April 16, 2012

Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-6037-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Medicare Program; Reporting and Returning of Overpayments; [CMS-6037-P]; RIN 0938-AQ58

Dear Acting Administrator Tavenner:

On behalf of the American Association of Bioanalysts (AAB) and the National Independent Laboratory Association (NILA), representing independent community and regional clinical laboratories, we thank you for the opportunity to submit comments on the Medicare Program; Reporting and Returning of Overpayments proposed rule.

AAB and NILA represent the owners, directors, supervisors, and technologists of independent, regional and community clinical laboratories who currently work in contract arrangements with physician practices, outpatient care settings, skilled nursing facilities, and home health care agencies. In the rare instances when overpayments are made, our members currently have measures in place to ensure that appropriate corrective action is taken. Below are AAB's and NILA's specific comments on the proposed rule.

C. Requirements for Reporting and Returning of Overpayments (Proposed § 401.305)

1. General

Section 1128J of the Affordable Care Act ("ACA") mandates that if a person receives an overpayment, they must report and return the overpayment to CMS and notify CMS of the reason for the overpayment. CMS proposes to use the existing voluntary refund process to implement this section. AAB and NILA appreciate CMS utilizing an existing process that providers and Medicare contractors understand and have worked with. CMS also indicates its intent to develop a uniform reporting form that will ensure consistent reporting across all Medicare contractors. AAB and NILA have regional laboratory members, and a consistent reporting form would ensure against confusion and allow for appropriate compliance among laboratories.

3. Reporting and Returning Deadlines

The proposed rule provides for specific requirements regarding an overpayment and by when it must be returned. It states that overpayments must be returned within 60 days after the identification of the overpayment (§ 401.305(b)) and that a person must return these overpayments if they have actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the existence of the overpayment (§ 401-305(a)(2)). However, in some cases it may be possible to determine that an overpayment has been made, though not possible for a provider or supplier to quantify the exact amount of the overpayment within 60 days. In addition, some providers utilize an adjustment bill process whereby providers reconcile payments on a roving basis. In promulgating the final regulations, we urge CMS to provide additional clarification to providers in cases where the amount of the overpayment may not be known and whether the adjustment bill process to resolve overpayments within a one-year window will be allowed.

Moreover, in the preamble, CMS states that in some cases, "a provider or supplier may receive information concerning a potential overpayment that creates an obligation to make a reasonable inquiry to determine whether an overpayment exists." AAB and NILA strongly urge CMS to provide additional clarification concerning instances where a provider and supplier have an affirmative obligation to conduct an inquiry to determine where overpayments exist. For example, if it is determined that an overpayment has occurred for a specific diagnostic test, we question the extent to which that creates an obligation for the laboratory to conduct an inquiry in regard to similar diagnostic tests where Medicare reimbursement has been received by the laboratory.

In the preamble, CMS lists several examples where an overpayment has been identified, including an instance where the provider or supplier experiences a significant increase in Medicare revenue for which there is no apparent reason for the increase. We recognize instances with other providers where this example may be appropriate to determine the existence of overpayments. However, we are concerned about the unintended consequences of applying a uniform standard across providers to examine changes in provider volume of Medicare payments. Laboratories, for example, represent a unique provider of care that is not in a position to determine the medical necessity of tests ordered by physicians. Laboratories do not order patient lab tests or make decisions on which lab tests are to be conducted for a patient. The labs only conduct the tests that are ordered by a physician. Also, for some laboratories, a majority of their work is within long term care facilities, where patients have multiple chronic conditions and the type and volume of tests ordered by physicians who service those patients fluctuate and vary. We are concerned that there could be false implications for a laboratory that sees changes in the type and volume of Medicare tests it performs in relation to the patient population it serves.

In its final rule, we urge CMS to acknowledge the unique role of those Medicare providers, including laboratories, that do not have the ability to determine what tests or services or the volume of such that are ordered for a patient. CMS should clarify that laboratories and other providers who do not directly order tests or services would be exempt from any requirement to proactively conduct an inquiry into whether an overpayment exists based on the volume of Medicare work it conducts. In the example provided here, a laboratory would only be able to verify that it performed the number of tests that were ordered by physicians within a defined period of time.

6. Lookback Period and Related Issues

CMS proposes a 10-year lookback period for the reporting and repayment of overpayments (§ 401.305(g)). In the preamble, CMS justified its selection in order to be consistent with the requirements of the outer limits of the False Claims Act (77 Fed. Reg. at 9184). While we appreciate CMS' acknowledgement that providers should have certainty after a reasonable period of time, we are concerned that a 10-year lookback period is unnecessarily and unreasonably burdensome, particularly in light of the fact that many of our members are small, community laboratories. Given that Medicare payment rules and regulations are constantly changing, the proposed regulation would require our members to create and maintain an expensive and extraordinarily burdensome records system. Therefore, we urge CMS to consider a more reasonable lookback period of no longer than four years. A more reasonable lookback period strikes the right balance of providing an adequate period of time with which to examine whether overpayments were made, while at the same time minimizing the administrative burdens to providers.

Conclusion

We thank you for the opportunity to submit comments on the Reporting and Returning of Overpayments proposed rule. Please contact me if you have any questions.

Sincerely,

Mark S. Birenbaum, Ph.D.
Administrator