

- In the same physical area immediately adjacent to the institution's main buildings;

- Other areas and structures that are not strictly contiguous to the main buildings but are located within close proximity of the main buildings; and

- Any other areas that we determine on an individual basis, to be part of the institution's campus.

While we understand the concerns expressed by these commenters, we are retaining the language in the proposed rule regarding location and close proximity to afford flexibility in our determinations. It is our view that, in order to meet the requirements for supervision and control, and to function as an integral and subordinate part of the institution, with significant common resource usage of buildings, equipment, personnel and services, a distinct part would need to be located in close proximity to the institution of which it is a part. However, to clarify and address some of the commenters' concerns, we are revising § 483.5(b)(1) by clarifying that a distinct part SNF or NF is "physically distinguishable from the larger institution" rather than "a physically identifiable component." As for concerns with respect to locations outside the institution's main building, we believe the definition provides flexibility to recognize distinct part SNFs or NFs that are not co-located at the institution's main building and, in conformity with the regulations as finalized, will continue to do so by making such determinations on an individual basis.

*Comment:* A commenter suggested that, instead of creating the term "composite distinct part," we broaden the definition of distinct part, thus negating the necessity to make composite distinct part a separate term.

*Response:* Although we certainly want to keep our definitions of terms as simple and as realistic as possible, we are retaining our definition of a composite distinct part because the term best describes the situations we have encountered that were not previously addressed in regulations.

*Comment:* Several commenters recommended that existing SNFs and NFs that are a physically identifiable component of an institution be grandfathered as appropriate as a distinct part of that institution without having to submit a written request to us. Another commenter encouraged us to provide a transition period before implementation of the distinct part definition and composite distinct part definition to allow providers time to come into compliance with the accompanying requirements.

*Response:* We do not agree that existing distinct part SNFs and NFs should be grandfathered. All proposed and existing distinct parts must submit a written request to us as set forth at § 483.5(b)(2)(vi). At a minimum, an SNF and/or NF must demonstrate in writing how it meets the definition of a distinct part or composite distinct part. This definition has been discussed in detail in both the proposed rule and in this final rule, and provides extensive guidance to providers on compliance with these requirements.

The effective date of this final rule is October 1, 2003. However, in response to these comments, we will disseminate administrative guidance to implement the regulation with minimal burden to providers and States, in accordance with the requirement at § 483.5(b)(2)(vi).

*Comment:* A commenter suggested that we allow the approval to be a distinct part to be made on a retroactive basis.

*Response:* We disagree. The purpose of this regulation is to codify existing criteria for approval of distinct parts. For most facilities, the impact of this regulation will be that the criteria are easier to understand and can be more readily used by facility staff to monitor continued compliance. For those entities requesting initial Medicare and/or Medicaid approval, there is no reason that the SNF or NF could not be in compliance with the criteria at the time approval is requested. Indeed, we are requiring that a request for a distinct part be part of the Medicare and/or Medicaid approval process. The same is true in situations where there is a change of ownership or a change in bed size of an existing facility. When a provider is contemplating a change of ownership, the provider must notify us in advance; thus, we are requiring that a request for distinct part approval be included as part of its notification to us. In those instances where an existing SNF or NF requests a change in bed size, that request must be filed 45 days in advance of the change as stated in established policy; therefore, we are requiring that the request for distinct part approval be included in the request for a change in bed size.

*Comment:* There were a number of comments regarding specific administrative procedures, such as those relating to the process for requesting a distinct part approval and the appeal of a denial of a request.

*Response:* We believe that the detailed distinct part criteria set forth in the regulations, as discussed further in the proposed rule and in this final rule, already provide extensive guidance to providers on compliance with these

requirements. However, as we noted in the July 31, 2000 final rule (65 FR 46791), and again in the July 31, 2001 final rule (66 FR 39588), specific operational instructions are beyond the scope of the SNF PPS final rule, and are addressed instead through program issuances.

*Comment:* A commenter had several questions regarding the term "composite distinct part." The commenter asked whether an institution may operate two or more physically separate locations all of which would qualify as SNFs, and whether we will treat them as if they are a single SNF. On the other hand, if an institution operates a SNF at two locations, will only one location qualify as a SNF and the other will qualify as a NF? The commenter also asked whether all of the various locations comprise a single composite distinct part or whether each location itself qualifies as a composite distinct part.

*Response:* By definition, a composite distinct part is a combination of two or more physically separate locations where SNF and/or NF services are provided, all of which operate under a single Medicare or Medicaid provider agreement, constituting a single distinct part SNF and/or a single distinct part NF.

*Comment:* A commenter requested that we further explain the administrative implications relating to a composite distinct part SNF or NF. The commenter specifically asked for guidance with respect to the filing of the Medicare cost report, the selection of a cost reporting period, the issuance of a provider number, the selection of a fiscal intermediary, and any additional administrative requirements.

*Response:* As we have stated above, a composite distinct part is in fact a combination of two or more physically separated locations where SNF and/or NF services are provided, all of which operate under a single Medicare or Medicaid provider agreement, constituting a single distinct part SNF and/or a single distinct part NF. Therefore, a composite distinct part SNF must file a single Medicare cost report, use the same cost reporting period selected by the institution of which it is a distinct part, use a single provider number and the same fiscal intermediary as that selected by the institution of which it is a distinct part. The composite distinct part is subject to the change in bed size policies that we establish for all SNFs and NFs.

*Comment:* Several commenters were unclear as to the reason why we were creating the term "composite distinct part."