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Health -E- News

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SECTION NEWS

HAPPY NEW YEAR !

THE NEXT BOARD MEETING will be held at the State Bar offices **on January 18, 2007 at 12:00** noon. The Board plans to meet on the third Thursday of every third month, unless a special meeting is called. At the January meeting the Board will elect a Secretary, a Budget Officer and a Chair-Elect. It will also discuss CLE and other programs for 2007. Section members are encouraged to attend and participate. The dining option is Bring-Your- Own-Lunch.

KNOW YOUR BOARD MEMBERS – GEORGE KOINIS – CHAIR

Born in Toledo, Ohio, the new Chair of the Health Law Section received his undergraduate degree in 1976 and law degree from the University of Toledo in 1979. After practicing with a small, business-tax-commercial law firm in Toledo for several years, George returned to school and received an LLM in Taxation from NYU in 1984. He joined the Modrall law firm in 1984 and practiced there until 1997 when he left to join some of his former Modrall partners in the firm Foster Johnson McDonald Lucero Koinis LLP. In January, 2006, George went into solo practice. In addition to health law, his practice includes business and commercial transactions, corporate law, tax law, real estate law and wills, trusts and probate.

George is a member of the American Bar Association and the American Health Lawyers Association. He has a special interest in health information technology and the legal issues related to electronic health records and patient privacy. He currently serves on the Board of Directors of the New Mexico Coalition for Healthcare Information Leadership Initiatives (NMCHILI), a New Mexico non-profit corporation. George also was the Vice Chair of the New Mexico Legal Working Group for the national Privacy and Security Project.

George is a frequent speaker at seminars and has lectured on HIPAA, Stark, anti-kickback and medical record issues, as well as other topics. The past two years he was a speaker at the Section's CLE break-out session and the annual State Bar meetings. He has been a member of the Health Law Section for many years and has been on the Board of Directors since summer of

2005.

An avid music fan and amateur musician, George is a big supporter of the New Mexico Jazz Workshop and the Outpost Performance Space. He lives in Placitas with his wife of 27 years, Cheri, and their two dogs and cat. His offices are located at 620 Roma NW and he may be contacted at (505) 244-4110 or gfkoinis@swcp.com.

THE SECTION LIST SERVE IS UP AND RUNNING

You will soon receive an email form the State Bar office, accompanied by a letter from George Koinis, explaining the new list serve. It is only available to members of the Health Law Section. The fact that it is hosted by Yahoo does not mean that anyone can gain access to it. The moderator is Charles Gurd, whose phone is 505-856-1468 and whose email is Charles@GurdLaw.com. Initially the List serve will be "open" in the sense that Charles will not screen every posting.

Standards for Usage

The List serve is to be used only for discussions regarding health related matters**. It is not to be used for:**

Sending jokes or cartoons of any kind.
Advertising, other than health-related CLE, seminars, meetings and similar health related educational issues.
Statements in support of, or personal attacks against, politicians or political issues.
Comments regarding attorneys or health care providers. If you want to know about an expert, please use the NM Trial Lawyers Association's or NM Defense Lawyers Association's services.
Any other inappropriate behavior or comments (as determined by the Moderator).

Those who violate these standards for usage will receive a call from the Moderator. If you become concerned about postings, please call Charles.

Set Your Spam Filters and Don't Use Auto Reply

It is also suggested if you elect to participate on the List Serve that you adjust your email spam filters to allow the receipt of emails from the list serve. We also ask that if you use an auto-reply function on your email when you are out of the office that you unsubscribe from the list serve until you return. Your auto reply may go all members of the list serve.

Maintain the Privilege and Client Confidences.

Please remember that any member of the section who has subscribed will be able to read your posting. It will be your responsibility to maintain client confidences and the attorney-client privilege while using the List Serve.

Share Attachments

As was the case with the Discussion Forum (which will be discontinued), you are encouraged to attach to listings and share health related forms, checklists, articles and similar documents with the members of the section. All subscribers will have access to the List Serve archives.

NEWSLETTER CONTRIBUTIONS WANTED!

The Health-E-News will accept contributions of material from any member of the section and those who contribute will be given a byline. Many lawyers have memos that were prepared for a client on a dis-

crete health care issue that with a little tweaking and redacting could be shared with the section. Please, do not be bashful about helping out the Editor. We are particularly interested in any new decisions that may not yet be reported that would impact New Mexico Health care providers.

DEVELOPMENTS IN HEALTH LAW

CMS ISSUES LONG AWAITED GUIDANCE ON FALSE CLAIMS ACT AND WHISTLEBLOWER EDUCATION REQUIREMENT

On December 13, 2006, the Centers for Medicare & Medicaid Services (CMS) released guidance to State Medicaid agencies on the implementation of Section 6032 of the Deficit Reduction Act of 2005 (DRA). The DRA imposes new compliance program requirements on healthcare entities that receive $5 million dollars or more in Medicaid funds in a fiscal year. Effective January 1, 2007, the DRA required these entities to educate their employees, contractors, and agents about federal and state false claims acts and about the whistleblower protections under the acts. In a letter to State Medicaid Directors, CMS clarified a number of unanswered issues about DRA's education program requirements. The letter answers these questions: What is a Covered Entity? What is a Contractor or Agent? What is the effective date? What is required?
Attached to the letter is a sample revision for the State Medicaid Plan document.
If you are a member of the AHLA go to http://www.healthlawyers.org/email/pg/061218ltc/061213_cms.pdf for the letter. If you are not a member and/or cannot access this site, contact the Editor of this newsletter.

