office no longer meet the conditions specified in regulations. This development results in a corresponding change in claims data to lower inpatient and higher physician's office site-ofservice performance percentages, and these procedures no longer meet our 20/ 50 site-of-service criteria. By 20/50 siteof-service criteria, we mean that if a procedure is performed on an inpatient basis 20 percent of the time or less, or in a physician's office 50 percent of the time or more, it should not be covered when performed in an ASC. We may make exceptions and override the criteria if we believe the data are inaccurate or if there are medical reasons to override the data.

If we had strictly applied the 20/50 criteria to our current ASC list without making exceptions, we would have been proposing deletion of a number of procedures, such as cataract removal, that we believe are appropriate to the ASC setting. We were also concerned with what might be termed a "pingpong" situation; that is, adding a procedure during one update with 49 percent physician's office performance and then deleting it during the next update if it reached 51 percent physician's office performance. Consequently, we proposed the following criteria for deleting a procedure from ASC coverage: The combined inpatient, OPD, and ASC siteof-service percentage is less than 46 percent of the total volume; and either-

• The procedure is performed 50 percent of the time or more in a physician's office; or

• The procedure is performed 10 percent of the time or less in an inpatient hospital setting.

This proposed change would allow the site of service for procedures in the physician's office to grow from below 50 percent (when it is added) to as high as 54 percent, as long as the percentage of time the procedure is performed in a facility with a dedicated operating room remains at 46 percent. Similarly, the criteria allow procedures to move from an inpatient hospital site of service to an OPD site of service and still remain on the ASC list. To determine whether a procedure should be *added* to the ASC list, we indicated that we would continue to use the 20/50 site-of-service criteria.

We incorporate annual revisions of the CPT into our list of procedures covered in an ASC. Therefore, we also proposed for public comment the procedure codes that were added to or deleted from the ASC list through changes to the Medicare Carriers Manual as a result of updates of the 1992 and 1993 editions of the CPT. In addition, we proposed to remove from the ASC list five CPT codes that involve procedures relating to the usage of implantable infusion pumps not covered by Medicare.

## III. Analysis of and Responses to Public Comments

In our December 1993 proposed notice, we requested comments on the proposed quantitative change in our deletion criteria; the development of alternatives to the proposed quantitative deletion criteria; proposed additions to and deletions from the ASC list; and the assignment of payment groups for each addition. In response, we received 558 timely public comments from 191 urologists, 107 ASCs, 52 anesthesiologists, 50 patients, 30 ophthalmologists, 26 psychiatrists, 28 plastic surgeons, 14 obstetrician/ gynecologists, 8 gastroenterologists, 6 dermatologists, 19 professional/medical societies, and 27 others (that is, neurologists, attorneys, radiologists, a Medicare director, a podiatrist, an accountant, otolaryngologists, a supplier, and an oncologist). A summary of these comments and our responses to them follows:

Criteria for Determining Procedures for Coverage in an ASC

In our December 1993 proposed notice, we announced our intention to apply alternative utilization threshold criteria for deleting procedures from ASC coverage. That is, rather than deleting procedures that fall below the current coverage threshold, we proposed alternative criteria for deleting procedures that examine the incidence of dedicated operating room use (combined ASC, OPD, and inpatient site-of-service utilization) in determining if a procedure that has dropped below the 20 percent inpatient criteria should remain covered in an ASC. We specifically solicited comments on the alternative criteria. However, we did not receive any comments on this issue.

In addition, we requested comments on developing alternatives to the quantitative criteria we currently use in developing the ASC list. We received 64 comments regarding our current site-of-service-based criteria. The commenters included 35 ASCs, 16 urologists, 4 anesthesiologists, and 9 professional societies.

Comment: Several commenters stated that our criteria are outdated, reflecting a period when surgery was rarely performed on an outpatient basis. They noted an absence of scientific or medical literature supporting the

thresholds used. Therefore, they believed the criteria are arbitrary.

Response: The inpatient and physician's office utilization thresholds serve as a reasonable interpretation of the statutory language "appropriately performed on an inpatient basis." That is, we believe that if a procedure is performed at least 20 percent of the time on an inpatient basis and no more than 50 percent of the time in a physician's office, we can reasonably regard the procedure as appropriate to the inpatient setting. Section 1833(i)(1) of the Act requires the Secretary to "specify those surgical procedures which are appropriately (when considered in terms of the proper utilization of hospital inpatient facilities) performed on an inpatient basis in a hospital but which also can be performed safely on an ambulatory basis" in an ASC. Thus, section 1833(i)(1) of the Act is clear that procedures included on the ASC list of covered procedures must be those that are appropriately performed on an inpatient basis.

În developing regulations that implemented section 1833(i)(1) of the Act, we prepared the criteria set forth at 42 CFR 416.65 ("Covered surgical procedures"). Those regulations specify conditions for coverage of procedures that are commonly performed on an inpatient basis but may be safely performed on an outpatient basis. These conditions include requirements such as operating room time not exceeding 90 minutes, recovery period not exceeding 4 hours, limited blood loss, and limited invasion of body cavities. We believe that these criteria reasonably meet the conditions set forth in the legislation.

For several years, we used only the qualitative criteria described in the regulations. We added procedures to the list based on physicians' review of procedures recommended by medical organizations. This system resulted in only a limited number of procedures being added to the ASC list.

Patient variability made it difficult for our physicians to accurately determine procedures that should be added to the list, especially procedures that are close to the cut-off of the qualitative criteria; for example, a surgery time of 2 hours or a recovery time of  $4\frac{1}{2}$  hours. A given procedure varies with patient condition. That is, a procedure that may be accomplished in 90 minutes for one patient may take 120 minutes for another.

In developing the 1987 update of the ASC list, we determined that a numerical threshold based on site of service should be used to assist us in implementing section 1833(i)(1) of the