OPD, but it did not provide for any limitations on the appropriateness of a procedure for the inpatient setting or for the establishment of a list of procedures. Consequently, it is reasonable to expect that procedures covered in an OPD will not always be the same as procedures covered by section 1833(i)(1) of the Act. For example, there is no limitation on an OPD to perform only surgical procedures. Thus, adopting the suggestion would result in a significant expansion of the ASC benefit beyond that contemplated in section 1833(i)(1).

*Comment:* One commenter believed that operating and recovery time usage are inaccurate indicators of the complexity of procedures, and clinical criteria should be used instead. The commenter stated that the overriding guideline should be that the patient can return home by the close of the business day.

*Response:* We recognize the commenter's concern that clinical criteria be considered in establishing the ASC list. However, we believe that general operating and recovery times are related to clinical criteria. That is, we do not look at operating and recovery room times on an isolated basis, but rather review the clinical information indicating that generally patients require 90 minutes or less operating time and 4 hours or less recovery time. We believe that these criteria are good indicators of a patient's ability to go home by the close of the business day. Procedures requiring longer times than those included in the criteria are unlikely to be completed within the business day. For example, we would expect that patients arrive at least 1 hour before the surgery begins. Thus, our criteria involve 61/2 hours of an 8 hour work day, allowing 11/2 hours leeway for any delays.

*Comment:* Some commenters believed that the Medicare program should allow for overnight stays in an ASC. The commenters stated that, initially, the inclusion of overnight stays could be part of a study with a Medicare review at the annual certification survey or a review by the Peer Review Organization (PRO).

*Response:* Section 1833(i)(i) of the Act provides for coverage of surgical procedures that, in addition to other criteria, "can be performed safely on an ambulatory basis." We believe section 1833(i)(1) is clear that coverage of overnight stays under the ASC benefit is prohibited. Rather, ambulatory care implies care that is furnished with the patient going home by the end of the day. Thus, it would require a legislative change to extend Medicare ASC benefits to overnight care or recovery care. Our Office of Research and Demonstrations has the authority to waive certain portions of the statute in order to study alternative means of furnishing or paying for services under the Medicare program. We solicit research proposals annually through a notice published in the **Federal Register**, and projects are selected on a competitive basis. ASCs are welcome to submit their research proposals for consideration under the routine solicitation process.

*Comment:* One commenter suggested that Medicare develop an alternative list of procedures that could be covered in an ASC upon precertification from the fiscal intermediary or the PRO. Another commenter suggested we establish "severity levels" that allow physician discretion for procedures and settings. The commenter believed that, as certain CPT codes are deleted from the list, the codes should continue to justify a facility fee if certain "severity levels" and health risks apply. The same commenter stated that these codes can be billed with a modifier or with the accompanying International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnostic codes explaining the patient's condition. Yet a third commenter suggested that an ASC site of service could be justified by evaluating certain parameters. The commenter believed that an outpatient setting, rather than a physician's office, would be appropriate if certain conditions, such as intravenous therapy or expensive equipment, are involved.

*Response:* For a procedure to be covered in an ASC, the procedure must meet the conditions set forth in section 1833(i)(1) of the Act. That is, procedures covered in an ASC must be appropriately furnished on an inpatient basis but also can be performed safely on an ambulatory basis.

There are some patients who, because of medical conditions, may require surgery in an ASC-like setting, that is, a dedicated operating room with a recovery area and emergency equipment, etc. Although some patients may require this setting because of health status, the procedure may still not meet the conditions for ASC coverage set forth in section 1833(i)(1)of the Act. That is, a procedure that is routinely performed in a physician's office is still not appropriate for the inpatient setting, although an occasional patient requires hospitalization for the procedure. Precertification of the specific needs of the patient does not make the procedure inpatient. Rather, it means that a particular physician attests

that a patient requires a more intensive setting for the procedure.

Moreover, there are no commonly accepted severity levels that we could easily accommodate in the development of the list of covered procedures for ASCs. Section 1833(i)(1) of the Act does not provide for an evaluation of individual patient conditions, such as severity, in the development of the ASC list. The list is required to reflect common practices. We would not expect physicians to perform procedures in offices not adequately equipped for the procedure. These cases should be handled in an OPD if the procedure is not on the ASC list.

*Comment:* One commenter stated that we should be aware that our ASC list is used by virtually all Medicaid programs in the U.S., as well as private insurers.

*Response:* The Medicare ASC list is not intended to be a list of all procedures performed in an ASC. Rather, it is a list of procedures that meet the requirements of section 1833(i)(1) of the Act. When we develop our list, we consider section 1833(i)(1) and the appropriateness of a given procedure for the Medicare population. For example, our list contains no pediatric procedures. Yet these procedures would be appropriate for Medicaid patients.

The Medicare program cannot be responsible for the actions of third party payers. Any programs that have decided to adopt our list should do so with appropriate modifications, keeping in mind the limitations of section 1833(i)(1) of the Act and the requirements of their customers.

*Comment:* Another commenter requested that we consider a list of approved procedures and minor surgeries that can be safely performed in a physician's office. The commenter believed that this list should contain no procedures requiring anesthesia or sedation of any kind.

*Response:* We do not believe it is appropriate to develop a list of procedures that can safely be performed in physicians' offices. Physicians' offices vary significantly in equipment and staffing. We have not established standards for physicians' offices, nor do we survey them. Because there is broad variability in these offices, the development of a list is likely to result in the exclusion of procedures that are safely performed in some locations and the unfair restriction of physicians practices. We believe that physicians will not perform a procedure in their offices unless they maintain appropriate facilities, equipment, and staff to perform the procedure safely.