STUDY INDICATES THAT A PATIENT'S BROAD DEFINITION OF MEDICAL 'ERRORS' CAN UNDERMINE SATISFACTION WITH CARE

On December 18, 2006, the Joint Commission issued a press release which begins as follows: "Hospital patients define medical errors much more broadly than the traditional clinical definitions of medical errors. The patient definition of medical errors includes communication problems, responsiveness and falls, according to a new study published in the January 2007 issue of the *Joint Commission Journal on Quality and Patient Safety.* The study points out the need for physicians and other health care professionals to clarify what patients mean when they talk about an "error" or "mistake." The study of more than 1,600 patients at 12 Midwestern hospitals also shows the importance of explaining exactly what is meant by the term "medical error" if patients are to be effectively engaged in programs to prevent them."

The study discussed in the press release points out that patients have a distinctly different point of view from doctors on what constitutes a medical error.

For more information go to www.jcrinc.com.

FINAL RULES ON HIPAA NONDISCRIMINATION RELEASED

DHHS, DOL, and the IRS unleashed a bureaucratic broadside on December 13, 2006 when they jointly issued final rules that provide guidance on complying with the nondiscrimination provisions of HIPAA. They address group health plan or group health insurance issuers from denying an individual eligibility for benefits based on health factors, and prohibit charging higher premiums. The final rule, found at **71 Fed. Reg. 75014**, is not materially different than the interim rule issued in 2001 (66 Fed. Reg. 1421).

THE TENTH CIRCUIT RULES A UNIVERSITY RUN LABORATORY IS NOT IMMUNE FROM A QUI TAM ACTION.

The 10th Circuit reversed the dismissal of claims against a University laboratory and a Medicare carrier involving allegedly improperly coded laboratory services. The court concluded that the carrier, while normally immune from suit under the federal False Claims Act (FCA) because it was a government contractor, was not entitled to immunity where gross negligence or intent to defraud was potentially involved. It

also concluded that the laboratory was not an arm of the state and was, therefore, subject to FCA liability. See *United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah, N*o. 05-4088 (10th Cir. Dec 5, 2006).

THE TENTH CIRCUIT "CLARIFIES' THE SCOPE OF ERISA REVIEW

What happens when ERISA Plan documents confer discretionary authority on the Plan fiduciary, who then designates coverage decisions to a non-fiduciary third party?

The Supreme Court has yet to rule on this issue, but it was most recently addressed by the Tenth Circuit in *Geddes v. United Staffing Alliance Employee Med. Plan*, 2006 WL 3307262 (10th Cir. Nov. 15, 2006). In *Geddes*, the ERISA plan at issue identified the plaintiff's employer as the "plan administrator" and a plan "fiduciary," and conferred it with discretionary authority to make "all final decisions about benefits paid from the Plan." The plan also provided that the employer would "engage an independent claims administrator [Everest Administrators, Inc.] to administer the Plan . . . ." The plaintiffs submitted claims for health benefits under the plan, but the employer, following Everest's claim determination, paid only a portion of the claims. The district court conducted a *de novo* review, reasoning that the employer forfeited deferential review by delegating claim administration responsibilities to a non-fiduciary. In the district court's view, if a plan administrator delegates such responsibility to a non fiduciary, "the plan effectively has no fiduciary exercising the sort of discretion that qualifies for *Firestone* deference." To secure deferential review, many ERISA Fiduciaries hire third parties to administer the Plan and are delegated duties expressly conferred by the Plan on its fiduciaries.

Applying trust law, the Tenth Circuit disagreed with the District Court and found that when the Plan confers discretionary authority on Plan fiduciaries to make coverage decisions, if the fiduciaries delegate portions of its authority to non-fiduciary third parties, as similarly situated trustees often do, the arbitrary and capricious standard of review applies.

Under this standard the United State District Courts in New Mexico handle the appeal of the third party administrator's decision under a Rule 56 Motion for Summary Judgment, and, absent a conflict of interest, seldom permit discovery. Normally, certified copies of the Plan document and the claims file are submitted to the court along with briefs arguing that the decision was or was not arbitrary and capricious. For anyone representing ERISA plans or ERISA claimants, this case is must reading.

