

[amending this section] shall be effective as of the date of the enactment of this Act [Oct. 8, 2008] and shall apply to grants made on or after January 1, 2009.’’

§ 300d-74. Rule of construction

Nothing in this part may be construed to ease any restriction in Federal law applicable to the amount or percentage of funds appropriated to carry out this part that may be used to prepare or submit a report.

(July 1, 1944, ch. 373, title XII, §1274, as added Pub. L. 108-194, §3, Dec. 19, 2003, 117 Stat. 2891.)

SUBCHAPTER XI—HEALTH MAINTENANCE ORGANIZATIONS

§ 300e. Requirements of health maintenance organizations

(a) “Health maintenance organization” defined

For purposes of this subchapter, the term “health maintenance organization” means a public or private entity which is organized under the laws of any State and which (1) provides basic and supplemental health services to its members in the manner prescribed by subsection (b) of this section, and (2) is organized and operated in the manner prescribed by subsection (c) of this section.

(b) Manner of supplying basic and supplemental health services to members

A health maintenance organization shall provide, without limitations as to time or cost other than those prescribed by or under this subchapter, basic and supplemental health services to its members in the following manner:

(1) Each member is to be provided basic health services for a basic health services payment which (A) is to be paid on a periodic basis without regard to the dates health services (within the basic health services) are provided; (B) is fixed without regard to the frequency, extent, or kind of health service (within the basic health services) actually furnished; (C) except in the case of basic health services provided a member who is a full-time student (as defined by the Secretary) at an accredited institution of higher education, is fixed under a community rating system; and (D) may be supplemented by additional nominal payments which may be required for the provision of specific services (within the basic health services), except that such payments may not be required where or in such a manner that they serve (as determined under regulations of the Secretary) as a barrier to the delivery of health services. Such additional nominal payments shall be fixed in accordance with the regulations of the Secretary. If a health maintenance organization offers to its members the opportunity to obtain basic health services through a physician not described in subsection (b)(3)(A) of this section, the organization may require, in addition to payments described in clause (D) of this paragraph, a reasonable deductible to be paid by a member when obtaining a basic health service from such a physician. A health maintenance organization may include a health service, defined as a supplemental health service by sec-

tion 300e-1(2) of this title, in the basic health services provided its members for a basic health services payment described in the first sentence. In the case of an entity which before it became a qualified health maintenance organization (within the meaning of section 300e-9(d)¹ of this title) provided comprehensive health services on a prepaid basis, the requirement of clause (C) shall not apply to such entity until the expiration of the forty-eight month period beginning with the month following the month in which the entity became such a qualified health organization. The requirements of this paragraph respecting the basic health services payment shall not apply to the provision of basic health services to a member for an illness or injury for which the member is entitled to benefits under a workmen’s compensation law or an insurance policy but only to the extent such benefits apply to such services. For the provision of such services for an illness or injury for which a member is entitled to benefits under such a law, the health maintenance organization may, if authorized by such law, charge or authorize the provider of such services to charge, in accordance with the charges allowed under such law, the insurance carrier, employer, or other entity which under such law is to pay for the provision of such services or, to the extent that such member has been paid under such law for such services, such member. For the provision of such services for an illness or injury for which a member is entitled to benefits under an insurance policy, a health maintenance organization may charge or authorize the provider of such services to charge the insurance carrier under such policy or, to the extent that such member has been paid under such policy for such services, such member.

(2) For such payment or payments (hereinafter in this subchapter referred to as “supplemental health services payments”) as the health maintenance organization may require in addition to the basic health services payment, the organization may provide to each of its members any of the health services which are included in supplemental health services (as defined in section 300e-1(2) of this title). Supplemental health services payments which are fixed on a prepayment basis shall be fixed under a community rating system unless the supplemental health services payment is for a supplemental health service provided a member who is a full-time student (as defined by the Secretary) at an accredited institution of higher education, except that, in the case of an entity which before it became a qualified health maintenance organization (within the meaning of section 300e-9(d)¹ of this title) provided comprehensive health services on a prepaid basis, the requirement of this sentence shall not apply to such entity during the forty-eight month period beginning with the month following the month in which the entity became such a qualified health maintenance organization.

(3)(A) Except as provided in subparagraph (B), at least 90 percent of the services of a phy-

¹ See References in Text note below.

sician which are provided as basic health services shall be provided through—

- (i) members of the staff of the health maintenance organization,
- (ii) a medical group (or groups),
- (iii) an individual practice association (or associations),
- (iv) physicians or other health professionals who have contracted with the health maintenance organization for the provision of such services, or
- (v) any combination of such staff, medical group (or groups), individual practice association (or associations) or physicians or other health professionals under contract with the organization.

(B) Subparagraph (A) does not apply to the provision of the services of a physician—

- (i) which the health maintenance organization determines, in conformity with regulations of the Secretary, are unusual or infrequently used, or
- (ii) which are provided a member of the organization in a manner other than that prescribed by subparagraph (A) because of an emergency which made it medically necessary that the service be provided to the member before it could be provided in a manner prescribed by subparagraph (A).

(C) Contracts between a health maintenance organization and health professionals for the provision of basic and supplemental health services shall include such provisions as the Secretary may require, but only to the extent that such requirements are designed to insure the delivery of quality health care services and sound fiscal management.

(D) For purposes of this paragraph the term "health professional" means physicians, dentists, nurses, podiatrists, optometrists, and such other individuals engaged in the delivery of health services as the Secretary may by regulation designate.

(4) Basic health services (and only such supplemental health services as members have contracted for) shall within the area served by the health maintenance organization be available and accessible to each of its members with reasonable promptness and in a manner which assures continuity, and when medically necessary be available and accessible twenty-four hours a day and seven days a week, except that a health maintenance organization which has a service area located wholly in a non-metropolitan area may make a basic health service available outside its service area if that basic health service is not a primary care or emergency health care service and if there is an insufficient number of providers of that basic health service within the service area who will provide such service to members of the health maintenance organization. A member of a health maintenance organization shall be reimbursed by the organization for his expenses in securing basic and supplemental health services other than through the organization if the services were medically necessary and immediately required because of an unforeseen illness, injury, or condition.

(5) To the extent that a natural disaster, war, riot, civil insurrection, or any other simi-

lar event not within the control of a health maintenance organization (as determined under regulations of the Secretary) results in the facilities, personnel, or financial resources of a health maintenance organization not being available to provide or arrange for the provision of a basic or supplemental health service in accordance with the requirements of paragraphs (1) through (4) of this subsection, such requirements only require the organization to make a good-faith effort to provide or arrange for the provision of such service within such limitation on its facilities, personnel, or resources.

(6) A health maintenance organization that otherwise meets the requirements of this subchapter may offer a high-deductible health plan (as defined in section 220(c)(2) of title 26).

(c) Organizational requirements

Each health maintenance organization shall—

- (1)(A) have—
 - (i) a fiscally sound operation, and
 - (ii) adequate provision against the risk of insolvency,

which is satisfactory to the Secretary, and (B) have administrative and managerial arrangements satisfactory to the Secretary;

(2) assume full financial risk on a prospective basis for the provision of basic health services, except that a health maintenance organization may (A) obtain insurance or make other arrangements for the cost of providing to any member basic health services the aggregate value of which exceeds \$5,000 in any year, (B) obtain insurance or make other arrangements for the cost of basic health services provided to its members other than through the organization because medical necessity required their provision before they could be secured through the organization, (C) obtain insurance or make other arrangements for not more than 90 per centum of the amount by which its costs for any of its fiscal years exceed 115 per centum of its income for such fiscal year, and (D) make arrangements with physicians or other health professionals, health care institutions, or any combination of such individuals or institutions to assume all or part of the financial risk on a prospective basis for the provision of basic health services by the physicians or other health professionals or through the institutions;

(3)(A) enroll persons who are broadly representative of the various age, social, and income groups within the area it serves, except that in the case of a health maintenance organization which has a medically underserved population located (in whole or in part) in the area it serves, not more than 75 per centum of the members of that organization may be enrolled from the medically underserved population unless the area in which such population resides is also a rural area (as designated by the Secretary), and (B) carry out enrollment of members who are entitled to medical assistance under a State plan approved under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] in accordance with procedures approved under regulations promulgated by the Secretary;

(4) not expel or refuse to re-enroll any member because of his health status or his requirements for health services;

(5) be organized in such a manner that provides meaningful procedures for hearing and resolving grievances between the health maintenance organization (including the medical group or groups and other health delivery entities providing health services for the organization) and the members of the organization;

(6) have organizational arrangements, established in accordance with regulations of the Secretary, for an ongoing quality assurance program for its health services which program (A) stresses health outcomes, and (B) provides review by physicians and other health professionals of the process followed in the provision of health services;

(7) adopt at least one of the following arrangements to protect its members from incurring liability for payment of any fees which are the legal obligation of such organization—

(A) a contractual arrangement with any hospital that is regularly used by the members of such organization prohibiting such hospital from holding any such member liable for payment of any fees which are the legal obligation of such organization;

(B) insolvency insurance, acceptable to the Secretary;

(C) adequate financial reserve, acceptable to the Secretary; and

(D) other arrangements, acceptable to the Secretary, to protect members,

except that the requirements of this paragraph shall not apply to a health maintenance organization if applicable State law provides the members of such organization with protection from liability for payment of any fees which are the legal obligation of such organization; and

(8) provide, in accordance with regulations of the Secretary (including safeguards concerning the confidentiality of the doctor-patient relationship), and effective procedure for developing, compiling, evaluating, and reporting to the Secretary, statistics and other information (which the Secretary shall publish and disseminate on an annual basis and which the health maintenance organization shall disclose, in a manner acceptable to the Secretary, to its members and the general public) relating to (A) the cost of its operations, (B) the patterns of utilization of its services, (C) the availability, accessibility, and acceptability of its services, (D) to the extent practical, developments in the health status of its members, and (E) such other matters as the Secretary may require.

The Secretary shall issue regulations stating the circumstances under which the Secretary, in administering paragraph (1)(A), will consider the resources of an organization which owns or controls a health maintenance organization. Such regulations shall require as a condition to consideration of resources that an organization which owns or controls a health maintenance organization shall provide satisfactory assurances that it will assume the financial obligations of the health maintenance organization.

(d) Application of rules by certain health maintenance organizations

An organization that offers health benefits coverage shall not be considered as failing to meet the requirements of this section notwithstanding that it provides, with respect to coverage offered in connection with a group health plan in the small or large group market (as defined in section 300gg-91(e) of this title), an affiliation period consistent with the provisions of section 300gg(g) of this title.

