biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the health of, human beings." In short, the services covered under CLIA and section 1877 are those conducted by these facilities and involving the examination of materials derived from the human body.

The commenter has asked specifically about consulting services designed to assist a physician in interpreting test results. We believe that CLIA covers the actual examination of materials, their analysis, and any interpretation and reporting of the results which are performed by a facility that qualifies as a laboratory, as defined in §493.2. If a laboratory interprets certain test results or hires a consultant who takes the responsibility to interpret them in lieu of laboratory personnel, we believe the interpretation would qualify as a clinical laboratory service. (If a consultant only offers input or information which the laboratory will use in making its own interpretation, the input would not qualify as a clinical laboratory service.)

However, if a laboratory sends test results to an independent physician, any interpretation performed by the physician would not be performed by the laboratory facility. As a result, the services would not constitute part of the clinical laboratory test. If a physician hires a consultant to help interpret the results, the same rule would apply: the consultant's services would not constitute clinical laboratory services if the consultant is performing outside the auspices of a laboratory facility. The services would not be subject to CLIA or section 1877.

If, on the other hand, a physician or group practice hires a consultant to perform, analyze or interpret test results that are performed in the physician's or group's own laboratory, the interpretation would qualify as part of the services performed by a laboratory. These interpretive services would be subject to CLIA and, as a result, to section 1877. If the physician or group practice wishes to qualify under the inoffice ancillary services exception, the physician or member of the group practice must supervise any nonphysician consultant when he or she performs clinical laboratory services. In addition, the tests must meet the section 1877(b)(2) location and billing requirements.

d. Services an Outside Laboratory May Provide to a Physician's Office Laboratory

Comment: One commenter had concerns about services a laboratory outside the physician's office may provide a physician's office laboratory. The commenter wrote that the final CLIA regulations contain personnel standards that require laboratories performing moderately complex testing to have a laboratory director, a technical consultant, a clinical consultant, and testing personnel who meet certain standards. (See 42 CFR part 493.) In physician office laboratories, for the most part, one of the practice's physicians will function as the laboratory director and also may function in one or more other roles. In some circumstances, however, physicians have asked an independent laboratory entity to serve in, or assist the physician in carrying out the duties of, one of the required positions to the extent permitted under CLIA. For example, an independent entity might serve as the clinical consultant for a number of its physician customers as well as assist a physician in carrying out the duties of the technical consultant. The commenter requested a clarification in the final regulations that such services would not defeat a physician office laboratory's qualification for the in-office ancillary services exception, since the independent contractors will not be employees of the physician.

The commenter believed that, since all laboratories, including physicians office laboratories, must meet the CLIA standards, the laboratory testing performed in these laboratories is covered under the provisions found in section 1861(s)(3). Since section 1861(s)(3) does not have an employment requirement, the commenter concluded that the physician does not have to employ the personnel as he or she would if the laboratory services were billed and covered as services performed incident to the professional services of the physician under section 1861(s)(2)(A).

Response: Regardless of the setting in which it is performed, if a service involves laboratory tests on human specimens by a laboratory as defined in § 493.2, the CLIA provisions apply. So we agree that the CLIA requirements apply to in-office laboratories of solo-practicing physicians and of group practices. It appears that the commenter is concerned about the requirement in the predecessor provision at section 1877(b)(2) that, in order for the in-office ancillary services exception to apply, services, when not furnished by a

member physician, must be performed by individuals who are *employed* by the physician or the group practice. The employment requirement was eliminated by OBRA '93 retroactively to January 1, 1992. Therefore, under amended section 1877(b)(2), referrals for services to be furnished by any individuals who are directly supervised by the referring physician or, in the case of group practices, by another physician in the same group practice, are excepted. In other words, the in-office ancillary services exception applies to a physician or group practice that has outside contractors furnishing laboratory services, as long as the physician or group practice physicians directly supervise these individuals. In addition, as mentioned previously, a contracting physician may be considered a "member" of a group practice. As a member, the contractor could perform the services without supervision or directly supervise other individuals who perform clinical laboratory services.

Also, in this regard, we have taken the position in the past that clinical laboratory testing performed in physicians' offices is covered only if furnished by the physicians or if the requirements are met for coverage of services incident to the professional services of the physicians under section 1861(s)(2)(A) (see section 2070 of the Medicare Carriers Manual (MCM)). One of the requirements has been that persons performing services incident to the services of a physician must be employed by the physician. However, section 1861(s)(3) states, in pertinent part, that "medical and other health services" covered by Medicare include "diagnostic laboratory test[s]." Section 1861(s)(3) does not exclude diagnostic tests performed in physicians' offices or clinics. The only restriction on coverage under section 1861(s)(3) is set forth in the language following section 1861(s)(14), which states that "[n]o diagnostic tests performed in any laboratory * * * shall be included within paragraph (3) unless such laboratory" meets the CLIA certification requirements or has a certificate of waiver. Because section 1861(s)(3) relates more specifically to laboratory testing than section 1861(s)(2)(A), and because most laboratory testing performed in a physician's office is subject to CLIA, we now take the position that it would be appropriate to provide coverage of these services under section 1861(s)(3). (We are in the process of changing the MCM to reflect this position.) This means that the employment requirement does not have