

Appendix F.—Amendments to Regulations Governing Reviews of CT Scanners Under 1122 and CON Programs (April 25, 1979)

Review of Proposed Capital Expenditures for CT Scanners Under the Capital Expenditure Program of Section 1122 of the Social Security Act

42 CFR Part 100

Inclusion of Computed Tomographic Scanning Services.

Agency: Public Health Service, HEW.

Action: Interim regulations.

Summary: This notice sets forth interim rules regarding reviews of proposed capital expenditures for computed tomographic (CT) scanner "services" under the capital expenditure review program of section 1122 regulations with minor revisions, a policy notice on this matter which has already been issued by the Department. Interested persons are invited to submit written comments and suggestions concerning these interim rules.

Dates: These regulations are effective on April 25, 1979. Comments must be received on or before June 25, 1979.

Address: Interested persons may submit written comments on these interim regulations to the Acting Director, Bureau of Health Planning, Health Resources Administration, Center Building, Room 6-22, 3700 East-West Highway, Hyattsville, Md. 20782. The comments will be available for public inspection at the above address between the hours of 8:30 a.m. and 5:00 p.m., Monday through Friday.

For Further Information Contact: Colin C. Riorrie, Jr., Ph. D., Acting Director, Bureau of Health Planning, 3700 East-West Highway, Center Building, Room 6-22, Hyattsville, Md. 20782, 301 /436-6850.

Supplementary Information: Section 1122 of the Social Security Act (42 U.S. C. 1320a-1) provides for a program for reviews of certain proposed capital expenditures by designated planning agencies (DPAs) in participating States to determine their conformity with applicable health plans, standards, and criteria. Subject to certain procedural requirements, the Department will not provide reimbursements, under the medicare, medicaid, and maternal and child health programs for expenses related to capital expenditures found by DPAs to use out of conformity with these plans, standards, and criteria. Section 1122(g) of the Social Security Act defines a capital expenditure subject to review as one which under generally accepted

accounting principles is not properly chargeable as an expense of operation and maintenance, and which: 1) exceeds \$100,000 or 2) changes the bed capacity of the facility with respect to which the expenditure is made, or 3) substantially changes the services of the facility with respect to which the expenditure is made. The third of these categories is further defined in the regulations under section 1122 (42 CFR part 100) as including an expenditure "which results in the addition of a clinically related (i. e., diagnostic, curative, or rehabilitative) service not previously provided in the facility . . . (42 CFR 100. 103(a)(2)(iv)).

On February 3, 1978, the Department issued section 1122 Notice 78-05 to clarify the requirements of section 1122 with respect to CT scanner services. The purpose of these interim regulations is to incorporate that policy notice with minor revisions, into the section 1122 regulations, to the extent it is not already a part of these regulations.

The Department recognizes that the existing regulations do not explicitly include all aspects of the February 3 notice and accordingly amends the regulations so that they will, subject to the following revisions. First, because the Health Maintenance Organization (HMO) Amendments of 1978 (Public Law 95-559) deleted from section 1122 all references to HMOs, expenditures by or on behalf of an HMO are no longer subject to review, unless they are also on behalf of a health care facility which is subject to review. Thus, if an HMO proposes to purchase a CT scanner on behalf of a hospital, the proposed expenditure is subject to review. Second, the regulations specify that the proposed expenditure for a CT scanner by or on behalf of a health care facility is subject to review, whether it is for a fixed or a mobile CT scanner. Third, the purchase of an additional CT head scanner by or on behalf of facility which already has such a scanner is not subject to review if it costs less than \$100,000 because this is a service which was "previously provided in the facility. " (See the present §100.103(a)(2)(iv).)

Accordingly, the regulations are amended as set forth below, so that the acquisition of a CT scanner costing \$100,000 or less will be governed by the following principles:

A. The purchase of a CT scanner by or on behalf of a health care facility involving a capital expend-

iture less than \$100,000 is subject to review if it results in the addition of a new diagnostic service.

B. Such a purchase involving a capital expenditure of less than \$100,000 is considered to be the addition of a new diagnostic service unless the CT scanner is in addition to or replaces an existing scanner.

C. If a health care facility proposes to purchase a CT full-body scanner to replace an existing CT head scanner or to purchase equipment to upgrade an existing head scanner to a full-body scanner, this purchase is considered to result in a new diagnostic service for the facility and, therefore, is subject to section 1122 review.

D. If a health care facility proposes to offer the services of a mobile CT scanner, this is considered the addition of a new diagnostic service unless it is in addition to or replaces an existing fixed or mobile CT scanner of the same type (head or full-body scanner).

E. The lease (acquisition through a comparable arrangement) or the donation of a CT scanner by or on behalf of a health care facility is also subject to section 1122 review if its purchase, under the principles noted above, would have required review. (See 42 CFR 100.103 (b).)

F. Any capital costs associated with installing a CT scanner, as well as the costs of any renovations to accommodate its installation or use, are to be included in the estimated cost of the proposed capital expenditure under the section 1122 review program.

