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HEALTH LAW PERSPECTIVES

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IRS Allows Nonprofit Hospitals to Assist Staff Physicians with EHR Software

On May 11, 2007, the Internal Revenue Service published a memorandum dealing with non-profit 501(c)(3) hospitals' financial assistance to their staff physicians to acquire and implement systems for creating, maintaining and processing electronic health records (EHRs).

Many hospitals are utilizing, or plan to utilize in the future, EHR systems to improve the effectiveness and efficiency of health care and reduce medical errors. Accordingly, as an incentive for staff physicians to use EHR software integrating with hospitals' EHR systems, the IRS allowed hospitals to provide subsidies to its medical staff for purchase and implementation of such EHR-capable software and related technical support.

Noteworthy, such subsidies, within certain parameters, have been held by the U.S. Department of Health and Human Services (HHS) to be permissible under the federal anti-kickback and Stark laws. The IRS similarly concluded that such subsidies will not be treated as impermissible private benefit or private inurement, as long as certain conditions are fulfilled.

For the EHR subsidy to be allowed under the IRS' directive, (a) the hospital and the physicians participating in the information technology (IT) subsidy program must continuously comply with HHS' regulations on the same subject; (b) under the subsidy agreement, the hospital must be able to access, to the extent permitted by law, the electronic medical records created by the physician using the IT systems subsidized by the hospital; (c) such subsidies must be available to all of the medical staff physicians; and (d) the levels of subsidies provided to all of the medical staff physicians either must be constant or may vary only based on criteria related to the community healthcare needs.

Finally, if the hospital allows its earnings to inure to the benefit of any of its medical staff physicians through other arrangements, this subsidy will not be allowed, because, in the IRS' view, such other private inurement would destroy the hospital's 501(c)(3) status.

The full text of the IRS' published memorandum is available at: http://www.irs.gov/pub/irs-tege/ehrdirective.pdf. ■

For additional information, please contact Leon Altman at 310.551.8111.

Legislation to Protect Hospitals and Physicians Advances

Two bills devised to protect hospitals and physicians from illegal health plan payment tactics are moving forward in the state Legislature.

The first bill, AB 1324 by Assemblyman De La Torre, affirms the current prohibition in state law against post claims underwriting by health plans. The bill, which is sponsored by the California Medical Association, affirms that if a health plan approves a service by a provider for a policyholder or member, it cannot later rescind or modify the authorization. Furthermore, the bill states that any changes to an insured's policy made after the treatment is approved does not change the health plan's obligation to provide payment for the services.

In addition, the bill affirms that a false statement in a life or disability insurance policy application does not bar the right of the beneficiary to recover under the policy unless the false statement was made with actual intent to deceive the health plan.

IN THIS ISSUE

In testimony supporting the bill provided at an Assembly Health Committee hearing, HLB attorney Daron Tooch outlined for the Committee the egregious behavior of health plans in post-claims underwriting and policy rescission. The Department of Managed Health Care also provided testimony in support of the spirit of legislation.

Mr. Tooch, along with HLB Attorney Glenn Solomon, currently represents the California Medical Association and the California Hospital Association in a class action complaint against Blue Cross of California, which seeks a halt to Blue Cross' post-claims underwriting activities. AB 1324 has passed the Assembly and will next be heard by the Senate Health Committee.

A second bill, AB 1155 by Assemblyman Huffman, requires the Director of the Department of Managed Health Care, upon a final determination that a health care service plan has underpaid or failed to pay a provider, to assess an administrative penalty and to require the plan to pay the provider, at a minimum, the amount owed plus interest. The bill authorizes the Director to exempt a plan from paying the penalty if the Director makes a written finding that paying the penalty would jeopardize the financial solvency of the plan. AB 1155 is currently in the Assembly Appropriations Committee. ■

For additional information, please contact Daron Tooch or Glenn Solomon at 310.551.8111.

