

# Healthcare Law Bulletin



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

Gregg D. Reisman, Roy W. Breitenbach, Managing Editors

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## The Joint Commission Announces Delay in Implementation of MS 1.20

By: Stacey L. Gulick, Esq.

The Joint Commission recently announced that it is suspending the July 9, 2009 deadline for implementation of revised Medical Staff Standard 1.20 (the “Revised Standard”). For hospitals, this means that medical staff bylaws will not need to be immediately revised to meet the July 9, 2009 deadline. Rather, because it is anticipated that there will be additional modifications to the Revised Standard, hospitals may want to refrain from taking any additional steps to comply with the current version of the Revised Standard until more information is available.

The Revised Standard, which was met with much outcry from the hospital community when it was originally published, requires certain information to be included in hospital medical staff bylaws rather than in the rules and regulations or policies. To address the confusion and criticism associated with the Revised Standard, the Joint Commission developed an Implementation Task Force, which is scheduled to present its finding to the Joint Commission Board in August. It is then anticipated that there will be field review of any proposed modifications, followed by a request to approve the final modifications at the November Joint Commission Board meeting. After the approval of the modifications to the Revised Standard, it is expected that a new effective implementation date will be announced. It is anticipated that hospitals will be

given at least 12 months to come into compliance with the Revised Standard once it is modified.

## Federal Court Dismisses Lawsuit Challenging New Anti-Markup Rule As Applied to Certain Anatomic Pathology Services and CMS’s Refusal to Delay Implementation.

By: Lucia F. Deng, Esq.

In November 2007, the Centers for Medicare & Medicaid Services (“CMS”) issued new rules regarding proper billing for the technical and professional component of diagnostic tests which were either “purchased” from an outside party or performed in an office where the practice did not provide substantially the full range of services provided by the practice. The rules would limit the amount that the provider would be able to bill Medicare or a beneficiary for the service. The original wording of the rule was unclear in many ways and raised material questions regarding its application. As a result, CMS delayed its effective date from its original scheduled date of January 1, 2008 to January 1, 2009.

When CMS delayed the original implementation date for its expanded anti-markup rule, CMS specifically excluded certain anatomic pathology diagnostic testing services (“anatomic pathology services”) as well as traditional “purchased diagnostic tests” from the benefit of the delayed implementation. Specifically, CMS refused to delay implementation of the anti-markup rule to anatomic pathology testing furnished in a group practice’s “centralized building” (as defined in the Stark Law), *if* the space did not meet the Stark definition of “the same building” (*i.e.*, in space which the group practice otherwise provides medical/physician services according to certain criteria set forth in the Stark regulations). In addressing this issue, CMS stated that anatomic pathology services arrangements remained its “core concern” that had in fact precipitated the new anti-markup rule.

In response to CMS’s actions, three urology groups and a laboratory management company (the “Plaintiffs”) filed a lawsuit against the Secretary of the U.S. Department of Health & Human Services (“HHS”) on January 24, 2008 in the U.S. District Court for the District of Columbia, challenging the anti-markup rule as it applied to the exception of the delay in implementation to anatomic pathology services. Initially, in response to the suit, the Federal court ordered HHS to delay enforcement of the anti-markup rule as applied to anatomic pathology ser-

### IN THIS ISSUE

- **The Joint Commission Announces Delay in Implementation of MS 1.20**
- **Federal Court Dismisses Lawsuit Challenging New Anti-Markup Rule As Applied to Certain Anatomic Pathology Services and CMS’s Refusal to Delay Implementation**
- **The Center for Medicare and Medicaid Services (“CMS”) Announced its Second Round of Competitive Bidding for Durable Medical Equipment, Prosthetics, Orthotics, And Supplies (DMEPOS) - What Does This Mean For You?**
- **OIG Advisory Opinion Permits “Prompt-Payment” Discount For Inpatient and Outpatient Hospital Services**
- **Cuomo Announced Intent to Sue UnitedHealth Group But Has Not Filed Suit**
- **OIG Approves of Two Additional Gainsharing Arrangements**

*Continued on page 2*

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vices in a centralized building. Specifically, the federal judge issued an interim order and then a preliminary injunction preventing HHS from enforcing the anti-markup rule as it applied to anatomic pathology services for any claims submitted as of February 1, 2008 until such time as the court either rendered a decision on the merits of the case, or issued an order revoking the ban. The court's decision to temporarily ban HHS's enforcement primarily turned on the fact that CMS's decision to exclude anatomic pathology services from the delayed implementation of the anti-markup rule was issued without notice and comment, which the court found to be evidence of arbitrary and capricious rule-making. The court also wanted to allow itself some time to consider all of the issues presented by the parties to the lawsuit before making a final ruling.