(July 1, 1944, ch. 373, title XIII, §1301, as added Pub. L. 93-222, §2, Dec. 29, 1973, 87 Stat. 914; amended Pub. L. 94-460, title I, §§101, 102(a), 103, 105(a), Oct. 8, 1976, 90 Stat. 1945-1947; Pub. L. 95-559, §§9(b), 10, 11(a)-(d), Nov. 1, 1978, 92 Stat. 2137-2139; Pub. L. 96-32, §2(b), July 10, 1979, 93 Stat. 82; Pub. L. 97-35, title IX, §942(a)(1), (2), (b)-(e), Aug. 13, 1981, 95 Stat. 573, 574; Pub. L. 100-517, §§2-4(a), 5(a)(1), (2), (b), Oct. 24, 1988, 102 Stat. 2578, 2579; Pub. L. 104-191, title I, §§102(b), 193, Aug. 21, 1996, 110 Stat. 1976, 1988.)

REFERENCES IN TEXT

Section 300e-9(d) of this title, referred to in subsec. (b)(1), (2), was redesignated section 300e-9(c) of this title by Pub. L. 100-517, §7(b), Oct. 24, 1988, 102 Stat. 2580.

The Social Security Act, referred to in subsec. (c)(3)(B), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title XIX of the Social Security Act is classified generally to subchapter XIX (§1396 et seq.) of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

CODIFICATION

Amendment to subsec. (b)(3)(D) by section 942(b)(2) of Pub. L. 97-35 was executed before redesignation by section 942(a)(1)(B) of Pub. L. 97-35, to reflect the probable intent of Congress.

AMENDMENTS

1996—Subsec. (b)(6). Pub. L. 104-191, §193, added par. (6).

Subsec. (d). Pub. L. 104-191, §102(b), added subsec. (d). 1988—Subsec. (a). Pub. L. 100-517, §2, substituted “public or private entity which is organized under the laws of any State and” for “legal entity”.

Subsec. (b)(1). Pub. L. 100-517, §3, inserted after second sentence “If a health maintenance organization offers to its members the opportunity to obtain basic health services through a physician not described in subsection (b)(3)(A) of this section, the organization may require, in addition to payments described in clause (D) of this paragraph, a reasonable deductible to be paid by a member when obtaining a basic health service from such a physician.”

Subsec. (b)(3)(A). Pub. L. 100-517, §4(a), substituted “at least 90 percent of the services of a physician” for “the services of a physician”.

Subsec. (c). Pub. L. 100-517, §5(a)(2), inserted at end “The Secretary shall issue regulations stating the circumstances under which the Secretary, in administering paragraph (1)(A), will consider the resources of an organization which owns or controls a health maintenance organization. Such regulations shall require as a condition to consideration of resources that an organization which owns or controls a health maintenance organization shall provide satisfactory assurances that it will assume the financial obligations of the health maintenance organization.”

Subsec. (c)(1)(A). Pub. L. 100-517, §5(a)(1), amended subpar. (A) generally. Prior to amendment, subpar. (A) read as follows: “have a fiscally sound operation and adequate provision against the risk of insolvency which is satisfactory to the Secretary, and”.

Subsec. (c)(5) to (9). Pub. L. 100-517, §5(b), redesignated pars. (6) to (9) as (5) to (8), respectively, and struck out former par. (5) which read as follows: "(A) in the case of a private health maintenance organization, be organized in such a manner that assures that (i) at least one-third of the membership of the policymaking body of the health maintenance organization will be members of the organization, and (ii) there will be equitable representation on such body of members from medically underserved populations served by the organization, and (B) in the case of a public health maintenance organization, have an advisory board to the policymaking body of the public entity operating the organization which board meets the requirements of clause (A) of this paragraph and to which may be delegated policymaking authority for the organization;".

1981—Subsec. (b)(3)(A)(iv). Pub. L. 97-35, §942(a)(2), substituted "physicians" for "subject to subparagraph (C), physicians".

Subsec. (b)(3)(B). Pub. L. 97-35, §942(b)(1), substituted "(B)" for "(B(i))", "(i)" for "(I)", and "(ii)" for "(II)" and struck out former cl. (ii) which related to the forty-eight-month period beginning after the month of qualification of a health maintenance organization.

Subsec. (b)(3)(C). Pub. L. 97-35, §942(a)(1), redesignated subpar. (D) as (C) and struck out former subpar. (C) which related to the expiration of the first four fiscal years as a qualified organization.

Subsec. (b)(3)(D). Pub. L. 97-35, §942(b)(2), amended subpar. (D) generally. Prior to amendment, subpar. (D) read as follows: "Contracts between a health maintenance organization and health professionals for the provision of basic and supplemental health services shall include such provisions as the Secretary may require (including provisions requiring appropriate continuing education)." See Codification note above.

Pub. L. 97-35, §942(a)(1)(B), redesignated subpar. (E) as (D). Former subpar. (D) redesignated (C).

Subsec. (b)(4). Pub. L. 97-35, §942(c), substituted "with reasonable promptness" for "promptly as appropriate" and inserted "except that a health maintenance organization which has a service area located wholly in a nonmetropolitan area may make a basic health service available outside its service area if that basic health service is not a primary care or emergency health care service and if there is an insufficient number of providers of that basic health service within the service area who will provide such service to members of the health maintenance organization" after "week".

Subsec. (c). Pub. L. 97-35, §942(d)(1), (e), in par. (2) substituted provisions specifying requirements with respect to insurance, etc., for provisions generalizing such insurance, etc., requirements, and added cl. (D), struck out par. (4) which related to open enrollment period, redesignated pars. (5) to (8) as (4) to (7), respectively, added par. (8), struck out pars. (9) and (10) which related to medical social and health education services, and continuing education, respectively, and redesignated par. (11) as (9).

Subsec. (d). Pub. L. 97-35, §942(d)(2), struck out subsec. (d) which related to requirements, etc., respecting open enrollment period.

1979—Subsec. (b)(3). Pub. L. 96-32 amended directory language of section 11(a) of Pub. L. 95-559 by substituting reference to section "1301" for "1310" of the Public Health Service Act, as section to be amended, and required no change in text because amendment made by Pub. L. 95-559 had been executed to this section as the probable intent of Congress.

1978—Subsec. (b)(1). Pub. L. 95-559, §§10(a), 11(b), inserted "except in the case of basic health services provided a member who is a full-time student (as defined by the Secretary) at an accredited institution of higher education," after "the requirement of clause (C)" and inserted provisions permitting the health maintenance organization to seek reimbursement for the cost of services provided to a member who is entitled to benefits under a workmen's compensation law or insurance policy.

Subsec. (b)(2). Pub. L. 95-559, §10(a), inserted "unless the supplemental health services payment is for a sup-

plemental health service provided a member who is a full-time student (as defined by the Secretary) at an accredited institution of higher education," after "community rating system".

Subsec. (b)(3). Pub. L. 95-559, §11(a), as amended by Pub. L. 96-32, inserted provisions limiting the health maintenance organization from entering into contracts for health services with physicians other than members of the staff of the health maintenance organization, medical groups, or individual practice associations.

Subsec. (b)(4). Pub. L. 95-559, §11(c), substituted "basic and supplemental" for "basic or supplemental" and "if the services were medically necessary and immediately required because of an unforeseen illness, injury, or condition" for "if it was medically necessary that the services be provided before it could secure them through the organization".

Subsec. (b)(5). Pub. L. 95-559, §11(d), added par. (5).
Subsec. (c)(1). Pub. L. 95-559, §10(b), designated existing provisions as subpar. (A) and added subpar. (B).

Subsec. (c)(3). Pub. L. 95-559, §9(b), designated existing provisions as subpar. (A) and added subpar. (B).

Subsec. (c)(6). Pub. L. 95-559, §10(c), designated existing provisions as subpar. (A), inserted "in the case of a private health maintenance organization," before "be organized in such", and substituted "(i)" for "(A)" and "(ii)" for "(B)", and added subpar. (B).

1976—Subsec. (b)(1). Pub. L. 94-460, §§101(a), 105(a)(1), provided that a health maintenance organization may include a health service, defined as a supplemental health service by section 300e-1(2) of this title, in the basic health services provided its members for a basic health service payment described in the first sentence, and also provided that, in the case of an entity which before it became a qualified health maintenance organization (within the meaning of section 300e-9(d) of this title) provided comprehensive health services on a prepaid basis, the requirement of clause (C) would not apply to such entity until the expiration of the forty-eight month period beginning with the month following the month in which the entity became such a qualified health organization.

Subsec. (b)(2). Pub. L. 94-460, §§101(b), 105(a)(2), substituted "the organization may provide to each of its members any of the health services which are included in supplemental health services (as defined in section 300e-1(2) of this title)" for "the organization shall provide to each of its members each health service (A) which is included in supplemental health services (as defined in section 300e-1(2) of this title), (B) for which the required health manpower are available in the area served by the organization, and (C) for the provision of which the member has contracted with the organization" and inserted "except that, in the case of an entity which before it became a qualified health maintenance organization (within the meaning of section 300e-9(d) of this title) provided comprehensive health services on a prepaid basis, the requirement of this sentence shall not apply to such entity during the forty-eight month period beginning with the month following the month in which the entity became such a qualified health maintenance organization" after "Supplemental health services payments which are fixed on a prepayment basis shall be fixed under a community rating system".

Subsec. (b)(3). Pub. L. 94-460, §102(a), inserted references to health professionals who have contracted with the health maintenance organization for the provision of such services and to the combination of staff, medical groups, individual practice associations, or health professionals under contract with the health maintenance organization, and inserted provisions allowing a health maintenance organization, during the thirty-six month period beginning with the month following the month in which the organization becomes a qualified health maintenance organization (within the meaning of section 300e-9(d) of this title), to provide basic and supplemental health services through an entity which but for the requirement of section 300e-1(4)(C)(i) of this title would be a medical group for

purposes of this subchapter, directing that after the expiration of such period, the organization may provide basic or supplemental health services through such an entity only if authorized by the Secretary in accordance with regulations which take into consideration the unusual circumstances of such entity, directing that a health maintenance organization may not, in any of its fiscal years, enter into contracts with health professionals or entities other than medical groups or individual practice associations if the amounts paid under such contracts for basic and supplemental health services exceed fifteen percent of the total amount to be paid in such fiscal year by the health maintenance organization to physicians for the provision of basic and supplemental health services, or, if the health maintenance organization principally serves a rural area, thirty percent of such amount, except that the sentence would not apply to the entering into of contracts for the purchase of basic and supplemental health services through an entity which but for the requirements of section 300e-1(4)(C)(i) of this title would be a medical group for purposes of this subchapter, and directing that contracts between a health maintenance organization and health professionals for the provision of basic and supplemental health services include such provisions as the Secretary may require (including provisions requiring appropriate continuing education).

Subsec. (b)(4). Pub. L. 94-460, §101(c), substituted "and only such supplemental health services as members have contracted for" for "and supplemental health services in the case of the members who have contracted therefor".

Subsec. (c)(4). Pub. L. 94-460, §103(a), substituted provisions making a simple reference to an open enrollment period in accordance with the provisions of subsec. (d) of this section for provisions spelling out in detail the requirements for a health maintenance organization with regard to an open enrollment period.