Battle Over Removal And Federal Jurisdiction Under ERISA

By Suzanne S. Chou

As health care providers are discovering, much to their chagrin, getting paid on a claim for health care services is not as straightforward as it used to be. Often, the road to getting paid begins with a tough and expensive battle with the health plan over whether the dispute belongs in state court, or whether it is completely preempted under the Employee Retirement Income Security Act of 1974, 29 U.S.C. §§ 1001, *et seq.* (ERISA). Health plans are taking the position with increasing frequency, particularly for non-contracted health care providers, that ERISA completely preempts a health care provider's state law claims for payment when those claims result from providing treatment to patients who are covered by employee benefit plans. Moreover, if a health care provider has an assignment from a patient for insurance benefits, health plans have latched onto the assignment language as automatic grounds for removal by claiming that the provider "stands in the shoes" of the patient. Hooper, Lundy & Bookman, Inc. has been successful in defeating these ERISA challenges on behalf of their provider clients.

This is exactly what happened to Coast Plaza Doctors Hospital when it filed a complaint in state court against Blue Cross of California for non-payment of emergency care provided to one of Blue Cross' members. In that case, Blue Cross filed a notice of removal to federal court on the grounds that the state law claims were completely preempted under ERISA. Coast Plaza disagreed with Blue Cross, and argued that Blue Cross had failed to meet both requirements for complete ERISA preemption: (a) Coast Plaza was not a "participant" or a "beneficiary" seeking to recover plan benefits under 29 U.S.C. § 1132(a), and (b) Coast Plaza's state law claims did not "relate to" an ERISA plan under 29 U.S.C. § 1144(a).

The district court remanded the case back to state court, and agreed with Coast Plaza that the mere existence of an assignment was not dispositive of the jurisdictional issue because an assignment is a right provided by contract, and the party holding such a right is free to exercise it or not. In other words, Blue Cross has no standing to force Coast Plaza to assert its rights as an assignee. Since Coast Plaza was not a "participant" or a "beneficiary" seeking to recover plan benefits under 29 U.S.C. § 1132(a), complete ERISA preemption did not apply. ■

For more information, please contact Ms. Chou or Daron Tooch at 310.551.8111.

U.S. District Court Grants Suppression Motion in Health Care Criminal Case

United States District Chief Judge Phillip Pro recently granted a defense motion to suppress all evidence seized by federal agents from SDI Future Health Care, Inc., a nationwide provider of diagnostic sleep studies, during the execution of a criminal search warrant at the company's Westlake Village, California headquarters in January 2002.

In his April 6, 2007 decision, Judge Pro ruled that the search warrant was invalid under the Fourth Amendment because it did not particularly describe the evidence to be seized, lacking any dates or a description of the crimes being investigated. Judge Pro also found that suppression of all evidence was appropriate because the searching agents should have known that the warrant was illegal and because they seized the vast majority of SDI's records, including many having no relevance to their investigation.

Judge Pro's ruling dealt a serious blow to the United States Attorney's high-profile criminal prosecution of SDI and two of its owners, President Todd Kaplan, 48 of Thousand Oaks, California and Vice-President Jack Brunk, 50, of Newbury Park, California. In 2005, the three defendants were charged in a 136-count indictment with allegedly participating in a massive scheme to fraudulently bill unnecessary sleep studies and cardiac risk assessment testing on patients with sleep apnea. The case had been scheduled to go to trial later this year.

"While our clients were eager to prove their innocence at trial, we're confident that the government cannot prosecute them without this illegally seized evidence," said Mark Hardiman, the Los Angeles attorney representing Brunk. "In our view, the district court's suppression order also reflects one of the many reasons why the United States Attorney's Office should never have chosen to pursue criminal charges in a case involving an expert debate over the medical necessity of sleep apnea testing." ■

For additional information, please contact Mr. Hardiman at 310.551.8111.

CMS Proposes Changes to Clinical Trial Policy

On April 10, 2007, the Centers for Medicare and Medicaid Services (CMS) issued a Proposed Decision Memo outlining potential revisions to the Medicare National Clinical Trial Policy, which governs what services rendered as part of clinical research will be covered by Medicare. The memo proposes significant changes to protocols, general and clinical standards, public information and approval processes.

Incorporating the changes, CMS proposes to change the name of the National Coverage Determination (NCD) to "Clinical Research Policy" in response to commentators' concerns that the title "Clinical Trial Policy" has been interpreted to exclude studies other than clinical trials.

