Dear Ms. DeParle:

The American College of Physicians–American Society of Internal Medicine (ACP–ASIM), representing 115,000 internists and medical students, is pleased to comment on the Health Care Financing Administration (HCFA) proposed rule, Medicare Program; Negotiated Rulemaking Coverage and Administrative Policies for Clinical Diagnostic Laboratory Services. As a member of the negotiated rulemaking committee that developed the proposed policies, ACP–ASIM has limited its comments to the specific areas in which HCFA has requested input from committee members and others.

III. Proposed Policy Changes and Clarifications

A. Information Required With Each Claim

3. Date of Service

We generally agree with HCFA's decision to designate the date of specimen collection as the date of service to be reported on a claim for a laboratory service. However, we note that it is difficult to apply this standard to tests performed months or even years after a specimen is collected. The lag time between specimen collection and processing can create confusion and potential billing problems. The HER-2 test provides an example. The HER-2 is a membrane associated cellular oncogene whose amplification/over expression is a marker of response to therapy and prognosis. The HER-2 is used in the treatment of patients with carcinomas. In addition to tests performed on preserved specimens, such as the HER-2, tests done on frozen serum can also cause billing problems due to lag time.

We urge HCFA to identify such tests and instruct carriers to avoid inappropriate claim processing disruptions associated with their billing. HCFA should work with the physician and laboratory communities to determine how to appropriately bill these special cases.
F. Limitation on Frequency

3. Notice to Beneficiaries (i.e. Sharing Frequency Information with Beneficiaries)

We believe that HCFA should develop a comprehensive database that contains patient-specific laboratory test frequency information. Ideally, the database would also contain test results. The database should be available electronically. Such a mechanism would permit a physician to determine how often a patient has received a laboratory test in real-time by checking the database. We encourage HCFA to explore the possibility of linking such a system to its Part B billing data (possibly by compiling a patient's explanation of Medicare benefit forms or Medicare summary notice) while protecting patient confidentiality.

An information sharing mechanism that relies on mailing paper notices to beneficiaries to share with their physician(s) is inefficient. The administrative burden and confusion that would likely result would far exceed any benefit the system could generate.

Further, we think HCFA should play a more active role in informing beneficiaries regarding the existence and implications of Medicare policies that restrict coverage of laboratory tests to specific diagnoses—whether the policies are national or local. ACP–ASIM policy states:

“ACP–ASIM will seek to have Medicare inform beneficiaries about policies that limit coverage of individual laboratory tests and alert beneficiaries that those policy changes may increase their out-of-pocket costs and alert beneficiaries that Medicare requires physicians to use Advanced Beneficiary Notification (ABN) forms in certain situations.”

While we welcome HCFA efforts to inform physicians regarding laboratory test coverage policies, beneficiary education must be brought into the equation. Beneficiaries are the common link when they see multiple physicians for their care. Beneficiaries should be encouraged to discuss the frequency in which they receive a specific laboratory test (e.g. the last time they had a specific test) with their physician(s). Physicians should also be encouraged to initiate such a discussion with their patients.

We appreciate the opportunity to serve on the negotiated rulemaking committee and the opportunity to comment on the proposed rule. Please contact Brett Baker, Senior Associate, Managed Care and Regulatory Affairs, by phone at (202) 261-4533 or by e-mail at bbaker@mail.acponline.org if you have any questions or comments.

Sincerely,

Cecil Wilson, MD, FACP
Chair, Medical Services Committee