■

Senate May Impose Rules on How Much Charity Care a Hospital Must Provide

Senator Charles Grassley (Iowa) proposed a rule requiring nonprofit hospitals to provide a minimum amount of charity care to the poor. The proposal coincides with a report recently released by the IRS that noted many hospitals spend 3 percent or less of their total revenue on care for the poor or those who are unable to pay. The proposal would require nonprofit hospitals to provide charity care totaling at least five percent of the greater of revenue or patient operating expenses. Failure to satisfy the minimum would jeopardize a hospital’s tax exemption. ■

The Health Information Privacy and Security Act of 2007

Senators Patrick Leahy (D-VT) and Edward Kennedy (D-MA) introduced a bill to revise HIPAA. The bill is called the Health Information Privacy and Security Act of 2007 (“HIPSA”). The bill seeks to tighten HIPAA loopholes.

HIPSA would allow every individual to inspect and copy his or her health records and to receive notice of the privacy practices of data brokers.

The bill would prohibit disclosure or use of health information without a patient’s authorization. Knowingly gaining and disclosing protected information could result in a criminal penalty of ten years in prison and/or a \$10,000 fine. HIPSA would also require that patients be notified within fifteen days of any security breach regarding their health information.

The bill proposes to permit health care providers to disclose health information to law enforcement personnel for legitimate purposes. Providers would also be allowed to disclose health information to a patient’s next of kin if the patient has been given the opportunity to object to such a disclosure. ■

CMS May Require Medical Suppliers to Post Bonds

The Centers for Medicare and Medicaid Services is proposing to require certain medical suppliers to post a \$65,000 bond in order to participate in Medicare. The purpose of the bond would be to ensure that Medicare can recover erroneous payments that result from fraudulent or abusive supplier billing.

Proposed Rule Would Allow PA's to Prescribe CDS

The State Board of Medical Examiners, in consultation with the Physician Assistant Advisory Committee, proposed a new rule allowing physician assistants ("PA"s) to prescribe controlled dangerous substances ("CDS"). PAs are currently prohibited from issuing prescriptions for CDS.

The proposed rule would allow a supervising physician to authorize a PA to continue, reissue, or adjust the dosage of a prescription for a Schedule II, III, IV, or V CDS. In addition, the rule would allow PAs to initiate a prescription for a CDS if the patient has a terminal illness or there has been a prior consultation with the supervising physician.

Under the proposal, a PA wishing to include CDS prescription within the scope of his or her practice must be registered with the appropriate New Jersey and federal agencies. In addition, PAs authorized to prescribe CDS would be required to include their Drug Enforcement Agency registration numbers on all prescription blanks.

New Regulations for Certificate of Need Applications

The New Jersey Department of Health and Senior Services ("DHSS") has proposed new regulations regarding Certificate of Need applications. The new rules require long-term acute care hospital applicants to comply with all of the respective planning and licensing rules. Similarly, both emergency and primary angioplasty service applicants must comply with the relevant cardiac services planning rules.

Other modifications include: increasing the filing fee from \$5,000 to \$7,500, providing that all forms necessary to file a Certificate of Need application shall be available online, eliminating the State Health Planning Board from participation in the process of reviewing applications, and disallowing modifications to applications unless directly in response to completeness review questions issued by the DHSS.

Tamper-Resistant Prescription Pads for Medicaid Participants

The Centers for Medicare and Medicaid Services requires the use of tamper-resistant prescription pads for all Medicaid prescription orders issued after October 1, 2007. The requirement is in compliance with recently issued Congressional guidelines. The rule is aimed at preventing fraud and abuse while making it harder for patients to illegally obtain controlled dangerous substances. The rule is projected to save the federal government \$355 million over the next ten years.

Proposed Amendment Re OD's

The New Jersey Board of Examiners of Ophthalmic Dispensers and Ophthalmic Technicians proposed an amendment to the regulations regarding ophthalmic dispensers ("OD"s). An OD is a licensed individual who dispenses eyeglasses, lenses, and spectacles pursuant to prescriptions issued by physicians or optometrists.

The proposed rule would require ODs to release an original prescription to a patient upon request. ODs who release original prescriptions would also be required to maintain a copy of each prescription for their records. The proposed rule would provide stricter requirements for businesses advertising ophthalmic dispensing services, such as requiring the name and New Jersey license number of at least one licensed OD working at the business.