Subsec. (d). Pub. L. 94-460, §103(b), added subsec. (d).

EFFECTIVE DATE OF 1976 AMENDMENT

Section 118 of title I of Pub. L. 94-460 provided that: "(a) Except as provided in subsection (b), the amendments made by this title [enacting section 300e-15 of this title and amending this section, sections 300e-1 to 300e-11, 300e-13, and 300n-1 of this title, and section 8902 of Title 5, Government Organization and Employees] shall take effect on the date of the enactment of this Act [Oct. 8, 1976].

"(b)(1) The amendments made by sections 101 [amending this section], 102 [amending this section and section 300e-1 of this title], 103 [amending this section], 104 [amending section 300e-1 of this title], and 106 [amending section 300e-1 of this title] shall (A) apply with respect to grants, contracts, loans, and loan guarantees made under sections 1303, 1304, and 1305 of the Public Health Service Act [sections 300e-2, 300e-3, and 300e-4 of this title] for fiscal years beginning after September 30, 1976, (B) apply with respect to health benefit plans offered under section 1310 of such Act [section 300e-9 of this title] after such date, and (C) for purposes of section 1312 [section 300e-11 of this title] take effect October 1, 1976.

"(2) Subsection (d) of section 1301 of the Public Health Service Act [subsec. (d) of this section] (added by section 103(b) of this Act) shall take effect with respect to fiscal years of health maintenance organizations beginning on or after the date of the enactment of this Act [Oct. 8, 1976].

"(3) The amendments made by section 107 [amending sections 300e-2, 300e-3, and 300e-4 of this title] shall apply with respect to grants, contracts, loans, and loan guarantees made under sections 1303, 1304, and 1305 of the Public Health Service Act [sections 300e-2, 300e-3 and 300e-4 of this title] for fiscal years beginning after September 30, 1976.

"(4) The amendments made by sections 109(a)(1) [amending section 300e-4 of this title] and 109(c) [amending section 300e-7 of this title] shall apply with respect to loan guarantees made under section 1305 of

the Public Health Service Act [section 300e-4 of this title] after September 30, 1976.

"(5) The amendment made by section 109(e) [amending section 300e-3 of this title] shall apply with respect to projects assisted under section 1304 of the Public Health Service Act [section 300e-3 of this title] after September 30, 1976.

"(6) The amendments made by paragraphs (1) and (2) of section 110(a) [amending section 300e-9 of this title] shall apply with respect to calendar quarters which begin after the date of the enactment of this Act [Oct. 8, 1976].

"(7) The amendments made by paragraphs (3) and (4) of section 110 [amending section 300e-9 of this title] shall apply with respect to failures of employers to comply with section 1310(a) of the Public Health Service Act [section 300e-9 of this title] after the date of the enactment of this Act [Oct. 8, 1976].

"(8) The amendment made by section 111 [amending section 300e-11 of this title] shall apply with respect to determinations of the Secretary of Health, Education, and Welfare described in section 1312(a) of the Public Health Service Act [section 300e-11(a) of this title] and made after the date of the enactment of this Act [Oct. 8, 1976]."

SHORT TITLE OF 1978 AMENDMENT

For short title of Pub. L. 95-559 as the "Health Maintenance Organization Amendments of 1978", see section 1 of Pub. L. 95-559, set out as a note under section 201 of this title.

SHORT TITLE OF 1976 AMENDMENT

For short title of Pub. L. 94-460 which substantially amended this subchapter, as the "Health Maintenance Organization Amendments of 1976", see section 1(a) of Pub. L. 94-460, set out as a note under section 201 of this title.

SHORT TITLE

For short title of Pub. L. 93-222, which enacted this subchapter, as the "Health Maintenance Organization Act of 1973", see section 1 of Pub. L. 93-222, set out as a Short Title of 1973 Amendments note under section 201 of this title.

QUALIFICATION OF HEALTH MAINTENANCE ORGANIZATION CONTINGENT UPON CONTROLLING ORGANIZATION'S ASSUMPTION OF FINANCIAL OBLIGATIONS AND MEETING OTHER REQUIREMENTS

Section 5(a)(3) of Pub. L. 100-517 provided that: "During the period prior to the effective date of regulations issued under section 1301(c) of the Public Health Service Act [subsec. (c) of this section] (as amended by paragraph (2)), the Secretary of Health and Human Services shall consider the application for qualification under section 1301(c)(1)(A) of such Act of a health maintenance organization—

"(A) which is owned or controlled by another organization, and

"(B) which requests that the resources of the other organization be considered in determining its qualification under such section,

if the Secretary receives satisfactory assurances from the other organization that it will assume the financial obligations of the health maintenance organization and if the Secretary determines that the other organization meets such other requirements as the Secretary determines are necessary."

STUDY ON HEALTH MAINTENANCE ORGANIZATION PROGRAM

Pub. L. 99-660, title VIII, §813, Nov. 14, 1986, 100 Stat. 3801, which provided for a study to assess the operation and impact of the provisions of this subchapter and a report to Congress on the findings and conclusions of such study within 18 months after Nov. 14, 1986, was repealed by Pub. L. 102-531, title III, §311(a), Oct. 27, 1992, 106 Stat. 3503, effective as if such repeal was enacted on Nov. 14, 1986.

HEALTH CARE QUALITY ASSURANCE PROGRAMS STUDY

Section 4 of Pub. L. 93-222 required Secretary of Health, Education, and Welfare to contract for conduct of a study of health care quality assurance programs and submit a final report to specific committees of Congress by Jan. 31, 1976.

§ 300e-1. Definitions

For purposes of this subchapter:

(1) The term "basic health services" means—

(A) physician services (including consultant and referral services by a physician);

(B) inpatient and outpatient hospital services;

(C) medically necessary emergency health services;

(D) short-term (not to exceed twenty visits), outpatient evaluative and crisis intervention mental health services;

(E) medical treatment and referral services (including referral services to appropriate ancillary services) for the abuse of or addiction to alcohol and drugs;

(F) diagnostic laboratory and diagnostic and therapeutic radiologic services;

(G) home health services; and

(H) preventive health services (including (i) immunizations, (ii) well-child care from birth, (iii) periodic health evaluations for adults, (iv) voluntary family planning services, (v) infertility services, and (vi) children's eye and ear examinations conducted to determine the need for vision and hearing correction).

Such term does not include a health service which the Secretary, upon application of a health maintenance organization, determines is unusual and infrequently provided and not necessary for the protection of individual health. The Secretary shall publish in the Federal Register each determination made by him under the preceding sentence. If a service of a physician described in the preceding sentence may also be provided under applicable State law by a dentist, optometrist, podiatrist, psychologist, or other health care personnel, a health maintenance organization may provide such service through a dentist, optometrist, podiatrist, psychologist, or other health care personnel (as the case may be) licensed to provide such service. Such term includes a health service directly associated with an organ transplant only if such organ transplant was required to be included in basic health services on April 15, 1985. For purposes of this paragraph, the term "home health services" means health services provided at a member's home by health care personnel, as prescribed or directed by the responsible physician or other authority designated by the health maintenance organization.

(2) The term "supplemental health services" means any health service which is not included as a basic health service under paragraph (1) of this section. If a health service provided by a physician may also be provided under applicable State law by a dentist, optometrist, podiatrist, psychologist, or other health care personnel, a health maintenance organization may provide such service through an optometrist, dentist, podiatrist, psychologist, or other health care personnel (as the case may be) licensed to provide such service.

(3) The term "member" when used in connection with a health maintenance organization means an individual who has entered into a contractual arrangement, or on whose behalf a contractual arrangement has been entered into, with the organization under which the organization assumes the responsibility for the provision to such individual of basic health services and of such supplemental health services as may be contracted for.

(4) The term "medical group" means a partnership, association, or other group—

(A) which is composed of health professionals licensed to practice medicine or osteopathy and of such other licensed health professionals (including dentists, optometrists, podiatrists, and psychologists) as are necessary for the provision of health services for which the group is responsible;

(B) a majority of which are licensed to practice medicine or osteopathy; and

(C) the members of which (i) as their principal professional activity engage in the coordinated practice of their profession and as a group responsibility have substantial responsibility for the delivery of health services to members of a health maintenance organization, except that this clause does not apply before the end of the forty-eight month period beginning after the month in which the health maintenance organization¹ becomes a qualified health maintenance organization as defined in section 300e-9(d)² of this title, or as authorized by the Secretary in accordance with regulations that take into consideration the unusual circumstances of the group; (ii) pool their income from practice as members of the group and distribute it among themselves according to a prearranged salary or drawing account or other similar plan unrelated to the provision of specific health services; (iii) share medical and other records and substantial portions of major equipment and of professional, technical, and administrative staff; (iv) arrange for and encourage continuing education in the field of clinical medicine and related areas for the members of the group; and (v) establish an arrangement whereby a member's enrollment status is not known to the health professional who provides health services to the member.

(5) The term "individual practice association" means a partnership, corporation, association, or other legal entity which has entered into a services arrangement (or arrangements) with persons who are licensed to practice medicine, osteopathy, dentistry, podiatry, optometry, psychology, or other health profession in a State and a majority of whom are licensed to practice medicine or osteopathy. Such an arrangement shall provide—

(A) that such persons shall provide their professional services in accordance with a compensation arrangement established by the entity; and

(B) to the extent feasible, for the sharing by such persons of medical and other records, equipment, and professional, technical, and administrative staff.

¹ So in original. Probably should be "organization".

² See References in Text note below.

(6) The term “health systems agency” means an entity which is designated in accordance with section 3007-4 of this title.

(7) The term “medically underserved population” means the population of an urban or rural area designated by the Secretary as an area with a shortage of personal health services or a population group designated by the Secretary as having a shortage of such services. Such a designation may be made by the Secretary only after consideration of the comments (if any) of (A) each State health planning and development agency which covers (in whole or in part) such urban or rural area or the area in which such population group resides, and (B) each health systems agency designated for a health service area which covers (in whole or in part) such urban or rural area or the area in which such population group resides.

(8)(A) The term “community rating system” means the systems, described in subparagraphs (B) and (C), of fixing rates of payments for health services. A health maintenance organization may fix its rates of payments under the system described in subparagraph (B) or (C) or under both such systems, but a health maintenance organization may use only one such system for fixing its rates of payments for any one group.

(B) A system of fixing rates of payment for health services may provide that the rates shall be fixed on a per-person or per-family basis and may authorize the rates to vary with the number of persons in a family, but, except as authorized in subparagraph (D), such rates must be equivalent for all individuals and for all families of similar composition.

