

Comment: Some commenters recommended that we withdraw our proposal because reasonable cost payment for clinical diagnostic laboratory tests on specimens collected in non-CAH settings can be an important revenue source for CAHs and yet would generate only a small amount of additional cost to the Medicare program.

Response: For the reasons stated above and in the preamble to the proposed rule, we do not believe it is appropriate to pay on a reasonable cost basis for these laboratory tests. Moreover, doing so might create an unintended incentive for laboratories processing a substantial volume of tests to affiliate with CAHs, in order to obtain the higher level of payment for tests on individuals who are only nominally patients of the CAH. Therefore, we are not adopting this recommendation.

Comment: Some commenters stated that beneficiaries, particularly frail, elderly individuals residing in remote rural areas, could be inconvenienced by our proposed clarification because they would now be required to travel to the CAH to obtain laboratory services payable on a reasonable cost basis. These commenters expressed concern that frail, elderly patients confined to nursing homes could be required by this policy to travel to CAHs to obtain needed laboratory tests.

Response: Under our proposed clarification, Medicare would not deny payment for medically necessary clinical diagnostic laboratory tests that the CAH performs on specimens collected from patients in non-CAH locations. On the contrary, clinical diagnostic laboratory tests performed by CAHs on such specimens would be paid under the same conditions as would apply to such tests furnished by an independent laboratory. In such a case, a CAH would be providing independent laboratory services and generally would be paid under the laboratory fee schedule.

Regarding the concern about the difficulty of travel for some beneficiaries, we believe it is an incorrect assumption that beneficiaries in rural areas will not have specimens collected in their homes or other locations if the CAH is not paid on a cost basis for the collection and travel. If it is medically necessary for the specimen to be collected in the patient's home, the laboratory benefit under Medicare Part B will pay the specimen collection fee (currently \$3 per specimen), plus a separate travel allowance (currently at least 75 cents per mile where the average round trip is more than 20 miles) for employees of

independent, mobile or hospital-based laboratories to travel to the beneficiary's home. These payments are in addition to payment for performing the tests. (For further details on how specimen collection and travel fees are calculated, see CMS Transmittal AB-98-33, Change Request #526, dated July 1998; this transmittal is available on the CMS Web site at www.cms.hhs.gov.) In many cases, the laboratories collect blood specimens in batches or groups of beneficiaries residing in neighboring areas. This can make the technicians' trips to beneficiaries' residences more cost-effective.

In addition to laboratories, home health agencies that have laboratory provider numbers can perform blood draws at a beneficiary's residence and bill Medicare under the laboratory benefit, using the appropriate codes for specimen collection and travel. Agencies would be reimbursed the \$3 specimen collection fee, plus travel costs determined by the Medicare contractor.

It is also important to note that home health agencies with laboratory provider numbers may conduct some of the less complex blood tests themselves, receive the collection and travel fee, and receive a fee through the laboratory benefit for performing the tests. These are called the Clinical Laboratory Improvement Amendments (CLIA)-waived tests, and, among others, include: glucose (blood sugar levels for diabetic patients), fructosamine (also checks blood sugar levels but over longer period of time), hemoglobin (tests hemoglobin levels for patients with anemia), urine dip stick (tests urine for a variety of diseases/infections), and cholesterol/triglyceride (checks for lipid levels for patients with cardiovascular disease) tests.

A variety of other providers can draw blood at a beneficiary's home, often in conjunction with other services necessitating the laboratory tests. For example, while a physician conducts a home visit for evaluation and management, the physician may also draw a blood specimen. If the physician meets applicable requirements under the laboratory benefit, he or she may receive an additional payment for the specimen collection.

The physician also can arrange for a nurse practitioner, physician assistant, or clinical nurse specialist to conduct a home visit and draw blood when they examine the beneficiary. These clinicians are reimbursed at a rate equal to 85 percent of the physician fee schedule for a home visit, and if all applicable billing requirements are met, they are also paid specimen collection and travel fees.

Regarding tests for nursing home patients, we note that if a CAH furnishes laboratory services to a beneficiary in an SNF stay covered by Part A, nonemergency diagnostic laboratory tests—regardless of whether furnished by the SNF directly or under an arrangement with the CAH—would be included within the SNF's bundled PPS per diem payment for the covered stay itself. If a CAH furnishes laboratory services to a beneficiary in an SNF stay not covered by Part A (for example, Part A benefits exhausted; no prior qualifying hospital stay; SNF level of care requirements not met), the SNF consolidated billing restrictions do not apply. However, if the SNF nonetheless elects to bill for such a beneficiary's laboratory services, section 1888(e)(9) of the Act provides that an SNF's Part B bills are to be paid in accordance with the fee schedule that applies to the particular item or service being billed.

In the case of beneficiaries in nursing homes, patients are already under the care of an institution staffed with registered nurses, licensed practical nurses, and nursing assistants, and other health care workers who are presumably well-trained in collecting specimens for analysis, and the nursing homes are already being paid, by Medicare, Medicaid, private insurers, or other means for caring for the patient. Under these circumstances, it would not seem unreasonable to expect the nursing home to take responsibility for collecting the specimens.

Because of the many ways in which specimen collection and travel are payable under Medicare, we do not expect beneficiaries to face reduced access to services under this proposal. We specifically reject the claims made by several commenters that beneficiaries would be able to obtain needed laboratory services only by traveling to the CAH to obtain them.

Comment: Some commenters took exception to the preamble statements that allowing cost reimbursement for laboratory tests on specimens obtained by CAH personnel in non-CAH settings would duplicate existing coverage, create confusion for beneficiaries, and add to the costs of care furnished to Medicare patients. Regarding the costs of care, the commenters stated that because clinical diagnostic laboratory tests are not subject to deductible or coinsurance liability under Medicare, there would be no increase in out-of-pocket costs for beneficiaries.

Response: Regarding duplication of coverage, we have explained in a response to an earlier comment the many ways in which Medicare now pays for specimen collection fees and