

New Guidance and Regulations Effecting Hospitals, Physicians, and Outpatient Facilities

The purpose of this Alert is to highlight new rules regarding hospital discharge notices to Medicare beneficiaries; new rules regarding the use of restraints and seclusion in Medicare-participating hospitals; new pediatric sedation guidelines; proposed FDA rules on patient access to experimental drugs; and CMS Guidance on False Claims Act and whistleblower education requirements. Your medical practice or health care facility may wish to review your current policies and procedures with respect to these new developments.

Hospital Discharge Notice Requirements

The Centers for Medicare and Medicaid Services (CMS) issued new requirements for hospital discharge notices under both the Medicare and the Medicare Advantage programs. The final rules were published in the Federal Register on November 27, 2006 and will become effective July 1, 2007.

The new rules require hospitals to use a revised version of the existing, statutorily-required "Important Message from Medicare" (IM) notice to explain discharge rights to Medicare beneficiaries. The new IM notice will be posted to the CMS website at http://www.cms.hhs.gov/BNI/10_IM.asp#TopOfPage before the July 1, 2007 implementation date. The revised IM includes a statement of patients' rights, information about a beneficiary's liability for continued-stay charges, and a more detailed description of the beneficiary's discharge appeal and expedited review rights. The rules require hospitals to obtain the beneficiary's signature on the IM notice within two days of admission. Hospitals must also deliver a copy of the signed IM notice to the beneficiary no more than two days prior to discharge.

Hospitals are required to deliver a second, more detailed notice to beneficiaries who appeal the discharge decision. Hospitals must also notify the QIO of a beneficiary's appeal and request for an expedited review on the day of discharge to prevent incurring additional expenses for the beneficiary's continued stay.

The final rules and comments are accessible at:
<http://a257.g.akamaitech.net/7/257/2422/01jan20061800/edocket.access.gpo.gov/2006/pdf/E6-20131.pdf>.

Restraints and Seclusion

CMS published new hospital conditions of participation (CoP) rules regarding the use of restraints and seclusion (R&S) on December 8, 2006 at 71 Fed. Reg. 71378 – 428. The rules make significant changes to current requirements for the use of R&S by hospitals participating in the Medicare program. The new rules will be codified at 42 C.F.R. § 482.13 and become effective January 8, 2007.

Training. The prior rules required hospitals to have a R&S staff training program in place. The new rules create detailed requirements for the hospital's staff training program including the frequency of training for staff, the documentation of staff training in personnel files, hospital validation of trainer qualifications, and detailed content requirements for the training program. The new rules also require hospitals to develop and maintain policies

defining the requirements that physicians and licensed independent practitioners (LIP) must meet to be authorized to order the R&S for a patient.

Documented Face-To-Face Evaluation Within 1 Hour. The prior rules required an evaluation of the patient within 1 hour of initiating the use of R&S, but the new rules require that the evaluation may only be accomplished through a face-to-face interaction between the patient and a qualifying practitioner. The new rules specify that the evaluation should address each of the following elements and be fully documented in the patient's medical record: the patient's immediate situation; the patient's reaction to the intervention; the patient's medical and behavioral condition; and the need to continue or terminate the R&S. The new rules also expand the categories of *qualifying practitioners* that may perform the evaluation to include registered nurses (RN) and physician assistants (PA) who are properly trained in accordance with the new rules. In the event that an RN or PA performs the evaluation, the RN or PA must consult the treating physician or LIP as soon as possible after the evaluation.

Devices and Methods The Are Not Restraints. The new rules specify that certain devices and methods are not within the definition of restraint, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, and other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests or to protect the patient from falling out of bed.

Death Reporting. The new rules expand and clarify the prior hospital reporting requirements for deaths related to R&S. Hospitals must report by telephone any death to CMS that occurs during R&S and any death that occurs less than 24 hours after a patient has been removed from R&S. Hospitals must also report by telephone any death that occurs within one week of a patient's removal from R&S if it is *reasonable to assume* that the death was the result of R&S. *Reasonable to assume* "includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation." Hospitals must contact CMS by telephone no later than the close of business the next business day following knowledge of the patient's death and to document in the patient's medical record the date and time the death was reported to CMS.

The final rules and comments are accessible at:

<http://a257.g.akamaitech.net/7/257/2422/01jan20061800/edocket.access.gpo.gov/2006/pdf/06-9559.pdf>.

Pediatric Sedation Guidelines for Outpatient Settings

The American Academy of Pediatrics (AAP) and the American Academy of Pediatric Dentistry (AAPD) recently released updated guidelines for pediatric sedation outside of hospital operating room environments. The guidelines are intended to unify past guidelines into one set of guidelines for medical and dental practitioners and apply to pediatric sedation in physician and dentist offices, emergency departments, and other outpatient settings such as ambulatory surgery centers.

The updated guidelines come in response to continued safety concerns specific to the sedation of pediatric patients. Some of the major risks associated with pediatric sedation include hypoventilation, apnea, airway obstruction, laryngospasm, and cardiopulmonary impairment. Pediatric patients, especially those younger than six years old, are susceptible to unique risks because some patients lack the ability to control their own behavior and may require deeper levels of sedation.

The guidelines apply to pediatric patients through 21 years of age and do not apply to the delivery of general anesthesia or monitored anesthesia outside or within the operating room by an anesthesiologist or other practitioners functioning within a department of anesthesia. The guidelines address pre- and post-procedure attention by accompanying adults attention, emergency rescue equipment, access to ambulance or emergency services, the availability of emergency supplies, patient health evaluations, and documentation requirements.