A NEW MEDICAID DRUG PRICING REGULATION PROPOSED : THE NEW MEXICO PERSPECTIVE

DHHS Secretary Mike Leavitt has announced proposed changes in the payment for generic prescription drugs in the Medicaid program. These changes implement provisions of the Deficit Reduction Act of 2005 (DRA) and are expected to *save taxpayers $8.4 billion in state and federal funds over five years.* Given this amount of savings, the impact on pharmacy providers will be significant.

The new regulation will require the Federal Upper Payment Limit to be calculated using a new pricing standard – the *Average Manufacturers Price* (AMP), which will replace *Average Wholesale Price* (AWP) as the federal government's touchstone for pricing drugs. AWP, traditionally considered the "sticker price" for drugs, has been intentionally inflated by many manufactures spawning a series of lawsuits by State Medicaid programs and other large payors. Many generic drugs are sold at 60% less than AWP. When a payor, like the New Mexico Medicaid program, reimburses a pharmacy at AWP-12% to -15%, the pharmacist is still theoretically making a 45% profit on the ingredient cost of the drug. CMS will calculate AMP and provide the data to the states, which will then be required to use it in their programs. In New Mexico, the New Mexico Pharmaceutical Association contends that Medicaid under pays pharmacies using AWP, and it insists that the Medicaid program should pay higher dispensing fees than those paid by commercial HMO plans to compensate for the allegedly lower reimbursement rate for the drug itself.

The proposed regulation also defines what constitutes a reasonable dispensing fee "in order to assist

States in their evaluation of factors in establishing a reasonable dispensing fee to pharmacy providers". In the President's Budget for FY 2005, there was a suggestion that for both Medicare and Medicaid a dispensing fee would be a percentage of AMP. The proposed regulation departs from this approach. While it is defining the term, CMS specifically states that it is not mandating a specific formula or methodology that a State must use to determine dispensing fees. However, citing an OIG report issued in 2005 (A-06-06-00063) CMS is encouraging States to analyze the relationship between AMP and pharmacy acquisition costs to ensure that the Medicaid program approximately reimburses pharmacies for estimated acquisition costs. The definition for "dispensing fee" is found in the proposed regulation at 42 CFR §447.502.

In March of 2006 the National Association of Chain Drug Stores (NACDS) submitted recommendations to the DHHS OIG relating to the proposed definition of AMP. This trade association for chain drug stores asked the OIG to include only the manufacturers sales to wholesales for traditional retail pharmacies; and to omit mail order and nursing home sales, rebates paid by manufacturers, customary prompt pay case discounts extended to wholesalers, payments made for pharmaceutical returns and payments got patient care programs. The association did not comment on dispensing fees, and few of its recommendations were adopted.

The National Community Pharmacists Association (NCPA) also submitted comments and asked that the study of pharmacy reimbursement called for in the DRA 2005 include an analysis of state-determined dispensing fees to ensure that pharmacy operating costs are adequately covered under state reimbursement formulas. The NCPA's comments may have focused on dispensing fee, because unlike the NACDS chains stores, the NCPA's smaller community pharmacies do not sign national contracts and do not deal in the volume of prescriptions as the major chains. In New Mexico, at least in the Medicaid managed care program, upwards of 70% of the Medicaid prescriptions are being filled by national or Regional chains – Wal-Mart, Walgreen, Smith's or Albertsons.
New Mexico law contains an outdated statute, passed in 1982 and last amended in 1984, which purports to regulate the ingredient cost of drugs dispensed in the New Mexico Medicaid program as well as the dispensing fee paid to pharmacies. It is unique, and no other state has a law like it. The statute, NMSA §27-2-16(B), has been the subject of a long-lived lawsuit filed in 1997, which was initially financially supported by the New Mexico Pharmaceutical Association. The association dropped its financial support of the lawsuit in 1998, but continues to promote the enforcement of the statute. Efforts to amend or repeal this statute have failed in the last three sessions of the New Mexico Legislature, despite the fact that in 2004 its repeal was included on the Top 10 List of Health Care Initiatives issued by the Governor's Office.

How this New Mexico statute will mesh with the new federal regulations, remains to be seen, although a mandated AMP will reduce one component of Medicaid drug pricing. For every dollar spent on prescription drugs by the New Mexico Medicaid program, the federal government contributes approximately 70 cents, and CMS has an important stake in making certain that New Mexico complies with the proposed regulation. It is ironic that the cost associated with Section 27-2-16(B) is now primarily aiding the bottom line of the large national and regional pharmacies. Every dollar saved on prescription drugs is a dollar that can be spent protecting the health of New Mexico's Medicaid population, and New Mexico's share of the $8.4 Billion projected savings will translate into more services for those who really need it.

THE USUAL DISCLAIMER

This Email Newsletter is a publication for the members of the Health Law Section of the State Bar of New Mexico State. Its contents may be time dated, and references to Internet sites may change. The Content of this Newsletter does not reflect the opinions of the Members of the Board of Directors of the Health Law Section of the SBNM. This Newsletter is informational only, does not constitute legal advice. Members of the Health Law Section may submits topics for the newsletter by emailing them, or the internet site at which they can be located, to JAB@NMCounsel.com .