(C) A system of fixing rates of payment for health services may provide that the rates shall be fixed for individuals and families by groups. Except as authorized in subparagraph (D), such rates must be equivalent for all individuals in the same group and for all families of similar composition in the same group. If a health maintenance organization is to fix rates of payment for individuals and families by groups, it shall—

(i)(I) classify all of the members of the organization into classes based on factors which the health maintenance organization determines predict the differences in the use of health services by the individuals or families in each class and which have not been disapproved by the Secretary,

(II) determine its revenue requirements for providing services to the members of each class established under subclause (I), and

(III) fix the rates of payments for the individuals and families of a group on the basis of a composite of the organization’s revenue requirements determined under subclause (II) for providing services to them as members of the classes established under subclause (I), or

(ii) fix the rates of payments for the individuals and families of a group on the basis of the organization’s revenue requirements for providing services to the group, except that the rates of payments for the individuals and families of a group of less than 100 persons may not be fixed at rates greater than 110 percent of the rate that would be fixed for such indi-

viduals and families under subparagraph (B) or clause (i) of this subparagraph.

The Secretary shall review the factors used by each health maintenance organization to establish classes under clause (i). If the Secretary determines that any such factor may not reasonably be used to predict the use of the health services by individuals and families, the Secretary shall disapprove such factor for such purpose. If a health maintenance organization is to fix rates of payment for a group under clause (ii), it shall, upon request of the entity with which it contracts to provide services to such group, disclose to that entity the method and data used in calculating the rates of payment.

(D) The following differentials in rates of payments may be established under the systems described in subparagraphs (B) and (C):

(i) Nominal differentials in such rates may be established to reflect differences in marketing costs and the different administrative costs of collecting payments from the following categories of members:

(I) Individual members (including their families).

(II) Small groups of members (as determined under regulations of the Secretary).

(III) Large groups of members (as determined under regulations of the Secretary).

(ii) Nominal differentials in such rates may be established to reflect the compositing of the rates of payment in a systematic manner to accommodate group purchasing practices of the various employers.

(iii) Differentials in such rates may be established for members enrolled in a health maintenance organization pursuant to a contract with a governmental authority under section 1079 or 1086 of title 10 or under any other governmental program (other than the health benefits program authorized by chapter 89 of title 5) or any health benefits program for employees of States, political subdivision of States, and other public entities.

(9) The term “non-metropolitan area” means an area no part of which is within an area designated as a standard metropolitan statistical area by the Office of Management and Budget and which does not contain a city whose population exceeds fifty thousand individuals.

(July 1, 1944, ch. 373, title XIII, §1302, as added Pub. L. 93-222, §2, Dec. 29, 1973, 87 Stat. 917; amended Pub. L. 94-460, title I, §§102(b), 104, 105(b), (c), 106, 117(b)(1), (2), Oct. 8, 1976, 90 Stat. 1946-1948, 1955; Pub. L. 95-559, §11(e), Nov. 1, 1978, 92 Stat. 2139; Pub. L. 97-35, title IX, §942(f)-(j), Aug. 13, 1981, 95 Stat. 574, 575; Pub. L. 97-414, §9(c), Jan. 4, 1983, 96 Stat. 2064; Pub. L. 99-660, title VIII, §§812(a), 814, Nov. 14, 1986, 100 Stat. 3801, 3802; Pub. L. 100-517, §6(b), Oct. 24, 1988, 102 Stat. 2579.)

REFERENCES IN TEXT

Section 300e-9(d) of this title, referred to in par. (4)(C), was redesignated section 300e-9(c) of this title by Pub. L. 100-517, §7(b), Oct. 24, 1988, 102 Stat. 2580.

AMENDMENTS

1988—Par. (8)(C). Pub. L. 100-517, §6(b)(1), amended third sentence generally. Prior to amendment, third

sentence read as follows: "If a health maintenance organization is to fix rates of payment for individuals and families by groups, it shall—

"(i) classify all of the members of the organization into classes based on factors which the health maintenance organization determines predict the differences in the use of health services by the individuals or families in each class and which have not been disapproved by the Secretary.

"(ii) determine its revenue requirements for providing services to the members of each class established under clause (i), and

"(iii) fix the rates of payment for the individuals and families of a group on the basis of a composite of the organization's revenue requirements determined under clause (ii) for providing services to them as members of the classes established under clause (i)."

Pub. L. 100-517, §6(b)(2), inserted at end "If a health maintenance organization is to fix rates of payment for a group under clause (ii), it shall, upon request of the entity with which it contracts to provide services to such group, disclose to that entity the method and data used in calculating the rates of payment."

1986—Par. (1). Pub. L. 99-660, §814(a), inserted "psychologist," in two places in fourth sentence.

Pub. L. 99-660, §812(a), (b)(1), temporarily inserted "Such term includes a health service directly associated with an organ transplant only if such organ transplant was required to be included in basic health services on April 15, 1985." in closing provisions. See Effective and Termination Dates of 1986 Amendment note below.

Par. (2). Pub. L. 99-660, §814(a), inserted "psychologist," in two places.

Par. (4)(A). Pub. L. 99-660, §814(b), substituted "podiatrists, and psychologists" for "and podiatrists".

Par. (5). Pub. L. 99-660, §814(c), inserted "psychology,".

1983—Par. (5)(B). Pub. L. 97-414 amended directory language of Pub. L. 97-35, §942(i), to correct a typographical error, and did not involve any change in text. See 1981 Amendment note below.

1981—Par. (1). Pub. L. 97-35, §942(f), struck out provisions authorizing health maintenance organizations to maintain, etc., drug use profiles of members.

Par. (2). Pub. L. 97-35, §942(g), substituted provisions to include services not included under par. (1), for provisions enumerating specific services, substituted "health service provided by a physician" for "service of a physician described in the preceding sentence", and struck out provisions authorizing health maintenance organizations to maintain, etc., drug use profiles of members.

Par. (4)(C)(i). Pub. L. 97-35, §942(h), inserted provisions relating to applicability to qualified organizations.

Par. (5)(B). Pub. L. 97-35, §942(i), as amended by Pub. L. 97-414, §9(c), struck out "(i)" after "feasible", and struck out cl. (ii) which related to continuing education.

Par. (8). Pub. L. 97-35, §942(j), reorganized and restructured provisions and, among many changes, provided for determinations based upon subpars. (B) and (C), and set out determinations respecting differentials contained in former subpars. (B) and (C) as subpar. (D).

1978—Par. (1). Pub. L. 95-559 inserted provisions to exclude a health service which the Secretary, upon application of a health maintenance organization, determines is unusual and infrequently provided and not necessary for protection of individual health and that the Secretary publish in Federal Register each determination made by him under preceding sentence.

1976—Par. (1). Pub. L. 94-460, §104(a), substituted reference to immunization, well-child care from birth, periodic health evaluations for adults, and children's ear examinations conducted to determine need for hearing correction for reference to preventive dental care for children in (H) and, in the provisions following subpar. (H), inserted reference to "other health care personnel".

Par. (2). Pub. L. 94-460, §104(b), substituted "basic health service" for "basic health service under paragraph (1)(A) or (1)(H)" in subpars. (B) and (C), added subpar. (G), and inserted reference to "other health care personnel" in provisions following subpar. (G).

Par. (4)(C). Pub. L. 94-460, §§102(b)(1), 106, substituted "as their principal professional activity engage in the coordinated practice of their profession and as a group responsibility have substantial responsibility for the delivery of health services to members of a health maintenance organization" for "as their principal professional activity and as a group responsibility engage in the coordinated practice of their profession for a health maintenance organization" in cl. (i), substituted "similar plan unrelated to the provision of specific health services" for "plan" in cl. (ii), struck out former cl. (iv) which covered the utilization of additional professional personnel, allied health professions personnel, and other health personnel as are available and appropriate for the effective and efficient delivery of the services of the members of the group, redesignated former cl. (v) as (iv), and added cl. (v).

Par. (5)(B). Pub. L. 94-460, §102(b)(2), struck out former cl. (i) which covered the utilization of additional professional personnel, allied health professions personnel, and other personnel as are available and appropriate for the effective and efficient delivery of the services of the persons who are parties to the arrangement, and redesignated former cls. (ii) and (iii) as (i) and (ii), respectively.

Par. (6). Pub. L. 94-460, §117(b)(1), substituted provisions defining "health systems agency" for provisions defining "section 314(a) State health planning agency" and "section 314(b) areawide health planning agency".

Par. (7). Pub. L. 94-460, §117(b)(2), substituted "State health planning and development agency which" for "section 314(a) State health planning agency whose section 314(a) plan" and "health systems agency designated for a health service area which" for "section 314(b) areawide health planning agency whose section 314(b) plan".

Par. (8). Pub. L. 94-460, §105(b), (c), substituted "to reflect differences in marketing costs and the different administrative costs" for "to reflect the different administrative costs" in subpar. (A) preceding cl. (i), added subpar. (B), and redesignated former subpar. (B) as (C).

EFFECTIVE AND TERMINATION DATES OF 1986 AMENDMENT

Section 812(b)(1) of Pub. L. 99-660, which provided that amendment by subsection (a), amending this section, was to take effect on Oct. 1, 1985, and was to cease to be in effect on Apr. 1, 1988, was repealed by Pub. L. 100-517, §6(a), Oct. 24, 1988, 102 Stat. 2579.

Section 815 of title VIII of Pub. L. 99-660 provided that:

"(a) Except as provided in subsection (b) and section 812(b) [enacting provisions set out as notes above and below], this title and the amendments made by this title [amending this section and sections 300e-4, 300e-5 to 300e-10, 300e-16, and 300e-17 of this title, repealing sections 300e-2, 300e-3, and 300e-4a of this title, and enacting provisions set out as notes under this section and sections 201, 300e, 300e-4, and 300e-5 of this title] shall take effect on October 1, 1985.

"(b) Section 813 [enacting provisions set out as a note under section 300e of this title] shall take effect on the date of enactment of this Act [Nov. 14, 1986]."

EFFECTIVE DATE OF 1976 AMENDMENT

Amendment by Pub. L. 94-460 effective Oct. 8, 1976, except that amendment of pars. (1) and (2) of this section by section 104 of Pub. L. 94-460 and the amendment of pars. (4)(C) and (5)(B) of this section by sections 102 and 106 of Pub. L. 94-460 applicable with respect to grants, contracts, loans, and loan guarantees made under sections 300e-2, 300e-3, and 300e-4 of this title for fiscal years beginning after Sept. 30, 1976, applicable

with respect to health benefit plans offered under section 300e-9 of this title after Sept. 30, 1976, and effective for purposes of section 300e-11 of this title on Oct. 1, 1976, see section 118 of Pub. L. 94-460, set out as a note under section 300e of this title.

CONSTRUCTION

Section 816 of title VIII of Pub. L. 99-660 provided that: "The provisions of this title and of the amendments made by this title [amending this section and sections 300e-4, 300e-5 to 300e-10, 300e-16, and 300e-17 of this title, repealing sections 300e-2, 300e-3, and 300e-4a of this title, and enacting provisions set out as notes under this section and sections 201, 300e, 300e-4, and 300e-5 of this title] do not authorize the appropriation of any funds for fiscal year 1986."

