

Health Law ADVISORY

Current legal insights for health care executives

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Julie A. Knutson, Editor

Break On Process for Extending Medicare Repayment Deadlines

Facing a repayment of erroneously paid Medicare amounts? Under final regulations issued July 28, 2008, providers and suppliers may request an extended payment schedule of up to six months under a substantially simplified process in order to spread out their repayments if repaying within the usual thirty days would be a “hardship.”

The final rule (42 CFR Part 401; subpart F, governing liability for Medicare overpayments) revises implementing Medicare regulations for the Medicare Prescription Drug Improvement and Modernization Act of 2003. Extended payment schedules were possible prior to the issuance of the final rule. However, requests for extended payment schedules of any duration were granted based on consideration of three factors--the amount of the claim, the debtor’s ability to pay and the cost to CMS of administering an installment payment plan. The main focus was on the debtor’s ability to pay. The process included review of financial statements, balance sheets, etc. and required a statement from financial institutions that alternative financing could not be obtained.

Under the new criteria of the final rule, a repayment schedule of up to six months may be granted based on a finding of “hardship” as determined without review of financial records. Hardship is defined in relation to the amount of the overpayment owed by the provider or supplier to the total amount of Medicare payments made to that provider or supplier over the immediately prior cost reporting period or calendar year (if not a cost reporting entity). If the amount of the repayment obligation is 10% or greater of the Medicare payments to the provider or supplier for the cost reporting or calendar year, a hardship exists.

Requests for extended repayment schedules in excess of six months still require a more intensive financial review process.

There are exceptions, even when the hardship test is met. For example, when CMS suspects that the provider or supplier may file for bankruptcy, cease to do business, discontinue participation in the Medicare program or when there is an indication of fraud or abuse, an extended payment schedule will not be granted. Also, extended payment schedules do not apply to repayment obligations already

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subject to an extended repayment schedule granted under earlier rules.

Default under a six-month extended repayment schedule is defined as missing one payment. Under all other repayment schedules of greater than six months, default occurs when two payments are missed. Default results in the entire amount of the debt becoming immediately due and payable.

The final rule does not affect Medicaid repayments which continue to be governed by state regulations.

Julie A. Knutson

We Don't Do Research--Do We?

Do Community Hospitals Conduct Research? Just what types of clinical activities require the approval of an Institutional Review Board (IRB)? The distinction between research and practice is often blurred—sometimes because the two occur at the same time (as in the case of research designed to evaluate a therapy) or because departures from standard practice (“off-label”) are referred to as “experimental.” Failing to clearly understand the difference between “experimental” practices and “research” requiring IRB approval often results in incorrect assumptions, e.g., “we’re a community hospital, not an academic medical center—so we don’t do research, right?”

Telling the Difference. For the most part, the term “practice” refers to interventions that are designed solely to enhance the well-being of an individual patient that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals. In contrast, “research” designates an activity designed to test an hypothesis, permit conclusions to be drawn and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.

When a clinician departs in a significant way from standard or accepted practice, the innovation does not, in and of itself, constitute research. The fact that a procedure is “experimental,” in the sense of new, untested or different, does not automatically place it in the category of research. Use of a drug or device “off label” on a patient-by-patient basis, where there is no element of data gathering and reporting, e.g., publishing a report or article) for the purpose of contributing to generalizable knowledge, does not meet the definition of human subject research.

As a general rule, physicians may, within the scope of their medical licenses, use any FDA-approved device or FDA-approved drug for any purpose they deem appropriate in the treatment of an individual patient, without IRB review, subject only to their professional judgment, as to what is in the patient’s best interest and consistent with acceptable medical standards, licensure and ethics, and subject to any applicable hospital policies or protocols. However, even if a drug or device is being used off-label on a patient-by-patient basis, if the physicians making such a use are gathering

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information for the purpose of later contributing to generalizable knowledge (through publication, or through the provision of support for an expanded FDA marketing approval for the drug or device), then human subject research and IRB review is required.

Radically new procedures of this description should, however, be made the object of formal research at an early stage in order to determine whether they are safe and effective. Thus, it is the responsibility of medical practice committees, for example, to insist that a major innovation be incorporated into a formal research project.

Research and practice may be carried on together when research is designed to evaluate the safety and efficacy of a therapy. This need not cause any confusion regarding whether or not the activity requires review; the general rule is that if there is any element of research in an activity, that activity should undergo IRB review for the protection of human subjects.

Federal law only mandates review and approval by an IRB when both of the following criteria are met:

1. There is “human subject research” being conducted; and
2. The research is either:
 - a. Conducted or supported, in whole or in part, by the United States Department of Health & Human Services or another federal agency; or
 - b. Conducted for the purpose of obtaining approval by the FDA for commercial marketing (i.e., new labeling).

If covered under paragraph (a), then IRB review is required under the federal

“common rule” at 45 C.F.R. Part 46. If covered under paragraph (b), then IRB review is required by regulations of the Food & Drug Administration at 21 C.F.R. Parts 50 and 56. The federal common rule and the FDA regulations are parallel, but not identical in all circumstances.

