located in the basement of the building. The physicians do not directly supervise the laboratory technician when the technician is performing services for the physicians. In addition, the laboratory bills for services furnished to the patients of the physicians.

In the first example, as long as the requirements of section 1877(b)(2) and § 411.355(b) are met, it would not matter if the physicians pooled resources to cover the costs of the space occupied by the laboratory or for the cost of the equipment or overhead. We emphasize that the in-office ancillary services exception has been amended by OBRA '93, effective retroactively to January 1, 1992. Before this amendment, the services under this exception had to be furnished by the referring physician or by another physician in the same group practice. Alternatively, services could be furnished by employees of the referring physician or of the physician's group practice, provided the employees were "personally supervised" by the referring physician or another physician in the group practice. This requirement has been changed by OBRA '93 to eliminate the requirement that only a physician's or group practice's employees can furnish services. Also, the term "personally supervised" has been changed to require that a technician's or other individual's services be "directly supervised" by the referring physician or by another physician in the group practice.

For purposes of this exception, we are explicitly defining "direct supervision" using the longstanding Medicare definition of this term. Under this definition, the physician must be present in the office suite and be immediately available to provide assistance and direction throughout the time a technician is performing services. We believe it is appropriate for us to define this term in this final rule with comment period, rather than in a new proposed rule. We have several bases for this conclusion.

First, we believe that the Secretary's definition for this term is interpretive. Interpretive, nonsubstantive agency promulgations fall into the Administrative Procedure Act (APA) exception to notice and comment rulemaking. See 5 U.S.C. 553(b)(A).

In defining "direct supervision," we are merely explicating the Congress' desires rather than adding substantive content of our own. That is, the definition is a clarification of what is implicitly in the statute. A rule that clarifies a statutory term is the classic example of an interpretive rule. Interpretive rules are those that merely clarify or explain existing law or regulations. They serve an advisory function, explaining the meaning given by the agency to a particular word or phrase in a statute or rule it administers.

The term "direct supervision" is a longstanding term of art with a very particular meaning in the Medicare program. It appears in section 2050.2 of the Medicare Carriers Manual, Part 3-Claims Processing, which describes services that are "incident to" a physician's professional services. This definition has appeared in the manual since the 1970's. It has, over the years, affected the many physicians who bill for services or supplies that are furnished as an integral, although incidental, part of a physician's personal professional services in the course of diagnosis or treatment of an injury or illness. The same definition appears in the regulations at §410.32(a), which states that, in general, diagnostic x-ray tests are covered only if performed under the "direct supervision" of certain physicians or by certain radiology departments. Congress, in using this term of art, has adopted and ratified the Secretary's definition.

We believe that in changing 'personally supervised'' to the familiar "directly supervised," Congress was intending to make clear that it wished to incorporate a concept that the agency and the provider community have long understood. For example, physicians are quite familiar with this term because they can only bill for nonphysician services that are "incident to" their own services if the nonphysician services are performed under "direct supervision." As such, we have reiterated in this regulation our long-standing definition for this term. The definition is a clarification of what the Secretary believes "direct supervision" means and has always meant; it does not add to the statute any additional substantive requirements.

We are aware of only one paragraph of legislative history for OBRA '93 that attempts to explain the meaning of the term "direct supervision." The Conference Report for OBRA '93 states that—

[T]he conferees intend that the requirement for *direct supervision by a physician* would be met if the lab is in a physician's office which is personally supervised by a lab director, or a physician, even if the *physician is not always on site*. [Emphasis added.] H.R. Rep. No. 213, 103d Cong., 1st Sess. 810 (1993).

We believe that this explanation provides no insight into the Congress' purpose in using the term "direct supervision." That is, it purports to explain what constitutes direct supervision, yet defines it by allowing a physician to "directly supervise" without even being present. This appears to us to be at total variance with the Medicare program's longstanding requirements for "direct supervision, and with the statute, which specifically requires that the referring physician or another physician in the same group practice have *direct* involvement with individuals performing laboratory tests. In addition, the statute is very specific about who must directly supervise; it does not say that a laboratory director who is not a group member can provide this supervision instead of a solo or group practice physician.

Also, it appears to us that the legislative history is inconsistent. If "direct supervision" is interpreted to allow a laboratory director to supervise individuals who are furnishing services, this could have the effect of creating an exception for shared laboratories. The very same conference report points out that the House Energy and Commerce Committee introduced a provision that would have added an exception for shared laboratories. The conference agreement, however, specifically rejected this amendment. H.R. Rep. No. 213, 103d Cong., 1st Sess. 810 (1993).

Even without the "interpretive" exception, we believe that there would be good cause to waive notice and comment for this particular term. Title 5 U.S.C. 553(b)(B) authorizes agencies to dispense with certain procedures for rules when they find "good cause" to do so. Under section 553(b)(B), the requirements of notice and comment do not apply when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest."

We believe that waiting to define "direct supervision" in a future notice of proposed rulemaking would be both impracticable and contrary to the public interest. To begin with, some of the amendments added by OBRA '93 relating to clinical laboratories have a retroactive effective date. The provision containing the "direct supervision" requirement is effective retroactively back to January 1992. The retroactive effective date for some provisions relating to clinical laboratory services, but not others, demonstrates the Congress' desire to expedite their implementation. Although an expedited timeframe alone may not justify a "good cause" exception, we believe it is a crucial factor when considered in conjunction with the entire set of circumstances.

The in-office ancillary services provision establishes an exception to the referral prohibition that is critical to