BASIC HEALTH SERVICE STATUS OF CERTAIN ORGAN TRANSPLANT SERVICES AFTER APRIL 1, 1988

Section 812(b)(2) of Pub. L. 99-660, which provided that after Apr. 1, 1988, for purposes of this subchapter, no health service directly associated with an organ transplant was to be considered to be a basic health service if such service would otherwise have been added as a basic health service between Apr. 15, 1985, and Apr. 1, 1988, was repealed by Pub. L. 100-517, §6(a), Oct. 24, 1988, 102 Stat. 2579.

REPORTS RESPECTING MEDICALLY UNDERSERVED AREAS AND POPULATION GROUPS AND NON-METROPOLITAN AREAS

Section 5 of Pub. L. 93-222 directed Secretary of Health, Education, and Welfare to report to Congress the criteria used in the designation of medically underserved areas and population groups for purposes of par. (7) of this section by Dec. 29, 1973, and report to Congress the areas and population groups designated under par. (7) of this section, the comments of State and area-wide health planning agencies, and areas which meet the definitional standards of par. (9) of this section for non-metropolitan areas by Dec. 29, 1974, and that the Office of Management and Budget may review such reports before their submission to Congress.

§§ 300e-2, 300e-3. Repealed. Pub. L. 99-660, title VIII, § 803(a), Nov. 14, 1986, 100 Stat. 3799

Section 300e-2, act July 1, 1944, ch. 373, title XIII, §1303, as added Dec. 29, 1973, Pub. L. 93-222, §2, 87 Stat. 920; amended Oct. 8, 1976, Pub. L. 94-460, title I, §§107(a), 109(d)(1), 117(b)(3), 90 Stat. 1948, 1950, 1955; Aug. 13, 1981, Pub. L. 97-35, title IX, §947(a), 95 Stat. 577, provided for grants and contracts for feasibility surveys.

Section 300e-3, act July 1, 1944, ch. 373, title XIII, §1304, as added Dec. 29, 1973, Pub. L. 93-222, §2, 87 Stat. 921; amended Apr. 21, 1976, Pub. L. 94-273, §40, 90 Stat. 381; Oct. 8, 1976, Pub. L. 94-460, title I, §§107(b), 108(a), (b), (d)(1), 109(d)(2), (3), (e), 113(a), 117(b)(4), 90 Stat. 1948-1950, 1953, 1955; Nov. 1, 1978, Pub. L. 95-559, §§2(a), 3(a)-(c), 6, 92 Stat. 2131, 2134; July 10, 1979, Pub. L. 96-32, §2(a), 93 Stat. 82; Aug. 13, 1981, Pub. L. 97-35, title IX, §§941(c), 947(b), 95 Stat. 573, 577, provided for grants, contracts, and loan guarantees for planning and for initial development costs.

EFFECTIVE DATE OF REPEAL

Repeal not applicable to any grant made or contract entered into under this subchapter before Oct. 1, 1985, see section 803(c) of Pub. L. 99-660, set out as an Effective Date of 1986 Amendment note under section 300e-5 of this title.

Repeal effective Oct. 1, 1985, see section 815(a) of Pub. L. 99-660, set out as an Effective and Termination Dates of 1986 Amendment note under section 300e-1 of this title.

§ 300e-4. Loans and loan guarantees for initial operation costs

(a) Authority

The Secretary may—

(1) make loans to public or private health maintenance organizations to assist them in meeting the amount by which their costs of operation during a period not to exceed the first sixty months of their operation exceed their revenues in that period;

(2) make loans to public or private health maintenance organizations to assist them in meeting the amount by which their costs of operation, which the Secretary determines are attributable to significant expansion in their membership or area served and which are incurred during a period not to exceed the first sixty months of their operation after such expansion, exceed their revenues in that period which the Secretary determines are attributable to such expansion; and

(3) guarantee to non-Federal lenders payment of the principal of and the interest on loans made to private health maintenance organizations for the amounts referred to in paragraphs (1) and (2).

No loan or loan guarantee may be made under this subsection for the costs of operation of a health maintenance organization unless the Secretary determines that the organization has made all reasonable attempts to meet such costs, and unless the Secretary has made a grant or loan to, entered into a contract with, or guaranteed a loan for, the organization in fiscal year 1981, 1982, 1983, 1984, or 1985 under this section or section 300e-3(b)¹ of this title (as in effect before October 1, 1985).

(b) Limitations

(1) Except as provided in paragraph (2), the aggregate amount of principal of loans made or guaranteed, or both, under subsection (a) of this section for a health maintenance organization may not exceed \$7,000,000. In any twelve-month period the amount disbursed to a health maintenance organization under this section (either directly by the Secretary, by an escrow agent under the terms of an escrow agreement, or by a lender under a guaranteed loan) may not exceed \$3,000,000.

(2) The cumulative total of the principal of the loans outstanding at any time which have been directly made, or with respect to which guarantees have been issued, under subsection (a) of this section may not exceed such limitations as may be specified in appropriation Acts.

(c) Source of loan funds

Loans under this section shall be made from the fund established under section 300e-7(e) of this title.

(d) Time limit on loans and loan guarantees

No loan may be made or guaranteed under this section after September 30, 1986.

(e) Repealed. Pub. L. 97-35, title IX, § 947(c), Aug. 13, 1981, 95 Stat. 577

(f) Medically underserved populations

In considering applications for loan guarantees under this section, the Secretary shall give special consideration to applications for health maintenance organizations which will serve medically underserved populations.

¹ See References in Text note below.

(July 1, 1944, ch. 373, title XIII, §1305, as added Pub. L. 93-222, §2, Dec. 29, 1973, 87 Stat. 924; amended Pub. L. 93-641, §8, Jan. 4, 1975, 88 Stat. 2276; Pub. L. 94-273, §2(21), Apr. 21, 1976, 90 Stat. 376; Pub. L. 94-460, title I, §§107(c), 108(c), (d)(2), 109(a)(1), (2), 113(b), Oct. 8, 1976, 90 Stat. 1949, 1953; Pub. L. 95-559, §§2(b), 4(a), (b), Nov. 1, 1978, 92 Stat. 2131, 2132; Pub. L. 96-32, §2(d), July 10, 1979, 93 Stat. 82; Pub. L. 97-35, title IX, §§943(a)-(c), 947(c), Aug. 13, 1981, 95 Stat. 576, 577; Pub. L. 99-660, title VIII, §804(a), Nov. 14, 1986, 100 Stat. 3800.)

REFERENCES IN TEXT

Section 300e-3(b) of this title, referred to in subsec. (a), was repealed by Pub. L. 99-660, title VIII, §803(a), Nov. 14, 1986, 100 Stat. 3799.

AMENDMENTS

1986—Subsec. (a). Pub. L. 99-660 inserted “, and unless the Secretary has made a grant or loan to, entered into a contract with, or guaranteed a loan for, the organization in fiscal year 1981, 1982, 1983, 1984, or 1985 under this section or section 300e-3(b) of this title (as in effect before October 1, 1985)” at end of last sentence.

1981—Subsec. (a). Pub. L. 97-35, §943(a), in pars. (1) and (2) struck out “nonprofit” before “private”, and in par. (3) substituted provisions respecting guarantees for private health maintenance organizations, for guaranties for nonprofit private health maintenance organizations.

Subsec. (b)(1). Pub. L. 97-35, §943(b), generally revised limitations and, among many changes, increased amounts subject to coverage, and struck out requirements respecting Congressional oversight for increases in amounts.

Subsec. (d). Pub. L. 97-35, §943(c), substituted “1986” for “1981”.

Subsec. (e). Pub. L. 97-35, §947(c), struck out subsec. (e) which related to projects in nonmetropolitan areas.

1979—Subsec. (b)(1). Pub. L. 96-32 substituted “\$4,500,000” for “\$4,000,000” in two places.

1978—Subsec. (a). Pub. L. 95-559, §4(b)(1), substituted “costs of operation” for “operating costs” wherever appearing.

Subsec. (b)(1). Pub. L. 95-559, §4(a), (b)(2), inserted “(or \$4,000,000 if the Secretary makes a written determination that such loans or loan guaranties are necessary to preserve the fiscally sound operation of the health maintenance organization and to protect against the risk of insolvency of the health maintenance organization and, within 30 days of the making of such loans or loan guaranties, furnishes the Committee on Human Resources of the Senate and the Committee on Interstate and Foreign Commerce of the House of Representatives with written notification of the making of the loans or loan guaranties and a copy of the written determination made with respect to the loans or loan guaranties and the reasons for the determination) through September 30, 1979, and \$4,000,000 thereafter” after “\$2,500,000” and “(or \$2,000,000 if the Secretary makes a written determination that such disbursements are necessary to preserve the fiscally sound operation of the health maintenance organization and protect against the risk of insolvency of the health maintenance organization and, within 30 days of such disbursement, furnishes the Committee on Human Resources of the Senate and the Committee on Interstate and Foreign Commerce of the House of Representatives with written notification of the making of the disbursement and a copy of the written determination made with respect to it and the reasons for the determination) through September 30, 1979, and \$2,000,000 thereafter” after “\$1,000,000” and substituted “any twelve-month period” for “any fiscal year”.

Subsec. (d). Pub. L. 95-559, §2(b), substituted “September 30, 1981” for “September 30, 1980”.

1976—Subsec. (a)(1), (2). Pub. L. 94-460, §§107(c), 109(a)(1), substituted “during a period not to exceed the

first sixty months” for “in the period of the first thirty-six months”.

Subsec. (a)(3). Pub. L. 94-460, §108(c), substituted reference to loans made to nonprofit private health maintenance organizations for the amounts referred to in paragraph (1) or (2), or to other private health maintenance organizations for such amounts but only if the health maintenance organization will serve a medically underserved population for reference to loans made to any private health maintenance organization (other than a private nonprofit health maintenance organization) for the amounts referred to in paragraph (1) or (2), but only if such health maintenance organization will serve a medically underserved population.

Subsec. (b)(1). Pub. L. 94-460, §109(a)(2), substituted “In any fiscal year the amount disbursed to a health maintenance organization under this section (either directly by the Secretary or by an escrow agent under the terms of an escrow agreement or by a lender under a loan guaranteed under this section) may not exceed \$1,000,000” for “In any fiscal year, the amount disbursed under a loan or loans made or guaranteed under this section for a health maintenance organization may not exceed \$1,000,000,000”.

Subsec. (d). Pub. L. 94-460, §113(b), substituted “No loan may be made or guaranteed under this section after September 30, 1980” for “A loan or loan guarantee may be made under this section through the fiscal year ending June 30, 1978”.

Pub. L. 94-273 substituted “September” for “June”.

Subsec. (f). Pub. L. 94-460, §108(d)(2), added subsec. (f).

