HOOPER LUNDY & BOOKMAN, INC.
HEALTH LAW PERSPECTIVES

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Drug Manufacturer Gifts to Providers Limited Under Bill

Legislation devised to curb the pharmaceutical industry's influence of health care providers becomes effective July 1.

SB 1765, introduced by former Sen. Byron Sher (D-San Mateo) and enacted in 2004, requires each pharmaceutical company to adopt and update a Comprehensive Compliance Program (CCP) for interactions with health care providers and to post its CCP on the company's web site.

According to the bill, "pharmaceutical companies" are defined as manufacturers, compounders and distributors of dangerous drugs, and prescription medical devices, as well as marketers working on behalf manufacturers and wholesalers. Licensed pharmacists are specifically excluded from the definition.

Under SB 1765, each pharmaceutical company is required to adopt a CCP that is in accordance with a 2003 OIG publication, *Compliance Guidance for Pharmaceutical Manufacturers.* Each company must further include in its CCP the policies for compliance adopted in 2002 by the Pharmaceutical Research and Manufacturers of America (PhRMA).

The bill requires CCPs to include a specific annual dollar limit on gifts, promotional materials or other items or activities that the company may give a health care provider. Exempt from this requirement are drug samples for distribution to patients, financial support for continuing medical education forums and financial support for health educational scholarships. Payments for legitimate professional services provided by health care professional, such as consulting, are also excluded, provided the payment does not exceed the fair market value for the service rendered.

In addition to posting its CCP on it its web site, each company will also be required to declare that it is in compliance with its CCP and SB 1765.

As compliance requirements for SB 1765 near, at least one unsuccessful attempt has been made to exclude medical device manufacturers from the new marketing limitations. Assemblywoman Lois Wolk introduced AB 1187 earlier this year at the behest of medical device manufacturers. That bill stalled in Assembly Health without reaching a vote.

For more information, please contact Brad Tully at 310.551.8160

In this issue:

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HEALTH CARE LAWYERS

Proposed Rule Brings Potential Penalty for Any HIPAA Violation

By Arnold Pamplona

The Secretary of Health and Human Services has proposed rules to amend existing regulations relating to the compliance with, and the enforcement of, the Health Insurance Portability and Accountability Act (HIPAA). HIPAA applies to most health care providers, billing companies and health plans.

The current enforcement rules apply exclusively to the enforcement of HIPAA's privacy standards, and set forth the principles for the imposition of civil monetary penalties for the violation of those privacy standards. The proposed rules would expand the scope of the enforcement rules to address all of the HIPAA Administrative Simplification rules, including the rules for security, transactions and code sets, and standard unique health identifiers for health care providers. The proposed enforcement rules would also provide further guidance on the imposition of civil monetary penalties, and clarify the investigation, hearing, and appeal processes.

A "violation" under the proposed enforcement rules would be defined as a "failure to comply with an administrative simplification provision." The commentary to the proposed rule cautions that there is to be no distinction between commissions and omissions that lead to violations: "a violation occurs when a covered entity fails to take an action required by a HIPAA rule, as well as when a covered entity takes an action prohibited by a HIPAA rule."

Significant provisions of the proposed rules are:

- Evidence obtained by HHS in any investigational proceeding would be admissible in any administrative or judicial proceeding (unless it consists of protected health information).
- Covered entities would be prohibited from threatening, intimidating, coercing, discriminating against, or taking any other retaliatory actions against persons who report any violation of an administrative simplification provision.
- If the Secretary determines that a covered entity has violated an administrative simplification provision, the imposition of a civil monetary penalty would be mandatory. This provision would not limit the Secretary's ability to encourage voluntary compliance, or to settle any matter in which monetary penalties have been proposed.
- Each covered entity that is a member of an affiliated covered entity would be jointly and severally liable for a violation by the affiliated covered entity.
- A covered entity could be held liable for a civil monetary penalty based on the actions of its agent (unless the agent is a business associate complying with the HIPAA business associates rules).
- In determining how many violations of an administrative simplification provision occurred, the Secretary would be vested with the authority to choose between considering (1) the number of times the covered entity failed to engage in required conduct, or engaged in a prohibited act; (2) the number of persons involved in, or affected by, the violation; or (3) the duration of the violation, counted in days.
- The factors the Secretary could use in determining the amount of a civil monetary penalty would be (1) the nature of the violation; (2) the circumstances under which the violation occurred; (3) the degree of culpability of the covered entity; (4) the history of prior offenses of the covered entity; (5) the financial condition of the covered entity; and (6) such other matters as justice may require.
- Certain limitations on the Secretary's ability to impose civil monetary penalties would be characterized as "affirmative defenses" that could be waived if not appropriately asserted.
- The Secretary would be permitted to use statistical sampling as prima facie evidence in determining how many violations of an administrative simplification provision occurred. Statistical sampling would also be permitted in evaluating the factors used to determine the amount of penalty imposed.
- An Administrative Law Judge (ALJ) decision regarding a violation would no longer be the final determination of the Secretary. Any party could appeal an ALJ decision to the Departmental Appeals Board within 30 days. Any DAB decision would be the final determination of the Secretary from which a party could appeal to the federal courts.

