Act. We believed criteria based on site of service, as shown in our current claims data, would yield a range of procedures for review by our staff of physicians to include on the ASC list. In this way, we would have support for the addition of procedures physicians generally perform on an inpatient basis. Our physicians then review the complete list of procedures that meet the threshold criteria and determine which meet the qualitative criteria in our regulations.

We acknowledge that utilization of outpatient surgical settings has increased considerably since we first initiated the threshold criteria in 1987. For this reason, we proposed altering the criteria for deleting procedures from the ASC covered procedures list. We thus recognize some movement to the outpatient setting without eliminating coverage. However, once a procedure is performed in a physician's office the majority of the time and does not require the setting of an ASC, OPD, or inpatient hospital 46 percent of the time, we believe that section 1833(i)(1) of the Act requires that we delete ASC coverage of the procedure.

When preparing the December 1993 proposed notice, we considered policy alternatives and discussed reverting to physician judgment exclusively. However, we believe that this option is too subjective, leaving policy decisions solely to the discretion of a few. If we were challenged by another physician's opinion, we could be presented with the situation of two equally qualified professionals with different opinions. Thus, we believe that some objective criteria are essential in determining coverage of procedures in an ASC.

Comment: Some commenters believed that the Common Working File (CWF) is inadequate for assessing site of service. (The CWF is a Medicare Part A and Part B benefit coordination and prepayment claims validation system that uses localized databases maintained by designated carriers. The CWF indicates site of service for surgical procedures.) The commenters believed that the data produced are skewed, especially for periods before the last 2 years when site-of-service data had been emphasized. They stated that CPT coding practices vary greatly, resulting in the same procedure being coded differently in different areas.

Response: We acknowledge that the early data using site-of-service codes contained errors. Those data may have skewed results, particularly for low-volume procedures or procedures near the threshold levels. Consequently, our criteria allow for exceptions if the data appear flawed, or our physicians, after

consultation with medical societies and local experts, believe a procedure is appropriate to the inpatient setting despite the data. Under this exceptions authority, we have retained procedures such as cataract extractions, which have not met the inpatient criterion for several years. In addition, the public has an opportunity to comment, through our rulemaking process, on what they believe are errors in the data.

With regard to the issue of varying CPT coding practices, we acknowledge that not all physicians code a particular procedure identically. Unfortunately, this variation in coding is often the result of an attempt to maximize Medicare payment to the physician for the procedure, rather than the result of ambiguous coding guidelines. While this upcoding occasionally affects the ASC list, we attempt to identify these situations and retain the procedure on the ASC list through the exceptions authority if the procedure is appropriate to the inpatient setting. We ask physicians to encourage their peers to code procedures appropriately to avoid these situations.

Comment: One commenter believed we should use a 10 percent inpatient criterion for adding procedures to the list. The commenter also suggested that any procedure generally requiring the prior or concurrent administration of general, spinal, or regional anesthesia, or of sedation or analgesia sufficient to compromise a patient's protective reflexes, be included on the ASC list regardless of utilization data.

Response: The type of anesthesia necessary for a given procedure varies among patients. Some patients have very low pain thresholds, special psychological needs, or anatomical conditions warranting a higher level of anesthesia than others. We encourage every physician to use his or her judgment in selecting the appropriate anesthesia. We do not encourage the use of anesthesia in settings not appropriately equipped for emergency situations.

The need for an operating room setting for a particular patient is not equivalent to a procedure meeting the conditions of section 1833(i)(1) of the Act for ASC coverage. As discussed above, section 1833(i)(1) requires that we cover procedures in an ASC only if they are appropriately performed on an inpatient basis. Thus, if a patient requires a higher degree of anesthesia than is reflected in the utilization data, that procedure would be covered in an OPD, or, if necessary, in an inpatient hospital setting.

We had considered revising the criterion for adding procedures on the

ASC list to 10 percent inpatient utilization. However, we believe that the current threshold of 20 percent represents a reasonable portion of use necessary to meet the statutory requirement of appropriately performed on an inpatient basis.

Comment: One commenter believed that our physician's office threshold should focus on the percentage of physicians performing the procedure in the office, rather than the percentage of procedures being performed in the office.

Response: We do not believe that the percentage of physicians performing a procedure in their offices, rather than the total site-of-service utilization data, is preferable for determining ASC coverage. Many physicians perform a given procedure only once or twice during the year. These physicians are not likely to maintain the specialized equipment necessary to perform the procedure in their offices, and, therefore, are not likely to perform it in that location. Also, a particular physician may not be proficient with the procedure and may desire to perform the procedure where there are resources available, should a mishap occur.

We do not believe that a large percentage of physicians performing a few procedures should serve as the basis for determining whether a procedure meets the conditions of section 1833(i)(1) of the Act. It is difficult to ignore the data indicating a procedure is commonly performed in a physician's office, if only relatively few physicians perform the majority of the procedures, in favor of those physicians performing the same procedure on an occasional basis. In addition, accurately determining the percentage of physicians performing a procedure in their offices would be extremely difficult.

Comment: One commenter believed that the criteria result in a competitive advantage to an OPD over an ASC. The commenter recommended that if a procedure can be safely performed in an OPD, it can be safely performed in an ASC and should be on the list.

Response: Section 1833(i)(1) of the Act established criteria for coverage in an ASC when the ASC services were added as a Medicare benefit in 1980. Section 1833(i)(1) of the Act requires that we develop a list of procedures covered in an ASC and base the list on procedures that are appropriately performed on an inpatient basis.

These requirements for ASC coverage are not applicable to an OPD. The original Medicare statute provided for coverage of all services furnished by an