In relation to these regulations, attention is called to another interim regulation, also being issued in this edition of the Federal Register, which amends 42 CFR parts 122 and 123 to require review of fixed and mobile computed tomographic scanners in satisfactory certificate of need programs under title XV of the Public Health Service Act.

For the reasons set forth below, the Secretary has determined that public participation in rulemaking before issuance of these regulations and a delay in their effective date would be impracticable, unnecessary, and contrary to the public interest. First, this is in large part simply a clarification of the Department's interpretation of the existing regulations. Second, given the recent proliferation of CT scanners, a delay in implementing these revisions and clarifications would likely result in the purchase or other acquisition of scanners which are not needed. Third, because these amended regulations complement amendments to regulations governing certificate-of-need reviews under title XV of the PHS Act and because those regulations are being issued on an interim basis to give those States needing revised legislative authority the maximum time possible to obtain it. Proper coordination of reviews requires that these regulations also be effective upon publication. As

noted above, however, the public is invited to submit comments on these amended regulations during the next 60 days, and the Secretary will revise the regulations further as warranted by his evaluation of the comments received.

The Assistant Secretary for Health, with the approval of the Secretary of Health, Education, and Welfare, amends 42 CFR Part 100 as set forth below.

Dated: January 30, 1979.

Julius H. Richmond, Assistant Secretary for Health.

Approved: April 16, 1979.

Joseph A. Califano, Jr., Secretary

Section 100.10 is amended by adding at its end the following sentences:

§100.103 Expenditures covered

(a) . . .

(2) . . .

(iv) . . . The addition of CT scanner services not previously provided in or through the facility is a substantial change of services within the meaning of this subparagraph, whether these services are provided through a fixed or mobile CT scanner. The addition of CT full-body scanner services is included in the previous sentence if it is added to or replaces existing CT head scanner services.

(Sec. 1122, Social Security Act, 86 Stat. 1386 (42 U.S. C. 1320a-1); sec. 1102, Social Security Act, 49 Stat. 647, as amended (42 U.S. C. 1302).)

(FR Doc. 79-12637 Filed 4-24-78, 8:45 a.m.) Billing Code 411 O-83-M.

Reviews of Proposed New Institutional Health Services by SHPDAs and HSAs Under State CON Programs

42 CFR Parts 122 and 123

Inclusion of Computed Tomographic Scanning Services.

Agency: Public Health Service, HEW.

Action: Interim regulations.

Summary: The Assistant Secretary for Health, with the approval of the Secretary of Health, Education, and Welfare, proposes to amend the regulations governing reviews of proposed new institutional health services by State health planning and development agencies (SHPDAs) and health systems agencies (HSAs). These regulations set forth requirements for satisfactory State certificate-of-need (CON) programs. The amendments would require review of radiological diagnostic health services which are proposed to be offered in, at, through, by, or on behalf of a health care facility or health maintenance organization, which are to be provided by fixed or

mobile CT scanning equipment whether or not an addition to or replacement of these services offered by fixed or mobile CT equipment. Interested parties are invited to submit written comments and suggestions concerning these proposed amendments.

Dates: These regulations are effective on April 25, 1979, subject to the discussion set forth under "Supplementary Information" below. Comments received on or before June 25, 1979, will be considered.

Address: Interested persons may submit written comments on the interim regulations to the Acting Director, Bureau of Health Planning, Health Resources Administration, Center Building, Room 6-22, 3700 East-West Highway, Hyattsville, Md. 20782. The comments will be available for public inspection at the above address between the hours of 8:30 a.m. and 5:00 p.m., Monday through Friday.

For Further Information Contact: Colin C. Rorrie, Jr., Ph. D., Acting Director, Bureau of Health Planning, 3700 East-West Highway, Center Building, Room 6-22, Hyattsville, Md. 20782, 301/436-6850.

Supplementary Information: Section 1523(a)(B) of the Public Health Service Act ("the Act") requires each fully designated SHPDA to "administer a State CON program which applies to new institutional health services propose to be offered or developed within the State and which is satisfactory to the Secretary" of Health, Education, and Welfare, Section 1523(a)(5) of the Act requires each SHPDA to make findings as to the need for proposed new institutional health services, after consideration of recommendations submitted by HSAs. Section 1513(f) requires HSAs to assist SHPDAs by reviewing and making recommendations concerning the need for proposed new institutional health services. Institutional health services are defined in section 1531(5) of the Act, and at §122.304 and §123.401 of title 42, Code of Federal Regulations. Sections 122.304 and 123.404 establish thresholds for review of institutional health services. The amendments add an additional threshold: radiological diagnostic health services provided by fixed or mobile CT scanning equipment.

The Secretary, wishing to contain the rising costs of health care, is concerned with the high cost of CT scanning, both as to the initial cost of the equipment and its subsequent operating expenses. These amendments require review of CT scanning services proposed to be performed in space leased or made available to any person by a health care facility or HMO. As to mobile scanners, although it is realized that there may be cost saving, since a number of institutions may share the same equipment, the offering by a health care facility or HMO of services of mobile scanners is also subjected to review by health planning agencies.