The proposed rule was published in the April 18, 2005 Federal Register. The Secretary will accept public comments until June 17, 2005.

For more information, please contact Elspeth Delaney or Arnold Pamplona at (310) 551-81111.

Proposed Bill Would Ease Medi-Cal Provider Ownership Transition

By Stacie Neroni

The California Assembly Committee on Health has approved proposed legislation that would require the Department of Health Services (DHS) to develop a process by which purchasers of existing Medi-Cal providers would be permitted to continue to render services to Medi-Cal beneficiaries and receive reimbursement for those services by using the selling providers' existing Medi-Cal provider numbers during the time the purchasing providers' enrollment applications are pending.

If enacted, AB 1485, introduced by Assemblyman Wyland, would remove a significant disadvantage for first time Medi-Cal providers who are interested in purchasing existing providers. It currently takes up to six months or more for a buying provider's enrollment application to be processed by DHS and a buyer may not use the selling provider's Medi-Cal number during that application process. The significant delay in receiving a Medi-Cal provider number and resulting inability to receive reimbursement for Medi-Cal services can result in the loss of most if not all the existing Medi-Cal business at a provider for the new owner.

The ability to bill using the selling provider's Medi-Cal number would make it much easier for providers to purchase existing providers with a significant amount of Medi-Cal business and would allow Medi-Cal beneficiaries to continue to receive uninterrupted services at those providers.

At the Assembly Health hearing, DHS stated that it is currently in the process of finalizing the adoption of regulations which would address the change of ownership concerns outlined in AB 1485. Specifically, DHS intends to add successor liability language to the current enrollment regulations in an effort to provide a mechanism for new owners to use the provider numbers of previous owners during the enrollment period.

However, the ability to use the selling provider's Medi-Cal number would only be granted if the new owner agrees to assume the liability for the debts and obligations of the prior owner. DHS also stated that since AB 1485 does not include any such successor liability requirement it would increase the risk of allowing new fraudulent providers into the Medi-Cal program.

While the proposed DHS regulations would create a mechanism by which a buyer could use the seller's Medi-Cal provider number, any requirement that the buyer agree to assume the seller's liabilities to Medi-Cal would create a significant obstacle to buyers taking advantage of this new regulation. AB 1485 has been heard by the Assembly Appropriations Committee but had not been up for a vote at press time.

Related provider enrollment legislation (Assembly Bill 119-Cohn) has passed the Assembly Floor and is currently awaiting hearing in the Senate. AB 119 would permit a current Medi-Cal provider in good standing to change locations within the same county and continue enrollment at the new location by simply filing a change of location form. Within 15 days of receipt of the change of location form, DHS would be required to notify the provider in writing that the provider may continue to use their existing provider number at the new location or that the provider does not meet the criteria and must file a new enrollment application.

Currently, any change of address requires a provider to submit a new enrollment application and triggers the discontinuance of the provider's existing provider number. Additionally, AB 119 would allow for automatic enrollment in the Medi-Cal program of physicians and surgeons with current unrevoked, unsuspended licenses who are enrolled in good standing in the Medicare program and do not have an adverse entry in the Healthcare Integrity and Protection Databank. AB 119 also reduces the length of time for DHS to process preferred provider applications from 90 days to 60 days and reduces the maximum time for DHS to process and enroll most other Medi-Cal provider applications from 180 days to 90 days.

For more information, please contact Stacie K. Neroni at (310) 551-8124.

Doc-Owned Labs Must Have Licenses

Effective immediately, physician-owned laboratories established on or after January 1, 1996 must either be licensed by or registered with the California Department of Health Services.

Licensure or registration is now required for all labs that are used by five or fewer physicians. Licensure is required for labs that perform moderate and high-complexity tests. Registration is required for labs that perform waived or provider-performed microscopy tests. Previously, physician operated labs used by five or fewer physicians and performed moderate and high-complexity tests did not require state licensure.

Labs that were inexistence prior to January 1, 1996, continue to be exempt providing that they have not had a change in status, location or ownership.

For more information, please contact Brad Tully at 310.551.8160.

CALENDAR

June 7, 16, 21 HLB Attorneys present a full-day *Hospital Reimbursement Seminar* for the California Healthcare Association in Costa Mesa, Oakland and Pasadena.

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