Reimbursement Concerns

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ASCLS, through the vigilance of its Government Affairs Committee (GAC) members, the legislative consultant, and the executive vice president, watches for changes and developments in payment policies for laboratory services that will be of concern to our members. ASCLS' participation in collaborative efforts with other professional organizations, such as with the Clinical Laboratory Coalition, is another venue from which to watch for and comment on changes in reimbursement policy.

There are a number of areas of activity that are "heating up" at the moment, any of which could become an issue that would require a full-fledged advocacy effort by the ASCLS membership. Whether or not these are officially implemented remains to be seen, but they provide a snapshot of the type of activity that goes on continually and needs our attention.

Competitive bidding: One of the provisions of the Medicare Modernization Act (MMA) of 2004 was a Congressional mandate for the Center for Medicare and Medicaid Services (CMS) to conduct a competitive bidding project for clinical laboratory services. ASCLS has long vigorously opposed the concept of competitive bidding for laboratory services, holding that laboratory tests are services, not commodities. Quality and access are important features of laboratory testing and as important, or more important, than price.

To comply with the MMA legislation, CMS appointed a director of the project and hired a contractor, Research Triangle Institute, to plan and conduct the bidding process. The purpose of the demonstration is twofold:

- To determine whether competitive bidding can be used to provide Part B clinical laboratory services at fees below current Medicare reimbursement rates while simultaneously maintaining quality and access to care
- To gain valuable information on the relative costs of laboratory tests

Washington Beat is intended to provide a timely synopsis of activity in the nation's capitol of importance to clinical laboratory practitioners. This section is coordinated jointly by Kathy Hansen, Chair of the ASCLS Government Affairs Committee, and Don Lavanty, ASCLS Legislative Counsel. Direct all inquiries to ASCLS (301) 657-2768 extension 3022; (301) 657-2909 (fax); or mail to ASCLS, 6701 Democracy Blvd., Suite 300, Bethesda MD 20814, Attention: Washington Beat.

The details of the competitive bidding demonstration project were outlined in the Washington Beat column in the Winter 2006 edition.

An initial report was due to Congress by December 31, 2005, but had not been published as of mid-February, 2006. The demonstration project was to last three years in order to allow time for analysis of the impact on quality, access, and savings. However, President Bush's proposed 2007 budget (to be effective October 2006) calls for competitive bidding nationwide for Medicare outpatient laboratory services, without waiting for the results of a demonstration project.

The following wording is found in the administration's budget proposal: "Competitive Bidding for Labs: CMS successfully tested a competitive bidding model for DME (durable medical equipment) in Polk County, Florida and San Antonio, Texas. Based on that success, MMA expanded DME competitive bidding nationwide and required a similar competitive process for outpatient drugs [Note: this refers to drugs administered during a clinic visit, not those purchased by the patient for home use.] The Budget proposes to build on these successful competition models by extending competitive bidding to Medicare laboratory services."

Estimated savings are $1.43 billion over the period 2007-2011.

Implementation of nationwide competitive bidding could have a devastating effect on hospital outreach programs, many of which could be shut out of performing testing for Medicare beneficiaries. ASCLS will oppose this proposal.

Medically Unbelievable Edits: CMS proposes to implement new edits called Medically Unbelievable Edits (MUEs) as of July 1, 2006. These frequency edits would be added to the Correct Coding Initiative (CCI) edits already in place for

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analyzing Medicare outpatient claims. Previous CCI edits have looked at pairs of current procedural terminology codes and banned certain ones from being billed on the same date of service. For example, there is a CCI edit that prevents billing a hemoglobin on the same date of service as a hemogram, since the hemoglobin is part of the hemogram or complete blood count. This particular example can be problematic for a same-day surgery patient, for example, who may have a hemogram ordered pre-operatively, and then a hemoglobin rechecked later in the day post-op. The proposed MUEs go a step further and set limits for nearly every CPT code as to how many can be billed on one date of service. There are many examples that are creating concern in the laboratory community, such as:

88305 Level IV – Surgical pathology gross and microscopic examination. MUE limits to two per day. This code is used for many common types of biopsies such as skin biopsies or prostate needle biopsies, where many more than two distinct specimens are commonly taken at the same time. Some institutions estimate that 25% to 50% of their claims for this service would be denied under this MUE.

82784 Gammaglobulin, IgA, IgD, IgG, IgM, each. MUE limits to one per day. Accepted ordering practice is to order IgA, IgG, and IgM together on the same sample.

83896 Molecular diagnostics; nucleic acid probe, each. MUE limits to one per day. Most molecular assays use multiple probes, from as few as two to as many as 90 or more per sample to look for mutations. The MUE limit would mean that laboratories would lose money on all these tests.

ASCLS is preparing comments, due in March, about these edits. We feel strongly that these edits do not reflect current accepted (not excessive) ordering practices.

Clinical laboratory fee schedule: The Medicare laboratory fee schedule was developed in 1984. While there have been some inflationary updates, the relative pricing of laboratory services has not changed to keep pace with changes in technology that make some older tests less expensive to run, while expensive tests based on new technology are often not reimbursed adequately to cover costs. CMS and Congress recognize the limitations of the fee schedule, and this may be a reason why the laboratory is vulnerable to so many cuts.

ASCLS and CLMA have offered the time of laboratory professionals to develop an alternative logic for the fee schedule, possibly based on some sort of relative value unit system which is commonly used for other Medicare providers.

Advamed, the trade association representing the vendors of laboratory equipment and supplies, has developed a proposal to CMS which would establish an advisory group to deal specifically with reimbursement for molecular-based tests. ASCLS shares Advamed's concerns about the inadequate process for evaluating new technology and establishing fair pricing. However, we are also concerned about carving out one particular segment of testing for attention, when we see the problems with the fee schedule as being much more extensive than this one area of testing.

State billing regulations: Pathology societies in a growing number of states are addressing the issue of markups added to pathology services provided by physician offices. The offices purchase tests and professional services from a laboratory on a client basis, then inflate that price when billing the patient or their insurance. Many consider this to be "fee-splitting" or fraudulent billing practice that drives up the cost of healthcare.

Some states have passed laws requiring that the laboratory bill the insurance company or other payer directly, rather than billing the physician office as a middle man. Others are working through their state board of medical practice to have the markups declared unethical. In some instances, the ban on markups has been limited to surgical pathology and cytology services; in others, all laboratory services have been included. In some states, ASCLS constituent societies have been asked to support direct billing initiatives.

These examples are only a sample of the issues that the GAC monitors on ASCLS members' behalf. If you become aware of things that concern you, please contact a GAC member. Email addresses are on the ASCLS web site.

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