In summary, if a physician uses a drug or device off-label, based on his or her professional judgment on an individual patient basis, without gathering data for the purpose of contributing to generalizable knowledge as defined above, IRB review is not required by law. However, there are potential legal issues which merit review by some body of the hospital. Those issues include, at a minimum:

1. **Informed Consent.** Whether, and to what extent, the patient should be informed about the use of a drug and/or a device in a manner other than that for which it is currently approved by the FDA. The extent of information which needs to be provided to the patient will vary from case to case, depending on the degree to which the drug or device is being used off-label, the risks and potential benefits, and so forth. While obtaining proper informed consent is generally the responsibility of the physician and not the hospital, hospitals generally define or oversee the process.
2. **Quality of Care.** The hospital and its medical staff have an interest in ensuring that patient care is delivered in a high quality manner, consistent with generally accepted medical standards. Off-label use may be subjected to review by an appropriate department or committee to assure it meets acceptable quality standards.

When IRB review and approval is required,

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the hospital may go through the process of designating an IRB in accordance with federal regulations or it may seek the assistance of a larger facility with an IRB.

Julie A. Knutson

The 2009 OIG Work Plan

The OIG Work Plan is issued annually by the Office of Inspector General (“OIG”) of the Department of Health and Human Services. It is an important tool in assessing compliance risks for health care providers and suppliers. The Work Plan sets forth the OIG’s points of emphasis for the coming year. This should serve notice to the health care industry as to which compliance vulnerabilities the OIG considers “low hanging fruit.” As such, the compliance committees of all health care providers and suppliers should review the Work Plan for issues pertinent to their activities and consider the topics listed to be a high priority for compliance risk assessment in the coming year.

The 2009 OIG Work Plan is available online at <http://www.oig.hhs.gov/publications/docs/workplan/2009/WorkPlanFY2009.pdf>.

Below we highlight some topics in the 2009 Work Plan:

- **Provider-Based Status for Inpatient and Outpatient Facilities and Hospital Owned Physician Practices.** The OIG intends to review cost reports of hospitals claiming provider-based status for inpatient and outpatient facilities. The OIG is concerned because hospitals with provider-based facilities may receive higher reimbursement when they include the costs of a provider-based entity on their cost reports. The OIG will review the compliance of various departments that providers treat as provider-based with the relevant regulatory requirements. The OIG also intends to give great attention to physician practices that are acquired by hospitals and designated as provider-based. Much like its concern with inpatient and outpatient provider-based departments, the OIG is concerned that many of these purchased medical practices do not satisfy the provider-based regulatory requirements.
- **Critical Access Hospitals.** The OIG intends to review payments made to critical access hospitals (CAHs) and determine whether CAHs satisfy the CAH designation criteria and conditions of participation. The OIG will also review whether payments made to CAHs were made in accordance with applicable Medicare requirements.
- **Provider Bad Debts.** The OIG will review Medicare bad debts claimed by acute care inpatient hospitals and other provider classifications to determine whether they were reimbursable. Pursuant to regulations certain uncollectible debts related to unpaid deductible and coinsurance amounts may be claimed as Medicare bad debt. The OIG will consider whether the bad debt payments were appropriate and whether the recovery of amounts written off in prior years were properly accounted for in the period in which the recoveries were made.
- **Oversight of Compliance with EMTALA.** The OIG will review CMS’s oversight of hospitals’ compliance with EMTALA. Citing a previous OIG review of CMS’s EMTALA oversight practices which raised concerns about long delays to investigate complaints and inadequate feedback provided to hospitals on alleged EMTALA violations, the OIG intends to specifically review any variances among regions in the review

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and referral of purported EMTALA violations to state agencies.

- **Serious Medical Errors (“Never Events”).** The OIG will review the occurrence of and payment for “never events” and CMS’s process for detecting such events. The OIG intends to review key issues, policies and practices regarding never events in hospitals and hospitals’ compliance with CMS’s requirements by identifying several hospital-acquired conditions using the Present on Admission coding system implemented on October 1, 2007.
- **Place of Service Errors.** The OIG will review the coding of place of service on Medicare Part B claims for services performed in ambulatory surgical centers and hospital outpatient departments. The OIG recognizes that Medicare pays a physician a higher amount when a service is performed in a non-facility setting, such as a physician’s office, than it does when the service is performed in a hospital outpatient department or, with certain exceptions, in an ASC. The OIG will review claims submitted by physicians to determine whether the places of service were properly coded.
- **Appropriateness of Medicare Payments for Polysomnography and CPAP Devices.** The OIG will examine the appropriateness of Medicare payments for sleep studies and CPAP devices given the recent changes in reimbursement rules associated with this service and equipment.
- **Care for Undocumented Aliens & Medical Identity Theft.** The OIG intends to review Medicaid payments made by state agencies for care provided to undocumented aliens. The OIG is concerned that state Medicaid agencies are reimbursing providers for more than the permitted scenarios. Currently only payments for emergency care are allowable under Medicaid regulations. The OIG will also be reviewing CMS’s efforts to protect Medicare beneficiaries

against medical identity theft.

- **Security of Protected Health Information on Portable Electronic Devices.** The OIG has for the first time indicated that it will audit contractors and hospitals on the security measures used to protect health information on PDAs and other electronic devices. Because privacy and security issues are not the OIG’s typical areas of enforcement, this indicates that the OIG is serious about its efforts to audit the compliance of providers and their data security programs.

The OIG is focusing on a wide array of topics that may impact a wide variety of health care providers. Providers are well advised to review the Work Plan in its entirety to get a sense for all of the OIG’s targets in the coming year.

Andrew D. Kloeckner

Upcoming Speaking Engagements

The New Form 990, Overview, Issues and Challenges, Nebraska Chapter HFMA, December 11, 2008, 12:30-4:30 Lincoln, Nebraska (John Holdenried, Barbara Fajen of Seim-Johnson and Lorraine Egger, KPMG).

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