1975—Subsec. (b)(1). Pub. L. 93-641 substituted provisions that amount disbursed under a loan or loans made or guaranteed under this section for a health maintenance organization may not exceed \$1,000,000,000 for provisions that principal amount of any loan made or guaranteed under subsec. (a) of this section for a health maintenance organization may not exceed \$1,000,000.

EFFECTIVE DATE OF 1986 AMENDMENT

Section 804(b) of Pub. L. 99-660 provided that: “The amendment made by subsection (a) [amending this section] does not apply to any loan or loan guarantee for the initial costs of operation of a health maintenance organization made under title XIII of the Public Health Service Act [this subchapter] before October 1, 1985.”

Amendment by Pub. L. 99-660 effective Oct. 1, 1985, see section 815(a) of Pub. L. 99-660, set out as an Effective and Termination Dates of 1986 Amendment note under section 300e-1 of this title.

EFFECTIVE DATE OF 1978 AMENDMENT

Section 4(d) of Pub. L. 95-559 provided that: “The amendments made by this section [amending this section and section 300e-7 of this title] shall only be effective for fiscal years beginning on or after October 1, 1978.”

EFFECTIVE DATE OF 1976 AMENDMENT

Amendment by Pub. L. 94-460 effective Oct. 8, 1976, except that the amendment of subsec. (a)(1), (2) of this section by section 107(c) of Pub. L. 94-460 applicable with respect to grants, contracts, loans, and loan guaranties made under this section and sections 300e-2 and 300e-3 of this title for fiscal years beginning after Sept. 30, 1976, and except that the amendment of subsec. (a)(1), (2) of this section by section 109(a)(1) of Pub. L. 94-460 applicable with respect to loan guaranties made under this section after Sept. 30, 1976, see section 118 of Pub. L. 94-460, set out as a note under section 300e of this title.

§ 300e-4a. Repealed. Pub. L. 99-660, title VIII, § 805(a), Nov. 14, 1986, 100 Stat. 3800

Section, act July 1, 1944, ch. 373, title XIII, §1305A, as added Nov. 1, 1978, Pub. L. 95-559, §5(a), 92 Stat. 2133; amended July 10, 1979, Pub. L. 96-32, §2(e), 93 Stat. 82;

Aug. 13, 1981, Pub. L. 97-35, title IX, §944, 95 Stat. 576, related to loans and loan guarantees for acquisition and construction of ambulatory health care facilities.

EFFECTIVE DATE OF REPEAL

Repeal not applicable to any loan or loan guarantee made under this section before Oct. 1, 1985, see section 805(c) of Pub. L. 99-660, set out as an Effective Date of 1986 Amendment note under section 300e-5 of this title.

Repeal effective Oct. 1, 1985, see section 815(a) of Pub. L. 99-660, set out as an Effective and Termination Dates of 1986 Amendment note under section 300e-1 of this title.

§ 300e-5. Application requirements

(a) Submission to and approval by Secretary required for making loans and loan guarantees

No loan or loan guarantee may be made under this subchapter unless an application therefor has been submitted to, and approved by, the Secretary.

(b) Application contents

The Secretary may not approve an application for a loan or loan guarantee under this subchapter unless—

(1) such application meets the requirements of section 300e-7 of this title;

(2) in the case of an application for assistance under section 300e-4 of this title, he determines that the applicant making the application would not be able to complete the project or undertaking for which the application is submitted without the assistance applied for;

(3) the application contains satisfactory specification of the existing or anticipated (A) population group or groups to be served by the proposed or existing health maintenance organization described in the application, (B) membership of such organization, (C) methods, terms, and periods of the enrollment of members of such organization, (D) estimated costs per member of the health and educational services to be provided by such organization and the nature of such costs, (E) sources of professional services for such organization, and organizational arrangements of such organization for providing health and educational services, (F) organizational arrangements of such organization for an ongoing quality assurance program in conformity with the requirements of section 300e(c) of this title, (G) sources of prepayment and other forms of payment for the services to be provided by such organization, (H) facilities, and additional capital investments and sources of financing therefor, available to such organization to provide the level and scope of services proposed, (I) administrative, managerial, and financial arrangements and capabilities of such organization, (J) role for members in the planning and policymaking for such organization, (K) grievance procedures for members of such organization, and (L) evaluations of the support for and acceptance of such organization by the population to be served, the sources of operating support, and the professional groups to be involved or affected thereby;

(4) contains or is supported by assurances satisfactory to the Secretary that the applicant making the application will, in accord-

ance with such criteria as the Secretary shall by regulation prescribe, enroll, and maintain an enrollment of the maximum number of members that its available and potential resources (as determined under regulations of the Secretary) will enable it to effectively serve;

(5) in the case of an application made for a project which previously received a grant, contract, loan, or loan guarantee under this subchapter, such application contains or is supported by assurances satisfactory to the Secretary that the applicant making the application has the financial capability to adequately carry out the purposes of such project and has developed and operated such project in accordance with the requirements of this subchapter and with the plans contained in previous applications for such assistance;

(6) the application contains such assurances as the Secretary may require respecting the intent and the ability of the applicant to meet the requirements of paragraphs (1) and (2) of section 300e(b) of this title respecting the fixing of basic health services payments and supplemental health services payments under a community rating system; and

(7) the application is submitted in such form and manner, and contains such additional information, as the Secretary shall prescribe in regulations.

An organization making multiple applications for more than one loan or loan guarantee under this subchapter, simultaneously or over the course of time, shall not be required to submit duplicate or redundant information but shall be required to update the specifications (required by paragraph (3)) respecting the existing or proposed health maintenance organization in such manner and with such frequency as the Secretary may by regulation prescribe. In determining, for purposes of paragraph (2), whether an applicant would be able to complete a project or undertaking without the assistance applied for, the Secretary shall not consider any asset of the applicant the obligation of which for such undertaking or project would jeopardize the fiscal soundness of the applicant.

(c) Regulations

The Secretary shall by regulation establish standards and procedures for health systems agencies to follow in reviewing and commenting on applications for loans and loan guarantees under this subchapter.

(July 1, 1944, ch. 373, title XIII, §1306, as added Pub. L. 93-222, §2, Dec. 29, 1973, 87 Stat. 925; amended Pub. L. 94-460, title I, §§105(a)(3), 117(b)(5), (6), Oct. 8, 1976, 90 Stat. 1948, 1955; Pub. L. 95-559, §12(b), (c), Nov. 1, 1978, 92 Stat. 2140; Pub. L. 99-660, title VIII, §§803(b)(1), 805(b), 806, Nov. 14, 1986, 100 Stat. 3799, 3800.)

AMENDMENTS

1986—Subsec. (a). Pub. L. 99-660, §803(b)(1)(A), substituted “loan” for “grant, contract, loan.”

Subsec. (b). Pub. L. 99-660, §803(b)(1)(A), substituted “loan” for “grant, contract, loan,” in introductory text and in second sentence.

Subsec. (b)(1). Pub. L. 99-660, §803(b)(1)(B), struck out “in the case of an application for assistance under sec-

tion 300e-2 or 300e-3 of this title, such application meets the application requirements of such section and in the case of an application for a loan or loan guarantee," before "such application".

Subsec. (b)(2). Pub. L. 99-660, § 805(b), struck out reference to section 300e-4a.

Pub. L. 99-660, § 803(b)(1)(C), struck out reference to section 300e-3.

Subsec. (b)(5) to (8). Pub. L. 99-660, § 806, redesignated pars. (6), (7), and (8) as (5), (6), and (7), respectively, and struck out former par. (5) which read as follows: "each health systems agency designated for a health service area which covers (in whole or in part) the area to be served by the health maintenance organization for which such application is submitted;"

Subsec. (c). Pub. L. 99-660, § 803(b)(1)(D), substituted "loans" for "grants, contracts, loans,".

1978—Subsec. (b). Pub. L. 95-559 in par. (2) inserted "in the case of an application for assistance under section 300e-3, 300e-4, or 300e-4a of this title," before "he determines" and in provisions following par. (8) inserted provision that in determining, for purposes of par. (2), whether an applicant would be able to complete a project or undertaking without the assistance applied for, the Secretary not consider any asset of the applicant the obligation of which for such undertaking or project would jeopardize the fiscal soundness of the applicant.

1976—Subsec. (b)(5). Pub. L. 94-460, § 117(b)(5), substituted "each health systems agency designated for a health service area which covers (in whole or in part) the area to be served by the health maintenance organization for which such application is submitted;" for "the section 314(b) areawide health planning agency whose section 314(b) plan covers (in whole or in part) the area to be served by the health maintenance organization for which such application is submitted, or if there is no such agency, the section 314(a) State health planning agency whose section 314(a) plan covers (in whole or in part) such area, has, in accordance with regulations of the Secretary under subsection (c) of this section, been provided an opportunity to review the application and to submit to the Secretary for his consideration its recommendations respecting approval of the application or if under applicable State law such an application may not be submitted without the approval of the section 314(b) areawide health planning agency or the section 314(a) State health planning agency, the required approval has been obtained;"

Subsec. (b)(7), (8). Pub. L. 94-460, § 105(a)(3), added par. (7) and redesignated former par. (7) as (8).

Subsec. (c). Pub. L. 94-460, § 117(b)(6), substituted "health systems agencies" for "section 314(b) areawide health planning agencies and section 314(a) State health planning agencies".

EFFECTIVE DATE OF 1986 AMENDMENT

Section 803(c) of Pub. L. 99-660 provided that: "The amendments made by this section [amending this section and sections 300e-6, 300e-8, and 300e-16 of this title and repealing sections 300e-2 and 300e-3 of this title] do not apply to any grant made or contract entered into under title XIII of the Public Health Service Act [this subchapter] before October 1, 1985."

Section 805(c) of Pub. L. 99-660 provided that: "The amendments made by this section [amending this section and repealing section 300e-4a of this title] do not apply to any loan or loan guarantee made under section 1305A of the Public Health Service Act [former section 300e-4a of this title] before October 1, 1985."

Amendment by Pub. L. 99-660 effective Oct. 1, 1985, see section 815(a) of Pub. L. 99-660, set out as an Effective and Termination Dates of 1986 Amendment note under section 300e-1 of this title.

EFFECTIVE DATE OF 1976 AMENDMENT

Amendment by Pub. L. 94-460 effective Oct. 8, 1976, see section 118 of Pub. L. 94-460, set out as a note under section 300e of this title.

§ 300e-6. Administration of assistance programs

(a) Recordkeeping; audit and examination

(1) Each recipient of a loan or loan guarantee under this subchapter shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of the loan (directly made or guaranteed), the total cost of the undertaking in connection with which the loan was given or used, the amount of that portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(2) The Secretary, or any of his duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipients of a loan or loan guarantee under this subchapter which relate to such assistance.