The Secretary notes that the amendments do not necessarily require changes in any State's statutes or regulations or in any lists of services which may be embodied therein. The amendments require simply that, for a State CON program to be satisfactory, the proposed services be required to be reviewed, and those services not be offered or developed without a prior determination of need and issuance of CON.

In relation to these amendments, the Secretary calls attention to another interim regulation, also in this edition of the Federal Register, which amends the regulations for review of proposed capital expenditures under section 1122 of the Social Security Act to clarify the coverage of CT scanners under that program.

Effective date provisions. --For the reasons set forth below, the Secretary has determined that public participation in rulemaking before issuance of these regulations and a delay in their effective date would be impractical and contrary to the public interest. First, given the recent proliferation of CT scanners, a delay in implementing these regulations would likely result in the purchase or other acquisition of scanners which are not needed. This is especially true with regard to mobile CT scanners. Hospitals can now receive reimbursement through medicare for fixed scanners, but not for scans from mobile scanners. Medicare, however, will soon begin reimbursing hospitals for scans from mobile scanners as well. As a result, it is expected that sales of mobile scanners will increase significantly. Second, in order to give those States which need revised legislative authority to implement these amendments the maximum time possible to obtain it, these regulations should be effective immediately.

As noted above, however, the public is invited to submit comments on these amended regulations during the next 60 days, and the Secretary will revise the regulations further as warranted by his evaluation of the comments received.

As noted above, these regulations are effective upon publication in the Federal Register. However, because the question of when the Secretary will determine whether a State's CON program is satisfactory is not addressed in the regulations themselves, the Secretary has decided as follows.

Initially, the Secretary notes the relevant statutory provisions under section 1521(b)(2)(B) of the Act the term of a conditional designation agreement of SHPDA may not exceed 36 months. A fully designated SHPDA must, under section 1521(b)(3) be capable of performing all of the functions specified in section 1523, including CON reviews, during its first year of full designation. If, on September 30, 1980, a designation agreement under section 1521 is not in ef-

feet in a State, the Secretary is prohibited by section 1521(d) from paying certain Federal funds for the development, expansion, or support of health resources in that State.

Accordingly, in determining whether a SHPDA is capable of administering a satisfactory CON program (which is a necessary element in establishing eligibility for full designation), the Secretary will require compliance with these revised regulations as follows:

(1) For States in which SHPDAs do not require additional legislative authority to implement the revisions to these regulations, the Secretary will require their implementation within 6 months after publication of this document in the Federal Register, and in accord with other SHPDA designation requirements.

(2) For those States in which the SHPDAs do require additional legislative authority to implement the revisions to these regulations, the Secretary will require their implementation within 6 months after the end of the earliest legislative session in which legislation to permit this implementation may be introduced and acted upon, and in accord with other SHPDA designation requirements.

After consulting with their legal counsel, SHPDAs should contact the appropriate DHEW Regional Office to determine into which of these categories they fall.

Accordingly, 42 CFR Part 122, subpart D, and 42 CFR part 12, subpart E, are amended in the manner set forth below.

Dated: April 13, 1979.

Julius B. Richmond, Assistant Secretary for Health.

Approved: April 16, 1979.

Joseph A. Califano, Jr., Secretary.

1. Section 122,304 of part 122 of title 42 is amended by adding to its a new paragraph (a)(5), to read as Follows:

§122.304 of part 122 of title 42 is amended by adding to it a new paragraph (a)(5), to read as follows:

(a) . . .

(5) Radiological diagnostic health services which are offered in, at, through, by or on behalf of a health care facility or HMO (including services offered in space leased or made available to any person by the health care facility or HMO), which are provided by fixed or mobile CT scanning equipment except where these services are an addition to or replacement of the same service offered in, at, through, by, or on behalf of the health care facility or HMO. For purposes of this subparagraph, a CT head scanner and a CT body scanner, do not provide the same service and a CT fixed scanner and a CT mobile scanner do not provide the same service.

2. Section 123.404 of part 123 of title 42 is amended by adding to it a new paragraph (a)(5), to read as follows:

§123.404. New institutional health services subject to review.

(a) . . .

(5) Radiological diagnostic health services which are offered in, at, through, by, or on behalf of a health care facility or HMO (including services offered in space leased or made available to any person by the health care facility or HMO), which are provided by fixed or mobile CT scanning equipment, except where these services are an addition to or replacement of the same service offered in, at, through, by, or on behalf of the health care facility or HMO. For purposes of this subparagraph, a CT head scanner and a CT body scanner do not provide the same service, and a CT fixed scanner and a CT mobile scanner do not provide the same service.

(Sec. 215 of the Public Health Service Act, 58 Stat. 690 (42 U.S. C. 216), sees. 1501-1536 of the Public Health Service Act, 85 Stat. 2225-57 (42 U.S. C. 300k-1-300n-5).)

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