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§ 413.321 if it decides that it can determine, without a full or simplified report, the reasonable cost of covered services provided during that period.

(2) If a full or simplified cost report is waived, the provider must submit within the same time period required for full or simplified cost reports:

- (i) The cost reporting forms prescribed by CMS for this situation; and
- (ii) Any other financial and statistical data the intermediary requires.

[51 FR 34793, Sept. 30, 1986, as amended at 57 FR 39829, Sept. 1, 1992; 59 FR 26964, May 25, 1994; 60 FR 33125, 33136, 33143, June 27, 1995; 60 FR 37594, July 21, 1995; 62 FR 31, Jan. 2, 1997; 65 FR 18537, Apr. 7, 2000; 66 FR 59920, Nov. 30, 2001; 68 FR 50721, Aug. 22, 2003]

Subpart C—Limits on Cost Reimbursement

§ 413.30 Limitations on payable costs.

(a) *Introduction*—(1) *Scope*. This section implements section 1861(v)(1)(A) of the Act by setting forth the general rules under which CMS may establish limits on SNF and HHA costs recognized as reasonable in determining Medicare program payments. It also sets forth rules governing exemptions and exceptions to limits established under this section that CMS may make as appropriate in considering special needs or situations of particular providers.

(2) *General principle*. Reimbursable provider costs may not exceed the costs CMS estimates to be necessary for the efficient delivery of needed health care services. CMS may establish estimated cost limits for direct or indirect overall costs or for costs of specific services or groups of services. CMS imposes these limits prospectively and may calculate them on a per admission, per discharge, per diem, per visit, or other basis.

(b) *Procedure for establishing limits*. (1) In establishing limits under this section, CMS may classify SNFs and HHAs by factors that CMS finds appropriate and practical, including the following:

- (i) Type of services furnished.
- (ii) Geographical area where services are furnished, allowing for grouping of noncontiguous areas having similar de-

mographic and economic characteristics.

- (iii) Size of institution.
- (iv) Nature and mix of services furnished.

(v) Type and mix of patients treated.

(2) CMS bases its estimates of the costs necessary for efficient delivery of health services on cost reports or other data providing indicators of current costs. CMS adjusts current and past period data to arrive at estimated costs for the prospective periods to which limits are applied.

(3) Before the beginning of a cost period to which revised limits will be applied, CMS publishes a notice in the FEDERAL REGISTER, establishing cost limits and explaining the basis on which they are calculated.

(4) In establishing limits under paragraph (b)(1) of this section, CMS may find it inappropriate to apply particular limits to a class of SNFs or HHAs due to the characteristics of the SNF or HHA class, the data on which CMS bases those limits, or the method by which CMS determines the limits. In these cases, CMS may exclude that class of SNFs or HHAs from the limits, explaining the basis of the exclusion in the notice setting forth the limits for the appropriate cost reporting periods.

(c) *Requests regarding applicability of cost limits*. For cost reporting periods beginning before July 1, 1998, a SNF may request an exception or exemption to the cost limits imposed under this section. An HHA may request only an exception to the cost limits. The SNF or HHA must make its request to its fiscal intermediary within 180 days of the date on the intermediary's notice of program reimbursement.

(1) *Home health agencies*. The intermediary makes a recommendation on the HHA's request to CMS, which makes the decision. CMS responds to the request within 180 days from the date CMS receives the request from the intermediary. The intermediary notifies the HHA of CMS's decision. The time required by CMS to review the request is considered good cause for the granting of an extension of the time limit for the HHA to apply for a PRRB review, as specified in § 405.1841 of this chapter. CMS's decision is subject to

review under subpart R of part 405 of this chapter.

(2) *Skilled nursing facility exception.* The intermediary makes the final determination on the SNF's exception request and notifies the SNF of its determination within 90 days from the date that the intermediary receives the request from the SNF. If the intermediary determines that the SNF did not provide adequate documentation from which a proper determination can be made, the intermediary notifies the SNF that the request is denied. The intermediary also notifies the SNF that it has 45 days from the date on the intermediary's denial letter to submit a new exception request with the complete documentation and that otherwise, the denial is the final determination. The time required by the intermediary to review the request is considered good cause for the granting of an extension of the time limit for the SNF to apply for a PRRB review, as specified in §405.1841 of this chapter. The intermediary's determination is subject to review under subpart R of part 405 of this chapter.

(d) *Exemptions.* Exemptions from the limits imposed under this section may be granted to a new SNF with cost reporting periods beginning before July 1, 1998 as stated in §413.1(g)(1). The intermediary makes a recommendation on the provider's request to CMS, which makes the decision. A new SNF is a provider of inpatient services that has operated as a SNF (or the equivalent) for which it is certified for Medicare, under present and previous ownership, for less than 3 full years. An exemption granted under this paragraph expires at the end of the SNF's first cost reporting period beginning at least 2 years after the provider accepts its first inpatient.