The guidelines provide specific requirements for three different levels of sedation: minimal sedation, moderate sedation, and deep sedation. The definitions of each sedation level and more information on the guidelines can be found at: <http://pediatrics.aappublications.org/cgi/content/full/118/6/2587>.

Proposed FDA Rules on Access to Experimental Drugs

The Food and Drug Administration (FDA) proposed new rules regarding patient access to experimental drugs on December 11, 2006. The purposes of the proposed rules are:

1. To modernize applicable regulations to include all circumstances under which access to experimental drugs is permitted, including: single patients in non-emergency and emergency settings; small groups of patients; and larger groups of patients under a treatment investigational new drug (IND);
2. To make experimental drugs more widely available in appropriate situations by establishing criteria that link the level of evidence needed to support the use of an experimental drug to the seriousness of the disease and the number of patients likely to be treated with the drug; and
3. To revise the current regulation regarding manufacturers' recovery of the costs of an experimental drug.

Permissible Access to Experimental Drugs. The proposed rules will allow patients to have access to drugs that are still in the investigational research phase, if the following conditions are met:

- The patient's condition is life-threatening;
- The patient does not have any viable, non-experimental treatment alternatives;
- The potential benefit for the patient justifies the potential risks; and
- Providing the experimental therapy will not interfere with the drug's development.

These requirements are drawn from the May 2, 2006 opinion in *Abigail Alliance v. von Eschenbach* from the D.C. Circuit Court of Appeals holding that "where there are no alternative government-approved treatment options, a terminally ill, mentally competent adult patient's informed access to potentially life-saving investigational new drugs determined by the FDA after Phase I trials to be sufficiently safe for expanded human trials, warrants protection under the Due Process Clause. The prerogative asserted by the FDA — to prevent a terminally ill patient from using potentially life-saving medication to which those in Phase II clinical trials have access — thus impinges upon an individual liberty deeply rooted in our Nation's history and tradition of self-preservation."

Permissible Manufacturer Recovery of Costs. The proposed rules will simplify the cost recovery calculation and permit drug manufacturers to recover direct and administrative drug development costs for the use of a drug in the investigational research phase for intermediate patient populations and under large scale treatment INDs:

- To facilitate development of drugs that promise significant advantages over existing therapies, and might not otherwise be developed because of their high cost; and
- To facilitate and encourage access to drugs that might not be made available for treatment use unless a manufacturer is able to recover its costs.

The proposed rules are available at http://www.fda.gov/cder/regulatory/applications/IND_PR.htm. Comments on the proposed rules may be submitted to the FDA until March 11, 2006.

CMS Guidance on False Claims Act and Whistleblower Education Requirements

On December 13, 2006, CMS released a guidance letter to State Medicaid agencies on the implementation of Section 6032 of the Deficit Reduction Act (DRA) of 2005. The DRA imposes new compliance program requirements on healthcare entities that receive \$5 million dollars or more in Medicaid funds in a fiscal year. The new requirements become effective January 1, 2007. Providers will be required to educate their employees, contractors, and agents about federal and state false claims acts and about the whistleblower protections under the acts. The guidance letter is available at <http://www.cms.hhs.gov/smdl/downloads/SMD121306.pdf> and clarifies the following issues about DRA's education program requirements.

What is a Covered Entity? An "entity" is defined as the term is used in Section 6032 of the DRA. If a healthcare provider or company receives or makes \$5 million dollars of aggregate Medicaid payments in a calendar year, they must comply with the training requirement of Section 6032. CMS's letter specifically confirms that that threshold will be calculated in the aggregate, regardless of whether a company or provider "furnishes items or services at more than a single location" or "using one or more provider numbers."

What is a Contractor or Agent? The DRA requires a covered entity to "establish and disseminate written policies that must be adopted by its contractors and agents." The guidance letter defines a "contractor or agent" to include any person, company or organization that is involved in providing or otherwise furnishing Medicaid healthcare items or services of the entity, performs billing or coding functions for the entity, or is involved in monitoring of healthcare provided by the entity. A provider must send its policies to its contractors and agents, apprise them of the fraud and abuse provisions of federal and state laws, and ensure that the contractors and agents are knowledgeable about how to report possible fraud or abuse to the entity and governmental entities.

What is the Effective Date? State Medicaid agencies must require all providers to be in compliance by January 1, 2007. CMS expects each state Medicaid program to amend its Medicaid provider contracts to accomplish this. Under CMS rules, a state could submit a state plan amendment as late as March 31, 2007, to be effective retroactively to the first day of the year. CMS will only allow a state to extend the implementation date if the state can certify to CMS, and CMS agrees, that state legislation is required to implement the provisions.

CMS also expects state Medicaid agencies to monitor compliance with the new law's requirements. In its state plan amendment, a state must include "a description of the methodology of compliance oversight and the frequency with which the State will re-assess compliance on an ongoing basis."

What is required? Providers must provide to "all employees, and agents and contractors":

- Written policies that include "detailed information" about the federal and state false claim acts, administrative remedies for false claims, whistleblower protections under federal and state laws, and the role of these laws in preventing and detecting fraud, waste, and abuse;
- Detailed provisions regarding the entity's policies and procedures for detecting and preventing fraud, waste, and abuse; and
- Such information or those policies within any employee handbook, if the entity has such a handbook.

CMS will allow an entity to provide its DRA policies to employees, contractors or agents in paper or electronic form, so long as they are "readily available." Providers wishing to post policies on an internal website may do so. Email may also be an effective way to disseminate those policies to contractors and agents.

If you would like more information or assistance in updating your practice's or facility's policies and procedures with respect to these new developments or submitting comments to the FDA, please contact one of the attorneys listed below in the Haynes and Boone Health Care Practice Group.

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