Medicaid Proposes to Prohibit Balance Billing

A rule proposed by the Department of Human Services would prohibit any health care provider, regardless of whether such provider is enrolled as a New Jersey Medicaid/NJ FamilyCare provider, from billing Medicaid/Family Care beneficiaries. The provider may seek payment from either the Division of Medical Assistance and Health Services (DMAHS) or the managed care organization with which DMAHS contracts to serve the beneficiary. If the provider is not enrolled as a Medicaid/Family Care provider, he or she can seek reimbursement as a one-time provider. Exceptions to the rule would include if the beneficiary has received payment from a third party payor or if the service is not covered and the beneficiary agrees in writing prior to receiving services to pay the provider's charges. ■

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New Jersey Hospitals Performing Angioplasty Without Cardiac Surgery Centers Will Continue to Operate

The New Jersey Department of Health and Senior Services (“DHSS”) proposed a regulatory amendment that allows hospitals to perform angioplasty despite lacking on-site cardiac surgery centers. The proposal directly responds to a recent New Jersey Supreme Court decision. The Supreme Court ruled that the nine hospitals currently performing elective angioplasty without having cardiac surgery centers were violating

DHSS regulations. The Supreme Court said that the hospitals would have to shut down their cardiac catheterization labs by November unless DHSS amended its regulations. The nine hospitals affected by the regulations are part of a study by Johns Hopkins University. The study seeks to determine whether elective angioplasty can safely be performed in community hospitals. ■

Striking Nurses Cannot Collect Unemployment During Work Stoppage

A court reversed a series of decisions by the New Jersey Department of Labor (“DOL”) that allowed nurses to collect unemployment benefits while on strike. By statute, former employees cannot receive unemployment benefits if their unemployment was caused by a stoppage of work resulting from a labor dispute. However, DOL regulations specify that a “stoppage of work” exists only where the former employer’s production of goods or services is not more than 80% of normal production. The

nurses argued that they were entitled to unemployment benefits because their former employer’s patient levels never fell below 80% of monthly averages. The court disagreed and held that the former employer’s revenue is a factor that must be considered in determining whether there was a stoppage of work. In so holding, the court noted that the health care industry is heavily regulated and nurses cannot easily be replaced because of strict licensure requirements. ■

Department of Banking and Insurance Prohibits Side Agreements

The New Jersey Department of Banking and Insurance (“DOBI”) reiterated its prohibition against side agreements between insurers and health care providers. Side agreements are often used to amend the terms of previously filed provider agreements. Provider agreements must be filed with and approved by DOBI. One of the most prevalent types of side agreements is the “most favored nation” clause. A “most favored nation” clause reduces a health care provider’s rate of compensation.

The prohibition against side agreements was first expressed by the Department of Health and Senior Services (“DHSS”) in 2004. DHSS regulated health insurance until the end of June 2005, when regulatory authority was transferred to DOBI. A bulletin issued by DOBI reminds insurers and providers that any positions expressed by DHSS regarding health insurance are still in force under DOBI. ■

Ambulance Company Pursues Claims Against Hospital Chain

The Federal District Court for the District of New Jersey allowed an ambulance services company to proceed with its anti-competition claims against a chain of hospitals. The chain allegedly conditioned bed availability at its tertiary care facility on the use of a particular ambulance company. That ambulance company is a subsidiary of the chain. The plaintiff asserted a tying claim and a monopolization claim under the Sherman Act and the New Jersey Antitrust Act. ■

About Garfunkel, Wild & Travis, P.C.

Garfunkel, Wild & Travis, P.C. (GWT) is among the most active health care specialty law firms in the country, with offices in New Jersey, New York and Connecticut. It serves numerous New Jersey hospitals, licensed health facilities, medical practices, physicians and other health care practitioners, and health care related companies.

The firm specializes in addressing the complex legal, regulatory, business and financial needs of its clients: it helps clients negotiate favorable reimbursement rates from insurers and government; gain regulatory approval for facilities expansion or new services; merge, acquire or network with other organizations; and purchase or lease new technology and equipment. GWT also assists numerous health care providers and others to comply with complicated, costly, and often onerous state and federal regulations.

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