(e) *Exceptions.* Limits established under this section may be adjusted upward for a SNF or HHA under the circumstances specified in paragraphs (e)(1) through (e)(5) of this section. An adjustment is made only to the extent that the costs are reasonable, attributable to the circumstances specified, separately identified by the SNF or HHA, and verified by the intermediary.

(1) *Atypical services.* The SNF or HHA can show that the—

(i) Actual cost of services furnished by a SNF or HHA exceeds the applicable limit because the services are atypical in nature and scope, compared to the services generally furnished by SNFs or HHAs similarly classified; and

(ii) Atypical services are furnished because of the special needs of the patients treated and are necessary in the efficient delivery of needed health care.

(2) *Extraordinary circumstances.* The SNF or HHA can show that it incurred higher costs due to extraordinary circumstances beyond its control. These circumstances include, but are not limited to, strikes, fire, earthquake, flood, or other unusual occurrences with substantial cost effects.

(3) *Areas with fluctuating populations.* The SNF meets the following conditions:

(i) Is located in an area (for example, a resort area) that has a population that varies significantly during the year.

(ii) Is furnishing similar services in an area for which the appropriate health planning agency has determined does not have a surplus of beds or similar services and has certified that the beds or similar services furnished by the SNF are necessary.

(iii) Meets occupancy or capacity standards established by the Secretary.

(4) *Medical and paramedical education.* The SNF or HHA can demonstrate that, if compared to other SNFs or HHAs in its group, it incurs increased costs for services covered by limits under this section because of its operation of an approved education program specified in §413.85.

(5) *Unusual labor costs.* The SNF or HHA has a percentage of labor costs that varies more than 10 percent from that included in the promulgation of the limits.

(f) *Operational review.* Any SNF or HHA that applies for an exception to the limits established under paragraph (e) of this section must agree to an operational review at the discretion of CMS. The findings from this review may be the basis for recommendations for improvements in the efficiency and economy of the SNF's or the HHA's operations. If recommendations are

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made, any future exceptions are contingent on the SNF's or HHA's implementation of these recommendations.

[64 FR 42612, Aug. 5, 1999; 65 FR 60104, Oct. 10, 2000, as amended at 67 FR 48802, July 26, 2002]

§ 413.35 Limitations on coverage of costs: Charges to beneficiaries if cost limits are applied to services.

(a) *Principle.* A provider of services that customarily furnishes an individual items or services that are more expensive than the items or services determined to be necessary in the efficient delivery of needed health services described in § 413.30, may charge an individual entitled to benefits under Medicare for such more expensive items or services even though not requested by the individual. The charge, however, may not exceed the amount by which the cost of (or, if less, the customary charges for) such more expensive items or services furnished by such provider in the second cost reporting period immediately preceding the cost reporting period in which such charges are imposed exceeds the applicable limit imposed under the provisions of § 413.30. This charge may be made only if—

(1) The intermediary determines that the charges have been calculated properly in accordance with the provisions of this section;

(2) The services are not emergency services as defined in paragraph (d) of this section;

(3) The admitting physician has no direct or indirect financial interest in such provider;

(4) CMS has provided notice to the public through notice in a newspaper of general circulation servicing the provider's locality and such other notice as the Secretary may require, of any charges the provider is authorized to impose on individuals entitled to benefits under Medicare on account of costs in excess of the costs determined to be necessary in the efficient delivery of needed health services under Medicare; and

(5) The provider has, in the manner described in paragraph (e) of this section, identified such charges to such individual or person acting on his behalf as charges to meet the costs in excess of the costs determined to be necessary

in the efficient delivery of needed health services under Medicare.

(b) *Provider request to charge beneficiaries for costs in excess of limits.* (1) If a provider's actual costs (or, if less, the customary charges) in the second preceding cost period exceed the prospective limits established for such costs, the intermediary will, at the provider's request, validate in advance the charges that may be made to the beneficiaries for the excess.

(2) If a provider does not have a second preceding cost period and is a new provider as defined in § 413.30(e), the provider, subject to validation by the intermediary, will estimate the current cost of the service to which a limit is being applied. Such amount will be adjusted to an amount equivalent to costs in the second preceding year by use of a factor to be developed based on estimates of cost increases during the preceding two years and published by SSA or CMS. The amount thus derived will be used in lieu of the second preceding cost period amount in determining the charge to the beneficiary.

(3) To obtain consideration of such a request, the provider must submit to the intermediary a statement indicating the charge for which it is seeking validation and providing the data and method used to determine the amount. Such statement should include the—

(i) Provider's name and number;

(ii) Identity of class and prospective cost limit for the class in which the provider has been included;

(iii) Amount of charge and cost period in which the charge is to be imposed;

(iv) Cost and customary charge for items and services furnished to beneficiaries; and

(v) Cost period ending date of the second reporting period immediately preceding the cost period in which the charge is to be imposed. The intermediary may request such additional information as it finds necessary with respect to the request.

(c) *Provider charges.*—(1) *Establishing the charges.* If the actual cost incurred (or, if less, the customary charges) in the prior period determined under paragraph (a) of this section exceeds the limits applicable to the pertinent