

addition, some commenters have presented a lengthy and elaborate description of the work in the service, but omitted, or provided an incomplete description of, the comparability of the work in the service to the work in a reference procedure or procedures identified.

Intensity of the work in the service is best compared by breaking the intensity into the following elements:

- **Mental effort and judgment**—Commenters should compare the service in question with a reference service as to the amount of clinical data that needs to be considered, the depth of knowledge required, the range of possible decisions, the number of factors considered in making a decision, and the degree of complexity of the interaction of these factors.

- **Technical skill and physical effort**—One useful measure of skill is the point in training when a resident is expected to be able to perform the procedure. Physical effort can be compared by dividing services into tasks and making the direct comparison of tasks. In making the comparison, it is necessary to show that the differences in physician effort are not reflected accurately by differences in the time involved; if they are, considerations of physician effort amount to double counting of physician work in the service.

- **Psychological stress**—Two kinds of psychological stress are usually associated with physician work. The first is the pressure involved when the outcome is heavily dependent upon skill and judgment and a mistake has serious consequences. The second is related to unpleasant conditions connected with the work that are not affected by skill or judgment. These circumstances would include situations with high rates of mortality or morbidity regardless of the physician's skill or judgment, difficult patients or families, or physician physical discomfort. Of the two forms of stress, only the former is fully accepted as an aspect of work; many consider the latter to be a highly variable function of physician personality.

Intensity often varies significantly in the course of furnishing a service. Sometimes commenters "anchor" the value of the service to a point of maximum intensity during the service as the basis for comparing services. It is unlikely that the maximum intensity is an accurate reflection of the average intensity of a service; a lengthy procedure that is simple except for a few moments of extreme intensity is probably less work than one of equal

length during which a fairly high level of intensity is maintained throughout.

This proposal reflects a policy change that is not explicitly addressed in our regulations.

I. Coverage of Mammography Services

In the December 31, 1990 interim final rule (55 FR 53510) and the September 30, 1994 final rule (59 FR 49808), we based our present definitions of "diagnostic" and "screening" mammography and related provisions on advice from the Food and Drug Administration (FDA), the National Cancer Institute (NCI), our own medical consultants, and other components of HHS.

These definitions are important because of the impact they can have on how frequently mammograms are covered under the Medicare program. The Medicare law and current regulations limit the frequency of coverage for "screening" mammography services according to the patient's age and for women over age 39 but under age 50 based on whether she is considered at high risk of developing breast cancer. On the other hand, coverage of "diagnostic" mammography is not restricted by specific statutory frequency limitations but depends on whether the examination has been (1) ordered by the patient's physician, and (2) is determined by the local Medicare contractor to be medically necessary for the patient.

In response to inquiries from beneficiaries, practicing physicians, and others in the medical community, we have reexamined our definitions of "diagnostic" and "screening" mammography in § 410.34 (Mammography services: Conditions for and limitations on coverage"). In addition, we have consulted further with FDA, NCI, and a Medicare Carrier Medical Director workgroup regarding the appropriateness of the definitions. We have also reexamined the current definitions in view of our previous Medicare policy on diagnostic mammograms as described in section 50-21 of the Coverage Issues Manual (HCFA Pub. 6) that permits coverage for diagnostic mammograms for patients with a personal history of breast cancer and certain other patients, even though they are not symptomatic (that is, they do not have any signs or symptoms of a medical problem with their breasts).

Based on our reexamination of this issue, we propose to revise the definitions of "diagnostic" and "screening" mammography in § 410.34 to make them consistent with previous Medicare coverage policy regarding "diagnostic" mammography, and with

the way these terms are used in general clinical practice in the United States.

Some clinicians and mammography experts consider patients with a personal history of breast disease, such as breast cancer and chronic fibrocystic disease, to be candidates for diagnostic mammography for a period following treatment of the disease and then candidates for screening mammography thereafter. However, most clinicians and mammography experts in the United States consider patients with a personal history of breast disease to be candidates for diagnostic mammography for the rest of their lives, following the onset of their disease and its treatment.

In view of the above information, we propose to expand the definition of "diagnostic" mammography to include patients with a personal history of breast disease; however, we propose to leave the definition of "screening" mammography unchanged so that patients with a personal history of breast cancer can be considered candidates for the "screening" examination, if the patients and their physicians decide that this is appropriate.

We propose that the present definition of "diagnostic" mammography in paragraph (a)(1) of § 410.34 be expanded to include also, as a candidate for this service, a patient who does not have signs or symptoms of breast disease but who has a personal history of biopsy-proven breast disease.

The present regulations include as candidates for "screening" mammography all asymptomatic women regardless of whether they have had a personal history of biopsy-proven breast disease. We propose to leave unchanged the substance of the present definition of "screening" mammography in paragraph (a)(2) of § 410.34 but clarify it to read as follows: "Screening mammography means a radiological procedure furnished to a woman without signs or symptoms of breast disease, for the purpose of early detection of breast cancer, and includes a physician's interpretation of the results of the procedure." This might include an asymptomatic woman (that is, a woman without signs or symptoms of breast disease) with a history of biopsy-proven breast disease who might otherwise qualify for a diagnostic mammography as defined in the current § 410.34(a)(1). The woman and her physician would determine which examination to request (that is, either a diagnostic or a screening mammography). Although a history of biopsy-proven breast disease would ordinarily require recurrent diagnostic examinations, in some cases, when the