New Medicare Screening Test Coverage

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An ongoing activity of the Government Affairs Committee of the American Society for Clinical Laboratory Science (ASCLS) is to respond to changes in laboratory regulations that are proposed by the Centers for Medicare and Medicaid Services (CMS) and other federal agencies. Typically regulations are published in the Federal Register in a proposed form, with a deadline for comments to be submitted. CMS then takes comments under advisement before a revised final regulation is published. Depending upon the volume of comments received, this process can take from a few months to many months before final regulations are published. Such responses to requests for comments are submitted several times each year. ASCLS tries to take every opportunity to express your views in the regulatory process.

A recent example is a proposed rule published on August 5, 2004 in the Federal Register Vol. 69, #150 titled Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005. The rules will implement the new cardiovascular and diabetes screening provisions mandated by the Medicare Prescription Drug and Modernization Act of 2003 (MMA).

In September, ASCLS submitted comments which commended CMS for the thorough, thoughtful process that was followed to solicit input concerning the types of tests to be covered for Diabetes and Cardiovascular Risk Screening. Excerpts from the ASCLS comments follow. Note that they focus on both scientific reasoning as well as practical operational considerations for laboratories. Whenever possible, ASCLS tries to coordinate its comments and opinions with other laboratory professional societies.

Section 613 – Diabetes Screening

ASCLS concurs with the CMS definition of "pre-diabetes" as stated in **410.18(a)**. This definition is consistent with the statements of the American Diabetes Association and the National Institute for Diabetes and Digestive and Kidney Diseases. In response to the request for suggestions to define "a family history of diabetes", we believe that CMS should use first-degree relatives, i.e., parents, siblings, and children to define family. The genetic links for the inheritance of a predisposition to diabetes have been found to be very direct. Risk factors for Type 1 and Type 2 diabetes have been documented to be inherited from first degree relatives. While we recognize that environment, lifestyle, and ethnicity affect the prevalence of manifesting the disease, the correlation to first degree inheritance still holds.

In **410.18(d) Amount of testing covered**, CMS is proposing that individuals diagnosed with pre-diabetes be screened twice per year and all others who qualify be screened once a year. We believe that the screening should be standardized to twice per year for all Medicare recipients for two reasons:

- The process that would be necessary to separate these two populations will be an administrative burden for laboratories. Clinical laboratories will not know whether the patient has pre-diabetes unless that patient has been tested at that laboratory in the past. The ICD-9-CM code being proposed, while correct for this screening, does not indicate that the patient has pre-diabetes and will be the only information the laboratory will have on most of these patients.

- It is our reading of the regulation that CMS is not including patients with risk factors in the population that will be screened twice per year. This is the population that is in most need of careful screening to monitor their potential transition to pre-diabetes and possibly to full disease. The sooner patients at risk are identified as pre-diabetic, the sooner modifications can be made that might avoid the onset of disease.

Section 612 – Cardiovascular Screening Blood Tests

As pertains to **410.17(a)**, as we stated in our joint comments with AACC in January of this year, we believe that Congress's intent in MMA was that Medicare only reimburse for scientifically valid screening measures. We realize that the language of MMA states that HHS should also include those tests that

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indicate an elevated risk of cardiovascular disease as long as they have been endorsed by the United States Preventive Services Task Force (USPSTF). However, we believe that the body of evidence outlining what constitutes appropriate screening tests for cardiovascular risk has changed since the USPSTF issued its guidance in 2001.

Over the past few years, a significant body of literature has been published indicating that high sensitivity C-reactive protein (hsCRP) is a key measure for assessing an individual's risk of heart disease. (Again, this data was published after the most recent USPSTF study in this area.) Only last year, AHA/CDC issued a Class IIa recommendation stating that hsCRP measurements for risk stratification add important information to the 'classic' cholesterol and HDL measurement. Thus, we urge CMS to include this measure in its initial list of 'approved' screening tests. If not, ASCLS requests that CMS immediately ask USPSTF conduct a formal review of hsCRP as a screening test. In addition, when appropriate, ASCLS will initiate a similar request through the National Coverage Determination Process.

We concur with the screening tests identified in this rule and their corresponding CPT codes:

- Cholesterol, blood, total (CPT 82465)
- HDL cholesterol (CPT 83718)
- Lipid profile (total cholesterol, HDL cholesterol, and triglycerides) (CPT 80061).

We do not agree with the limit of five years found in **410.17(c) Limitation on coverage of cardiovascular screening tests.** We believe that CMS should outline risk factors similar to those delineated for diabetes, such as cigarette smoking, hypertension, physical inactivity, obesity, etc., to identify that portion of the Medicare population that should be monitored more closely. Individuals with increased risk who have not demonstrated hyperlipidemia should be monitored every two years as the statute provides. One mechanism for implementing this recommendation would be to allow the physician to order the proposed screening tests initially. Patients with abnormal results would qualify for appropriate diagnostic (non-screening) tests as medically necessary. Patients with normal results but other risk factors such as family history, high blood pressure, etc. would qualify for screening again in two years. Patients with normal results and no risk factors would no longer qualify for the screening tests.

Again, any abnormal results would qualify the patient for appropriate follow-up diagnostic tests as medically necessary.

What will happen with the ASCLS comments regarding this particular proposed regulation? As of this writing, we don't know, but frequently our suggestions do become part of final regulations. It is ongoing, consistent participation in the process that gives ASCLS a recognized presence in the regulatory process.