(b) Report upon expiration of period

Upon expiration of the period for which a loan or loan guarantee was provided an entity under this subchapter, such entity shall make a full and complete report to the Secretary in such manner as he may by regulation prescribe. Each such report shall contain, among such other matters as the Secretary may by regulation require, descriptions of plans, developments, and operations relating to the matters referred to in section 300e-5(b)(3) of this title.

(c) **Repealed.** Pub. L. 99-660, title VIII, § 803(a), Nov. 14, 1986, 100 Stat. 3799

(d) Other entities considered health maintenance organizations

An entity which provides health services to a defined population on a prepaid basis and which has members who are entitled to insurance benefits under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] or to medical assistance under a State plan approved under title XIX of such Act [42 U.S.C. 1396 et seq.] may be considered as a health maintenance organization for purposes of receiving assistance under this subchapter if—

(1) with respect to its members who are entitled to such insurance benefits or to such medical assistance it (A) provides health services in accordance with section 300e(b) of this title, except that (i) it does not furnish to those members the health services (within the basic health services) for which it may not be compensated under such title XVIII [42 U.S.C. 1395 et seq.] or such State plan, and (ii) it does not fix the basic or supplemental health services payment for such members under a community rating system, and (B) is organized and operated in the manner prescribed by section 300e(c) of this title, except that it does not assume full financial risk on a prospective basis for the provision to such members of basic or supplemental health services with respect to which it is not required under such title XVIII or such State plan to assume such financial risk; and

(2) with respect to its other members it provides health services in accordance with section 300e(b) of this title and is organized and operated in the manner prescribed by section 300e(c) of this title.

An entity which provides health services to a defined population on a prepaid basis and which has members who are enrolled under the health benefits program authorized by chapter 89 of title 5, may be considered as a health maintenance organization for purposes of receiving assistance under this subchapter if with respect to its other members it provides health services in accordance with section 300e(b) of this title and is organized and operated in the manner prescribed by section 300e(c) of this title.

(July 1, 1944, ch. 373, title XIII, §1307, as added Pub. L. 93-222, §2, Dec. 29, 1973, 87 Stat. 926; amended Pub. L. 94-460, title I, §§109(b)(1), 112, Oct. 8, 1976, 90 Stat. 1950, 1953; Pub. L. 97-35, title IX, §943(d), Aug. 13, 1981, 95 Stat. 576; Pub. L. 99-660, title VIII, §803(a), (b)(2), Nov. 14, 1986, 100 Stat. 3799, 3800.)

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (d), is act Aug. 14, 1935, ch. 531, 49 Stat. 620, as amended. Titles XVIII and XIX of the Social Security Act are classified generally to subchapters XVIII (§1395 et seq.) and XIX (§1396 et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

AMENDMENTS

1986—Subsec. (a)(1). Pub. L. 99-660, §803(b)(2), substituted “loan or loan guarantee” for “grant, contract, loan, or loan guarantee”, “proceeds of the loan” for “proceeds of the grant, contract, or loan”, and “with which the loan was given” for “with which such assistance was given”.

Subsecs. (a)(2), (b). Pub. L. 99-660, §803(b)(2)(A), substituted “loan or loan guarantee” for “grant, contract, loan, or loan guarantee”.

Subsec. (c). Pub. L. 99-660, §803(a), struck out subsec. (c) which read as follows: “If in any fiscal year the funds appropriated under section 300e-8 of this title are insufficient to fund all applications approved under this subchapter for that fiscal year, the Secretary shall, after applying the applicable priorities under sections 300e-2 and 300e-3 of this title, give priority to the funding of applications for projects which the Secretary determines are the most likely to be economically viable.”

1981—Subsec. (e). Pub. L. 97-35 struck out subsec. (e) which related to limitation on cumulative total of loan guarantees in any fiscal year.

1976—Subsec. (d). Pub. L. 94-460, §112, inserted sentence at end setting conditions upon which an entity providing health services to a defined population on a prepaid basis may be considered as a health maintenance organization for purposes of receiving assistance under this subchapter.

Subsec. (e). Pub. L. 94-460, §109(b)(1), inserted “for a private health maintenance organization (other than a private nonprofit health maintenance organization)” after “may be made”, and “for private health maintenance organizations (other than private nonprofit health maintenance organizations)” after “guaranteed”.

EFFECTIVE DATE OF 1986 AMENDMENT

Amendment by Pub. L. 99-660 not applicable to any grant made or contract entered into under this subchapter before Oct. 1, 1985, see section 803(c) of Pub. L. 99-660, set out as a note under section 300e-5 of this title.

Amendment by Pub. L. 99-660 effective Oct. 1, 1985, see section 815(a) of Pub. L. 99-660, set out as an Effective and Termination Dates of 1986 Amendment note under section 300e-1 of this title.

EFFECTIVE DATE OF 1976 AMENDMENT

Amendment by Pub. L. 94-460 effective Oct. 8, 1976, see section 118 of Pub. L. 94-460, set out as a note under section 300e of this title.

§ 300e-7. General provisions relating to loan guarantees and loans

(a) Conditions

(1) The Secretary may not approve an application for a loan guarantee under this subchapter unless he determines that (A) the terms, conditions, security (if any), and schedule and amount of repayments with respect to the loan are sufficient to protect the financial interests of the United States and are otherwise reasonable, including a determination that the rate of interest does not exceed such per centum per annum on the principal obligation outstanding as the Secretary determines to be reasonable, taking into account the range of interest rates prevailing in the private market for loans with similar maturities, terms, conditions, and security and the risks assumed by the United States, and (B) the loan would not be available on reasonable terms and conditions without the guarantee under this subchapter.

(2)(A) The United States shall be entitled to recover from the applicant for a loan guarantee under this subchapter the amount of any payment made pursuant to such guarantee, unless the Secretary for good cause waives such right of recovery; and, upon making any such payment, the United States shall be subrogated to all of the rights of the recipient of the payments with respect to which the guarantee was made.

(B) To the extent permitted by subparagraph (C), any terms and conditions applicable to a loan guarantee under this subchapter (including terms and conditions imposed under subparagraph (D)) may be modified by the Secretary to the extent he determines it to be consistent with the financial interest of the United States.

(C) Any loan guarantee made by the Secretary under this subchapter shall be incontestable (i) in the hands of an applicant on whose behalf such guarantee is made unless the applicant engaged in fraud or misrepresentation in securing such guarantee, and (ii) as to any person (or his successor in interest) who makes or contracts to make a loan to such applicant in reliance thereon unless such person (or his successor in interest) engaged in fraud or misrepresentation in making or contracting to make such loan.

(D) Guarantees of loans under this subchapter shall be subject to such further terms and conditions as the Secretary determines to be necessary to assure that the purposes of this subchapter will be achieved.

(b) Application requirements

(1) The Secretary may not approve an application for a loan under this subchapter unless—

(A) the Secretary is reasonably satisfied that the applicant therefor will be able to make payments of principal and interest thereon when due, and

(B) the applicant provides the Secretary with reasonable assurances that there will be available to it such additional funds as may be necessary to complete the project or undertaking with respect to which such loan is requested.

(2) Any loan made under this subchapter shall (A) have such security, (B) have such maturity date, (C) be repayable in such installments, (D) on the date the loan is made, bear interest at a rate comparable to the rate of interest prevailing on such date with respect to marketable obligations of the United States of comparable maturities, adjusted to provide for appropriate administrative charges, and (E) be subject to such other terms and conditions (including provisions for recovery in case of default) as the Secretary determines to be necessary to carry out the purposes of this subchapter while adequately protecting the financial interests of the United States. On the date disbursements are made under a loan after the initial disbursement under the loan, the Secretary may change the rate of interest on the amount of the loan disbursed on that date to a rate which is comparable to the rate of interest prevailing on the date the subsequent disbursement is made with respect to marketable obligations of the United States of comparable maturities, adjusted to provide for appropriate administrative charges.

(3) The Secretary may, for good cause but with due regard to the financial interests of the United States, waive any right of recovery which he has by reason of the failure of a borrower to make payments of principal of and interest on a loan made under this subchapter, except that if such loan is sold and guaranteed, any such waiver shall have no effect upon the Secretary's guarantee of timely payment of principal and interest.

(c) Sale of loans

(1) The Secretary may from time to time, but with due regard to the financial interests of the United States, sell loans made by him under this subchapter.

(2) The Secretary may agree, prior to his sale of any such loan, to guarantee to the purchaser (and any successor in interest of the purchaser) compliance by the borrower with the terms and conditions of such loan. Any such agreement shall contain such terms and conditions as the Secretary considers necessary to protect the financial interests of the United States or as otherwise appropriate. Any such agreement may (A) provide that the Secretary shall act as agent of any such purchaser for the purpose of collecting from the borrower to which such loan was made and paying over to such purchaser, any payments of principal and interest payable by such organization under such loan; and (B) provide for the repurchase by the Secretary of any such loan on such terms and conditions as may be specified in the agreement. The full faith and credit of the United States is pledged to the payment of all amounts which may be required to be paid under any guarantee under this paragraph.

(3) After any loan under this subchapter to a public health maintenance organization has been sold and guaranteed under this subsection, interest paid on such loan which is received by the purchaser thereof (or his successor in interest) shall be included in the gross income of the purchaser of the loan (or his successor in interest) for the purpose of chapter 1 of title 26.

(4) Amounts received by the Secretary as proceeds from the sale of loans under this sub-

section shall be deposited in the loan fund established under subsection (e) of this section.

(5) Any reference in this subchapter (other than in this subsection and in subsection (d) of this section) to a loan guarantee under this subchapter does not include a loan guarantee made under this subsection.

(d) Loan guarantee fund

(1) There is established in the Treasury a loan guarantee fund (hereinafter in this subsection referred to as the "fund") which shall be available to the Secretary without fiscal year limitation, in such amounts as may be specified from time to time in appropriation Acts, to enable him to discharge his responsibilities under loan guarantees issued by him under this subchapter and to take the action authorized by subsection (f) of this section. There are authorized to be appropriated from time to time such amounts as may be necessary to provide the sums required for the fund. To the extent authorized in appropriation Acts, there shall also be deposited in the fund amounts received by the Secretary in connection with loan guarantees under this subchapter and other property or assets derived by him from his operations respecting such loan guarantees, including any money derived from the sale of assets.

(2) If at any time the sums in the funds are insufficient to enable the Secretary to discharge his responsibilities under guarantees issued by him before October 1, 1986, under this subchapter and to take the action authorized by subsection (f) of this section, he is authorized to issue to the Secretary of the Treasury notes or other obligations in such forms and denominations, bearing such maturities, and subject to such terms and conditions, as may be prescribed by the Secretary with the approval of the Secretary of the Treasury. Such notes or other obligations shall bear interest at a rate determined by the Secretary of the Treasury, taking into consideration the current average market yield on outstanding marketable obligations of the United States of comparable maturities during the month preceding the issuance of the notes or other obligations. The Secretary of the Treasury shall purchase any notes and other obligations issued under this paragraph and for that purpose he may use as a public debt transaction the proceeds from the sale of any securities issued under chapter 31 of title 31, and the purposes for which the securities may be issued under that chapter are extended to include any purchase of such notes and obligations. The Secretary of the Treasury may at any time sell any of the notes or other obligations acquired by him under this paragraph. All redemptions, purchases, and sales by the Secretary of the Treasury of such notes or other obligations shall be treated as public debt transactions of the United States. Sums borrowed under this paragraph shall be deposited in the fund and redemption of such notes and obligations shall be made by the Secretary from the fund.

