

19, 2003 proposed rule, we proposed to revise § 413.70(b)(2)(iii) to state that payment to a CAH for outpatient clinical diagnostic laboratory tests will be made on a reasonable cost basis only if the individuals for whom the tests are performed are outpatients of the CAH, as defined in § 410.2, “and are physically present in the CAH” at the time the specimens are collected. (We note that, in some cases, the CAH outpatients from whom specimens are collected at the CAH may include individuals referred to the CAH from RHCs or other facilities to receive the tests.) We proposed to further revise this paragraph to state that clinical diagnostic laboratory tests for individuals who do not meet these criteria but meet other applicable requirements will be paid for only in accordance with the provisions of sections 1833(a)(1)(D) and 1833(a)(2)(D) of the Act, that is, payment will be made only on a fee schedule basis. We emphasize that the second proposal does not mean that no payment would be made for clinical diagnostic laboratory tests performed by CAHs that do not meet the revised criteria. On the contrary, such tests would be paid, but on a fee schedule basis. We believe these clarifications are appropriate, as the CAH is not providing CAH services but is acting as an independent laboratory in providing these clinical diagnostic laboratory tests.

Comment: Some commenters stated that a major goal of the Medicare Rural Hospital Flexibility Program, under which reasonable cost payment to CAHs is authorized, is to ensure that isolated rural hospitals have access to critical health care services. The commenters believed that our proposal would undermine that goal by paying less than reasonable cost amounts for certain services. These commenters stated that, in some rural communities, there may be few, or no, reasonable alternatives to having laboratory tests performed by a CAH. Because of this, the commenters believed reasonable cost payment for CAH-performed laboratory tests is warranted, even when specimens are collected in settings other than the CAH from patients who are being registered as CAH patients for the sole purpose of generating higher Medicare payment for the tests.

Response: We agree that an important goal of the CAH legislation is to pay on a reasonable cost basis for services that CAHs provide in their facilities to their inpatients and outpatients. However, we do not believe that legislation can or should be read so broadly as to authorize payment on a reasonable cost basis for laboratory services to patients

who do not come to the CAH for those services, but receive them in other settings, including settings in which coverage for the services is available. We also do not agree that because the CAH may be one of only a few sources of laboratory services that the CAH should therefore be paid a higher amount for those services than would otherwise be the case. Therefore, we are not making any change to our proposal based on this comment.

Comment: Several commenters stated that even when a sample is collected outside a CAH, the cost of processing in a CAH laboratory is incurred by the CAH. Because of this circumstance, the commenters recommended that payment be based on the payment method applicable to the site where the processing is done, so that payment for laboratory tests processed at a CAH would be paid on a reasonable cost basis, not under the fee schedule.

Response: We believe the approach recommended by these commenters could create an inappropriate incentive to CAHs to expand their testing activities far beyond their normal service areas, in order to gain cost reimbursement for patients who have no other connection with the CAH other than having a specimen processed by the CAH. In some cases, this could result in payment being made on a cost basis for laboratory services to patients residing in suburban or even urban areas where there is no shortage of qualified laboratories. Such a result would only inappropriately increase payment to CAHs and create market distortions, because non-CAH laboratories performing exactly the same services may be paid substantially less for them. Therefore, we are not adopting this recommendation.

Comment: One commenter agreed with our proposal as it applies to laboratory specimens drawn in health care providers or suppliers other than CAHs, such as SNFs or RHCs, but recommended that we allow reasonable cost payment for clinical diagnostic laboratory tests on specimens drawn in physician clinics that are located in close proximity to the CAH, if the CAH owns the clinic and supplies the personnel who collect the specimens.

Response: While we considered this suggestion, we are not adopting it. A clinic of the type described by the commenter is not a part of the CAH, but is a physician office. We see no basis for treating such a non-CAH setting differently from other non-CAH facilities (such as RHCs) that are similarly owned and located. In the case of an ambulatory patient being seen in a physician office located in close

proximity to the CAH, we do not believe it is unreasonable to expect the patient to go to the CAH for the laboratory service as he or she would for therapy or any other CAH outpatient service. Alternatively, the specimen may be collected during the physician visit and payment could be made to the CAH under the laboratory benefit, generally on a fee schedule basis.

Comment: Some commenters stated that the proposed revision is not a clarification but a change from past policy.

Response: We disagree with the commenter, but we do recognize from the questions raised on the issue that there has been some confusion about the policy among rural facilities. To clarify the agency policy in this area and ensure that all relevant issues are publicly noted, we set forth the clarification through notice and comment rulemaking procedures rather than through other processes, such as a program memorandum, a set of responses to “frequently asked questions,” or other document.

Comment: One commenter stated that it is inappropriate for proposed changes to CAH payment to be published in the proposed IPPS regulation. The commenter recommended that if changes are to be made to the payment methodology for those facilities excluded from the IPPS rule, they should be published separately in the **Federal Register**, not in a proposed rule that would not normally be reviewed by officials associated with CAHs.

Response: The IPPS proposed and final rules are published on an established and regular annual cycle and have been read for many years by a large health care population, including national, State, and local hospital associations as well as individual hospitals, including hospitals paid under the reasonable cost payment system as well as those paid under the IPPS. Because we recognize this as an important tool for disseminating information, we have used the IPPS publication in order to implement several major payment issues relating to CAHs. For example, changes in the CAH payment rules in § 413.70 were included in the IPPS final rule published on August 1, 2002 (67 FR 49982) and the IPPS final rule published on August 1, 2001 (66 FR 39828). We believe this is an appropriate vehicle in providing the information necessary to allow the CAHs access to the information they need to continue to participate knowledgeably in the Medicare program. In fact, we received over 40 comments on the provision alone.