The proposed revisions to the NCD contain a definition of "clinical research," which was missing previously. Clinical research will be defined as: *"The observation of events in groups of individuals who share a particular characteristic, such as a symptom or illness; or who have the same treatment or diagnostic test provided for a symptom or illness. Inferences are made based on comparisons of predefined health outcomes among groups. Procedures are in place to assure that the rights, safety, and wellbeing of research study participants are protected. Research studies need to conform to all applicable Federal regulations concerning human subject protection and privacy including 45 C.F.R. Part 46 and Parts 160 and 164."* The new definition also contains three examples of types of clinical trials that might be supported by Medicare.

Clinical Trial Standards

Under the proposal, clinical trial standards will be reclassified into three categories: 1) general standards for a scientifically and technically sound clinical research study; 2) Medicare-specific standards of a clinical research study; and 3) National Coverage Determination Coverage with Evidence Development standards. The general standards will now include the seven highly desirable characteristics of a qualified trial, which will be modified slightly. The proposed NCD also renames these "general standards for a scientifically and technically sound clinical research study" and adds an additional standard requirement: the research study must now have a written protocol.

Proposed revisions to the other seven general standards are as follows: 1) the principle purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes; 2) the research study is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use; 3) the research study does not unjustifiably duplicate existing studies; 4) the research study design is appropriate to answer the research question being asked in the study; 5) the research study is sponsored by an organization or individual capable of executing the proposed study successfully; 6) the research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46. If a study is FDA-regulated, it also must be in compliance with 21 CFR Parts 50 and 56; 7) all aspects of the research study are conducted according to the appropriate standards of scientific integrity.

With regard to the Medicare-specific standard of therapeutic intent, the NCD proposes to directly address phase I clinical trials and clarify the definition of therapeutic intent as follows: *"The clinical research study is not designed to exclusively test toxicity or disease pathophysiology. Research studies, including some Phase I trials, whose protocols commit to measuring therapeutic outcomes as one of the objectives, may meet this standard only if the disease being studied is chronic, life threatening, or debilitating."*

An additional new Medicare-specific standard is proposed that will require public release of all primary and secondary outcomes measures as the analyses are completed. Public dissemination of study results can be made in peer-reviewed publications or in suitable public web-based databases. The proposed NCD will further require that each research study is registered on the NIH/National Library of Medicine clinical trials registry, clincialtrials.gov, prior to the enrollment of the first study subject.

Protocols and Approval Processes

CMS has also announced its proposed intention that covered study protocols address all populations affected by the technology under investigation in the study. Specifically, CMS proposed to require that subgroup differences (such as those based on gender, race/ethnicity, or age) be defined and that study protocols discuss how the study will evaluate any differences discovered. Additionally, research study protocols will be required to contain a discussion of how the results may impact the Medicare population. These new requirements will be included as Medicare-specific standards.

Several important changes are also proposed for approval processes that assure the general standards

are met. For example, CMS proposed to delete the deemed status of Investigational New Drug (IND) Exempt trials and instead require that IND Exempt studies meet the other approval process criteria. The self-certification process, which was never implemented, will likewise be deleted. Also, a new proposed approval process will be added if a study is required and approved by the FDA as a post-approval study. CMS acknowledged the need to explore alternative processes for approving other types of studies such as studies of orphan drugs, and is open to public comment regarding this.

The proposed NCD also contains new or revised definitions of Medicare-covered items and services, including routine costs, administrative services, and investigational costs or services.

The Proposed Decision Memo is available at www.cms.hhs.gov/mcd/ viewdraftdecisionmemo.asp?id=186. ■

For additional information, please contact Steve Phillips or Heidi Lamb in the San Francisco office at 415.875.8500; Larry Getzoff or Jordan Keville in the Los Angeles office at 310.551.8111; or Steve Treadgold or Amanda Abbott in the San Diego office at 619.744.7300.

CALENDAR

June 12, 13, 19 — **California Hospital Association Reimbursement Seminar, Costa Mesa, Pasadena, Sacramento.** Lloyd Bookman, Patric Hooper, John Hellow, Larry Getzoff, Byron Gross, Jon Neustadter and Mark Hardiman present a full day seminar covering significant reimbursement developments.

July 23 — **California Association of Health Facilities Quality Care Health Foundation Institute, Dana Point.** Mark Johnson Presents *DHS' Implementation of AB 1629.*

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