Although it appeared that the court might render a decision on the merits of the Plaintiffs' claims, the court ultimately dismissed the case on May 5, 2008 and also vacated the preliminary injunction. In dismissing the case, the court held, among other reasons, the Plaintiffs were not entitled to relief as they had not exhausted administrative remedies prior to filing suit in Federal court. Specifically, the court held that Section 405(h) of the Medicare Act requires rule-making challenges be channeled through HHS's administrative claims process before they can be heard before a court. Therefore, because the Plaintiffs did not first exhaust their administrative remedies, the court lacks the jurisdiction to render a decision on the merits of the case. The court further noted that to the extent the Plaintiffs sought modification of the final rule so that the implementation delay would also apply to anatomic pathology services, it was unclear that the court had the authority to make such a modification. The court also rejected the Plaintiffs' argument that the delay and cost of first exhausting administrative remedies would have been prohibitive.

The court's dismissal of the suit and the vacating of the injunction against HHS's enforcement of the anti-markup rule means that the anti-markup rule will clearly apply to claims submitted for anatomic pathology services furnished in a centralized building (as defined above) as of May 5, 2008 and going forward. The court's final decision does not address the status of claims submitted for such anatomic pathology services prior to this date.

### **The Center for Medicare and Medicaid Services ("CMS") Announced its Second Round of Competitive Bidding for Durable Medical Equipment, Prosthetics, Orthotics, And Supplies (DMEPOS)—What Does This Mean For Physicians?**

By: Randi E. Friedman, Esq.

CMS has announced that, with limited exceptions, suppliers of Medicare will no longer be permitted to provide many DMEPOS items to Medicare beneficiaries unless they are the winning bidder in a competitive bidding process.

In an apparent effort to reduce cost and limit the number of suppliers of DMEPOS to Medicare beneficiaries, CMS has announced that most areas in New York, New Jersey and Connecti-

cut will be subject to the competitive bidding process. The process requires a bidder to bid on all items in a specific category for an entire zip code or regional area. The types of DMEPOS subject to the bidding process include, but are not limited to, oxygen supplies, power wheelchairs, scooters, enteral nutrients and equipment, continuous positive airway pressure (CPAP) devices, negative pressure wound therapy pumps and walkers.

CMS plans to announce in the spring of 2008 the actual zip codes and the specific items in each product category that are included in the competitive bidding process. The actual bidding process is planned to begin in the summer of 2008 and will be open for sixty (60) days.

There are some exceptions to this rule, including an exception designed specifically for physicians. Physicians who have Medicare DMEPOS supplier numbers may continue to supply crutches, canes, walkers, folding manual wheelchairs, blood glucose monitors and/or infusion pumps to their own patients as part of their professional care, if those items are billed under the physician's, treating practitioner's, or group practice's billing number. Any other items will be subject to the competitive billing process.

### **OIG Advisory Opinion Permits "Prompt-Payment" Discount For Inpatient and Outpatient Hospital Services**

By: Shilpa Patel Larson, Esq.

The Office of Inspector General ("OIG") recently issued Advisory Opinion 08-03, indicating that a health care system's "Prompt-Pay Discount" arrangement, which will both give patients some "relief at the pump," so to speak, while also helping these hospitals improve cash flow and reduce accounts receivable and collection costs, would not result in sanctions or civil monetary penalties.

#### **I. The Discount Arrangement**

A health care system ("System") which owns and operates three hospitals proposed to offer a discount for prompt payment of any co-payments and monies owed for non-covered services to all insured patients, including beneficiaries of Federal health care programs, regardless of their financial status or ability to pay ("Discount"). The Discount would apply to inpatient and outpatient services, and, as indicated below, would vary depending on the timing of the payment and the size of the patient's remaining balance:

#### % Discount for Pre-Discharge Payments

Balances \$0 -- \$999 = 10%  
Balances = \$1,000 = 15%

#### % Discount for Post-Discharge Payments Made Within 30 Days of Offer

Balances \$0 -- \$999 = 5%  
Balances = \$1,000 = 10%

*Continued on page 3*

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Furthermore, the System certified to the OIG that:

- The amount of the Discount would bear a reasonable relationship to the collection costs to be avoided and be offered without regard to the reason for the patient's admission, length of stay, diagnostic-related group, or ambulatory payment classification.
- The System would not publicly advertise the Discount and would only notify patients about it in the ordinary course, such as when a patient registers for outpatient services and submits their co-payment; the System mails a statement to, or makes a financial arrangement with, a patient, or after admitting a patient for inpatient services.
- The System would disclose the Discount to, but would not make it part of any price reduction agreement with, third-party payers.
- The System would bear all of the costs associated with the Discount, but would not claim any waived amounts as bad debt or otherwise shift the financial burden to any Federal health care program or other third-party payer or individual.

## II. OIG Analysis

The OIG initially noted that the Discount posed no problem with respect to inpatient services because the System certified that it would comply with all of the requirements of the safe harbor expressly permitting the waiver of coinsurance and deductible amounts for these services. The Discount, however, also applies to outpatient services. As these are not covered under that safe harbor, the OIG separately evaluated whether a prompt-pay discount was actually a disguised inducement for referrals. Noting that the System had incorporated various safeguards which militated against this conclusion, such as not advertising the Discount, only informing patients of the Discount as part of the billing process, notifying other third-party payers of the Discount, paying all costs associated with the Discount and having the amount of the Discount bear a reasonable relationship to the amount of avoided collection costs, the OIG concluded that the "Discount would be a legitimate prompt payment incentive and not a means to induce patients to self-refer."

