Laboratory Compliance Guidance

The Office of Inspector General (OIG) revised the model Clinical Laboratory Compliance Program Guidance in August 1998 so the guidelines would parallel the OIG's February 1998 model Compliance Program Guidance for Hospitals.[1] [The previous version of the guidelines for laboratories was released in February 1997.]

The 34-page laboratory compliance document was also updated to include policy changes regarding advance beneficiary notices and anti-kickback statutes that have been implemented by the Health Care Financing Administration. [See the Glossary for an explanation of these terms.] The document is a suggested model, a guide for clinical laboratories to use in developing internal controls. A model does not have the force of a proposed rule or regulation.

General Provisions
The guidelines discuss how to ensure accurate billing using current procedural terminology (CPT) codes and International Classification of Diseases (ICD)-9 codes. The document also discusses the appropriate way to submit Medicare claim reimbursements, including how to avoid double billing and unnecessary reflex testing. It states: "Reflex testing occurs when initial test results are positive or outside normal parameters and indicate that a second related test is medically appropriate." It suggests that laboratories can avoid performing unnecessary reflex tests by careful requisition form design.

The OIG guidance explains that if a laboratory intends to bill Medicare for a test then it must have the proper documentation to support the medical necessity of the test from the ordering provider. In addition, laboratories must charge physicians uniform prices whether or not the claim is being submitted to Medicare. If not, the laboratory may be in violation of financial incentive statutes.

Self-Monitoring Tips
The OIG suggests that self-monitoring will assist laboratories in detecting potential billing problems. Unexplained increases in the utilization data for the 30 highest-volume tests may indicate a billing problem. A laboratory should calculate the percentage of growth for the top 30 tests and...
Capitol Chat

The General Accounting Office, the investigative arm of Congress, issued the report, “Blood Plasma Safety: Plasma Product Risks Are Low if Good Manufacturing Practices Are Followed.” For a copy, call the ASCP Washington Office.... The Clinical Laboratory Improvement Advisory Committee (CLIAC) recommends two major changes to the Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) rules—one is to regulate under CLIA-assisted reproductive technology testing and the second is to regulate genetic testing. CLIAC, an advisory committee to the Centers for Disease Control and Prevention (Atlanta), suggested specific rules that should apply to genetic tests when in the pre-analytic, analytic, or postanalytic phase of testing.... ASCP urges an increase in the payment rate for Pap smears. An ASCP letter to the Health Care Financing Administration outlines the need for payment to better reflect the costs associated with the test.... The Rhode Island Department of Health has proposed changes to the rules and regulations for the licensure of clinical laboratory practitioners. Olive Sturtevant, MT(ASCP)SBB, represented the ASCP before the Rhode Island Board of Clinical Laboratory Science to show support for licensure of medical laboratory personnel, and to suggest changes to the proposed regulatory amendments.... Effective September 30, 1998, the Food and Drug Administration will require all medical devices containing natural latex rubber that come into human contact carry the label, “Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.”... The Senate Appropriations Committee report to accompany S 2440, the fiscal year 1999 funding bill for the Departments of Labor, Health and Human Services, and Education and Related Agencies contains several laboratory provisions. The committee recommended $500,000 be used by the Institute of Medicine to study laboratory reimbursement policies, urged priority consideration of Allied Health Project Grants to schools that train professionals experiencing shortages, such as medical technologists and cytotechnologists, and outlined that the National Center for Research Resources at the National Institutes of Health “place a greater emphasis on clinical laboratories and increase the investment in research infrastructure.” The ASCP has worked with Congress to increase funding for the Allied Health Project Grants program and numerous public health initiatives.... California bill, SB 1125, which would prohibit unlicensed personnel from performing certain identified functions, including venipuncture, and moderate-complexity laboratory testing, was sent in September to California Governor Wilson for his signature into law. Until next month...©

Questions?
If you have questions about laboratory compliance or would like a copy of the Office of Inspector General’s revised Clinical Laboratory Compliance Program Guidance, call the ASCP Washington Office at (202) 347-4450.

Supporting Documentation
The revised model compliance guidance places a substantial amount of responsibility on the laboratory for producing or having the ability to obtain supporting documentation for submitted claims. To ensure against improper billing or unintentional fraud and abuse, laboratories should educate corporate officers, managers, and other employees whose actions affect the accuracy of the claims submitted to government or private payors. Educational programs should include information on federal and state statutes, regulations, program requirements, the policies of private payors, and corporate ethics. Laboratories should instruct employees on coding requirements, the claim submission process, and fraud and abuse laws.

Implementation
The OIG suggests that laboratory staff educate physicians as well as other laboratory employees on billing and coding procedures. This will increase communication and decrease the potential for inadequate documentation by the ordering physician.©

References
1. 63 Federal Register 8987 (February 23, 1998).
2. 63 Federal Register 45076 (August 24, 1998).