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July 18, 2007

Cassandra Black
Deputy Director, Division of Ambulatory Services
Center for Medicare Management
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Dear Ms. Black,

I am writing on behalf of the American Academy of Family Physicians (AAFP), which represents nearly 94,000 family physicians and medical students nationwide. Specifically, I am writing to offer our comments in response to the proposed deletion or inactivation of CPT codes 83036 and 83037 and the addition of a single G code for glycosylated hemoglobin (A1C) testing in the 2008 clinical laboratory fee schedule.

The AAFP strongly opposes this proposed change for the following reasons.

- The comments of interested parties presented at the July 16, 2007 laboratory public meeting did not present a compelling reason for this change.
- The AAFP and other organizations which support and advocate for improved management of diabetes have previously provided evidence that the A1C test described by CPT code 83037 should not be valued the same as the test described by CPT code 83036 due to differences in the method and cost of providing the tests.
- A compelling case that the change would likely be detrimental to the delivery of quality and cost-effective care to Medicare beneficiaries who suffer from diabetes was made by several presenters.

The Case Against Change
The reasons presented in favor of the proposed change were keeping the payments equal for old and new technologies so as to avoid a bias for new technology and that both tests measure the same analyte. Providers of laboratory tests and services cannot expect that new technology will be treated the same as old technology when substantial differences in methodology, costs or other factors warrant otherwise. The physicians of the Pathology Coding Caucus and the CPT Editorial Panel felt that the new technology was substantially different to warrant a separate code. The AAFP supported this decision and continues to participate in work by the Pathology Coding Caucus aimed at further developing the coding conventions for point-of-care tests. Therefore, we see no valid reasons to change the current clinical laboratory fee schedule as proposed.

The Current Fee Schedule Values
The cross-walk valuing of code 83037 to code 82985 at $21.06 was based upon the extensive input from stakeholders and reasonable estimation of the costs of this method of testing. While not likely seen as a payment incentive by family physicians as we have

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estimated the cost of providing the test to be closer to $34.00 per test, $21.06 may support utilization. If code 83037 is replaced in the clinical laboratory fee schedule with a G code which would also represent the lower cost test now reported with code 83036, it is likely that it would no longer be financially feasible to offer the test in the primary medicine practices where approximately 85% of diabetes patients receive care.

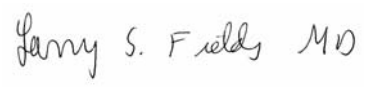
The Value of Point-of-Care A1C testing

Point-of-care A1C testing has been shown to have long-term reliability in helping to lower hemoglobin A1C levels as indicated by studies such as "Effect of Point-of-Care on Maintenance of Glycemic Control as Measured by A1C" (**Diabetes Care** 30:713-715, 2007). The American Diabetes Association also includes point-of-care testing in the 2007 Standards of Medical Care in Diabetes.

The case for supporting point-of-care A1C testing through payment which covers the cost of the testing is also supported by the recent announcement regarding results of the Medicare Pay for Performance Demonstration. The July 11th press release related to the Medicare Pay-for-Performance Demonstration stated, "Physician groups have transformed care by making lab results for diabetic patients available to physicians prior to patient encounters…" In this same press release, CMS Acting Administrator, Leslie Norwalk also supported the case for cost-effective payment of the point-of-care A1C. Her comments included, "Creating payment incentives that can lead to better patient outcomes and lower total costs is the right thing to do".

The State of Diabetes Complications in America report states that 22.9 billion dollars was spent in this nation for direct medical cost related to diabetes complication in 2006. The provision of any incentive to provide testing which may result in better diabetes control and fewer complications, even one that does not fully cover a physician's overhead costs, will likely lower total costs over time. Therefore, I respectfully request that CMS do the right thing and maintain codes 83036 and 83037 in the clinical laboratory fee schedule with no reduction in the current fee schedule amounts.

Sincerely,



Larry Fields, M.D., FAAFP
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