This opinion gives valuable guidance to hospitals as to whether they could offer a "prompt-pay" discount for both inpatient and outpatient services so long as the arrangement incorporates the kind of policies and procedures included here. However, it is important to keep in mind that the OIG limited its opinion to the unique set of facts of the System.

### Cuomo Announced Intent to Sue UnitedHealth Group But Has Not Filed Suit

By: Jessica M. Sperling, Esq.

On February 13, 2008, New York State Attorney General Andrew Cuomo announced that his office intends to file suit against insurer UnitedHealth Group ("UHG") and four of its subsidiaries, regarding an alleged scheme to defraud consumers by manipulating data and reimbursement rates for out-of-network services. To

date, the suit has not been filed. Specifically, Mr. Cuomo alleges that one of UHG's subsidiaries, Ingenix, Inc., ("Ingenix"), knowingly manipulated its database, which most health insurers use to calculate reimbursement for their members' out-of-network expenses. The AG contends that Ingenix effectively served as "a conduit for rigged data" to the nation's largest health insurers and that two UHG affiliates used this data to significantly under-reimburse their members for out-of-network expenses.

When individuals pay a higher premium for the right to go outside their plan's network of providers, insurers generally cover only 80 percent of the "usual, customary and reasonable charge" ("UCR"), which should theoretically reflect the current market rate for a particular service in a given geographic area. The AG alleges that Ingenix produced a "defective and manipulated" database by artificially undervaluing the UCR, thus forcing patients to either pay a greater portion of their bill or to use "in-network" providers, which cost the insurer less money. The AG further contends that UHG's ownership of Ingenix represents "a gross conflict of interest," and that UHG's affiliates did not disclose UHG's ownership of Ingenix to their members who appealed or otherwise questioned the calculation of their reimbursement. The AG alleges that the various UHG entities falsely advised these individuals that the reimbursement rates were the product of "independent research."

In addition, the AG has opened an industry-wide investigation into this matter by issuing subpoenas to 16 major health insurance companies, including UHG, Aetna, CIGNA Humana, Inc., Health Net, Inc. and Empire BlueCross BlueShield, a division of Wellpoint, Inc. The AG is seeking documents, which indicate how the companies compute UCRs and handle member complaints and appeals. The AG has also sought to depose the CEOs of these corporations. The AG's actions were praised by patient advocacy groups, the American Medical Association, and the Medical Society of The State of New York.

### OIG Approves of Two Additional Gainsharing Arrangements

By: Jessica M. Sperling, Esq.

The Department of Health and Human Services Office of Inspector General (OIG) issued two advisory opinions (No. 07-21 & 07-22) approving of two more gainsharing arrangements. Generally, gainsharing arrangements, in which hospitals apportion to physicians a percentage of its costs savings stemming from quality and efficiency efforts, are prohibited under federal fraud and abuse laws. Despite a 1999 Special Advisory Bulletin in which the OIG objected to almost all gainsharing arrangements, the OIG's subsequent advisory opinions have retracted from this narrow position, approving of gainsharing arrangements provided that certain patient protections and safeguards are in place.

In the first opinion (No. 07-21), a group of cardiac surgeons, the exclusive provider of cardiac surgery at a hospital, implemented several cost reduction measures, including using certain medical supplies on an as needed basis, using less costly products when clinically appropriate, and standardizing the use of certain cardiac devices and supplies where medically appropriate. Simi-

*Continued on page 4*

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larly, in the second opinion (No. 07-22), a group of anesthesiologists, the exclusive provider of administering cardiac anesthesia at a hospital, proposed ceasing the routine use of a certain drugs and devices for monitoring brain function, using a catheter and a nasogastric tube with less expensive material, and standardizing the use of fluid-warming hot lines. In both proposed arrangements, the duration was only one year and the potential costs savings were capped.

In concluding that it would not impose administrative sanctions, the OIG noted that the two arrangements had adequate precautions in place including the following: (1) the proposed measures were clearly identified, allowing for transparency and individual physician accountability; (2) the recommendations were supported by reliable medical evidence showing that the

cost savings measures did not have a negative impact on patient care; (3) the product standardization ensured that physicians had the same selection of supplies and devices available to them; (4) the physicians and the hospitals provided written disclosures of the measures to patients prior to admission or prior to consenting to surgery; (5) the financial incentives were reasonably limited in duration and amount; and (6) per capita distribution of profits among the physicians diminished the incentive for an individual physician within the group to create disproportionate cost savings.

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## About Garfunkel, Wild & Travis, P.C.

Garfunkel, Wild & Travis, P.C. was founded in 1980 with a single purpose in mind: to become a preeminent healthcare law firm attending to the unique business and legal needs of its clients. Since then, the firm has grown to almost 80 attorneys devoted to addressing the complex legal, regulatory, business and financial needs of its diverse clients.

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