(e) Loan fund

There is established in the Treasury a loan fund (hereinafter in this subsection referred to as the "fund") which shall be available to the Secretary without fiscal year limitation, in such

amounts as may be specified from time to time in appropriation Acts, to enable him to make loans under this subchapter and to take the action authorized by subsection (f) of this section. There shall also be deposited in the fund amounts received by the Secretary as interest payments and repayment of principal on loans made under this subchapter and other property or assets derived by him from his operations respecting such loans, from the sale of loans under subsection (c) of this section, or from the sale of assets.

(f) Actions to protect interest of United States in event of default

The Secretary may take such action as he deems appropriate to protect the interest of the United States in the event of a default on a loan made or guaranteed under this subchapter, including taking possession of, holding, and using real property pledged as security for such a loan or loan guarantee.

(July 1, 1944, ch. 373, title XIII, §1308, as added Pub. L. 93-222, §2, Dec. 29, 1973, 87 Stat. 927; amended Pub. L. 94-460, title I, §109(b)(2), (c), Oct. 8, 1976, 90 Stat. 1950; Pub. L. 95-559, §4(c), Nov. 1, 1978, 92 Stat. 2132; Pub. L. 97-35, title IX, §945, Aug. 13, 1981, 95 Stat. 577; Pub. L. 99-514, §2, Oct. 22, 1986, 100 Stat. 2095; Pub. L. 99-660, title VIII, §807, Nov. 14, 1986, 100 Stat. 3800.)

CODIFICATION

In subsec. (d)(2), "chapter 31 of title 31" and "that chapter" substituted for "the Second Liberty Bond Act" and "that Act", respectively, on authority of Pub. L. 97-258, §4(b), Sept. 13, 1982, 96 Stat. 1067, the first section of which enacted Title 31, Money and Finance.

AMENDMENTS

1986—Subsec. (c)(3). Pub. L. 99-514 substituted "Internal Revenue Code of 1986" for "Internal Revenue Code of 1954", which for purposes of codification was translated as "title 26" thus requiring no change in text.

Subsec. (d)(2). Pub. L. 99-660 inserted "before October 1, 1986," after "guarantees issued by him".

1981—Subsec. (b)(2). Pub. L. 97-35 inserted provisions relating to changes in the rate of interest by the Secretary, and in cl. (D) made changes in nomenclature.

1978—Subsec. (d). Pub. L. 95-559, §4(c)(2)(A), in pars. (1) and (2) inserted "and to take the action authorized by subsection (f) of this section" after "by him under this subchapter".

Subsec. (e). Pub. L. 95-559, §4(c)(2)(B), inserted "and to take the action authorized by subsection (f) of this section" after "loans under this subchapter".

Subsec. (f). Pub. L. 95-559, §4(c)(1), added subsec. (f). 1976—Subsec. (a)(1)(A). Pub. L. 94-460, §109(c)(1), substituted "for loans with similar maturities, terms, conditions, and security" for "for similar loans".

Subsec. (b)(2)(D). Pub. L. 94-460, §109(c)(2), substituted "marketable obligations of the United States of comparable maturities, adjusted to provide for appropriate administrative charges" for "loans guaranteed under this subchapter".

Subsec. (c)(5). Pub. L. 94-460, §109(b)(2), added par. (5).

EFFECTIVE DATE OF 1986 AMENDMENT

Amendment by Pub. L. 99-660 effective Oct. 1, 1985, see section 815(a) of Pub. L. 99-660, set out as an Effective and Termination Dates of 1986 Amendment note under section 300e-1 of this title.

EFFECTIVE DATE OF 1978 AMENDMENT

Amendment by Pub. L. 95-559 effective only for fiscal years beginning on or after October 1, 1978, see section

4(d) of Pub. L. 95-559, set out as a note under section 300e-4 of this title.

EFFECTIVE DATE OF 1976 AMENDMENT

Amendment by Pub. L. 94-460 effective Oct. 8, 1976, except that the amendment by section 109(c) of Pub. L. 94-460 applicable with respect to loan guarantees made under section 300e-4 of this title after Sept. 30, 1976, see section 118 of Pub. L. 94-460, set out as a note under section 300e of this title.

§ 300e-8. Authorization of appropriations

(a) For grants under section 300e-16 of this title there is authorized to be appropriated \$1,000,000 for each of the fiscal years 1982, 1983, and 1984.

(b) To meet the obligations of the loan fund established under section 300e-7(e) of this title resulting from defaults on loans made from the fund and to meet the other obligations of the fund, there is authorized to be appropriated to the loan fund for fiscal years 1987, 1988, and 1989, such sums as may be necessary.

(July 1, 1944, ch. 373, title XIII, §1309, as added Pub. L. 93-222, §2, Dec. 29, 1973, 87 Stat. 930; amended Pub. L. 94-460, title I, §113(c), Oct. 8, 1976, 90 Stat. 1954; Pub. L. 95-83, title I, §105(b), Aug. 1, 1977, 91 Stat. 384; Pub. L. 95-559, §§2(c), 7(b), Nov. 1, 1978, 92 Stat. 2131, 2135; Pub. L. 97-35, title IX, §941(a), (b), Aug. 13, 1981, 95 Stat. 572; Pub. L. 99-660, title VIII, §§803(b)(3), 811, Nov. 14, 1986, 100 Stat. 3800, 3801.)

AMENDMENTS

1986—Subsec. (a). Pub. L. 99-660, §803(b)(3), struck out par. (2) designation and struck out par. (1) which read as follows: "For grants and contracts under sections 300e-2 and 300e-3 of this title there is authorized to be appropriated \$20,000,000 for the fiscal years 1982, 1983, and 1984. No funds appropriated under this paragraph may be expended or obligated for a grant or contract unless the entity received a grant or contract under section 242a or 242b of this title during or before the fiscal year 1981."

Subsec. (b). Pub. L. 99-660, §811, amended subsec. (b) generally. Prior to amendment, subsec. (b) read as follows: "To maintain in the loan fund established under section 300e-7(e) of this title for the purpose of making new loans a balance of at least \$5,000,000 at the end of each fiscal year and to meet the obligations of the loan fund resulting from defaults on loans made from the fund and to meet the other obligations of the fund, there is authorized to be appropriated to the loan fund for fiscal years 1982, 1983, and 1984, such sums as may be necessary to assure such balance and meet such obligations."

1981—Subsec. (a). Pub. L. 97-35, §941(a), substituted provisions authorizing appropriations for fiscal years 1982, 1983, and 1984, and provisions respecting prior receipt of funds, for provisions authorizing appropriations for fiscal years ending June 30, 1974, 1975, and 1976, and Sept. 30, 1977, 1978, 1979, 1980, and 1981.

Subsec. (b). Pub. L. 97-35, §941(b), substituted provisions relating to maintenance of the loan fund for fiscal years 1982, 1983, and 1984, for provisions relating to maintenance of the loan fund for fiscal years ending June 30, 1974, and 1975.

1978—Subsec. (a). Pub. L. 95-559 substituted "300e-3(b) and 300e-16 of this title" for "and 300e-3(b) of this title" and ", \$31,000,000 for the fiscal year ending September 30, 1979, \$65,000,000 for the fiscal year ending September 30, 1980, and \$68,000,000 for the fiscal year ending September 30, 1981" for "and for the purpose of making payments under grants and contracts under section 300e-3(b) of this title for the fiscal year ending September 30, 1979, there is authorized to be appropriated \$50,000,000".

1977—Subsec. (a). Pub. L. 95-83 substituted, where appearing the second time, “September 30, 1979” for “September 30, 1977”.

1976—Subsec. (a). Pub. L. 94-460 substituted “\$40,000,000 for the fiscal year ending June 30, 1976, \$45,000,000 for the fiscal year ending September 30, 1977, and \$45,000,000 for the fiscal year ending September 30, 1978;” for “and \$85,000,000 for the fiscal year ending June 30, 1976;” and “for the fiscal year ending September 30, 1977, there is authorized to be appropriated \$50,000,000” for “for the fiscal year ending June 30, 1977, there is authorized to be appropriated \$85,000,000”.

EFFECTIVE DATE OF 1986 AMENDMENT

Amendment by section 803(b)(3) of Pub. L. 99-660 not applicable to any grant made or contract entered into under this subchapter before Oct. 1, 1985, see section 803(c) of Pub. L. 99-660, set out as a note under section 300e-5 of this title.

Amendment by Pub. L. 99-660 effective Oct. 1, 1985, see section 815(a) of Pub. L. 99-660, set out as an Effective and Termination Dates of 1986 Amendment note under section 300e-1 of this title.

EFFECTIVE DATE OF 1978 AMENDMENT

Amendment by section 7(b) of Pub. L. 95-559 effective only for fiscal years beginning on or after Oct. 1, 1978, see section 7(c) of Pub. L. 95-559, set out as an Effective Date note under section 300e-16 of this title.

EFFECTIVE DATE OF 1976 AMENDMENT

Amendment by Pub. L. 94-460 effective Oct. 8, 1976, see section 118 of Pub. L. 94-460, set out as a note under section 300e of this title.

§ 300e-9. Employees' health benefits plans

(a) Regulations; membership option

In accordance with regulations which the Secretary shall prescribe—

(1) each employer—

(A) which is required during any calendar quarter to pay its employees the minimum wage prescribed by section 206 of title 29 (or would be required to pay its employees such wage but for section 213(a) of title 29), and

(B) which during such calendar quarter employed an average number of employees of not less than 25, and

(2) any State and each political subdivision thereof which during any calendar quarter employed an average number of employees of not less than 25, as a condition of payment to the State of funds under section 247b, 247c, or 300a of this title,

which offers to its employees in the calendar year beginning after such calendar quarter the option of membership in a qualified health maintenance organization which is engaged in the provision of basic health services in a health maintenance organization service area in which at least 25 of such employees reside shall meet the requirements of subsection (b) of this section with respect to any qualified health maintenance organization offered by the employer or State or political subdivision.

(b) Nondiscriminatory contributions for services; payroll deductions; effect on costs

(1) If a health benefits plan offered by an employer or a State or political subdivision includes contributions for services offered under the plan, the employer or State or political subdivision shall make a contribution under the

plan for services offered by a qualified health maintenance organization in an amount which does not financially discriminate against an employee who enrolls in such organization. For purposes of the preceding sentence, an employer's or a State's or political subdivision's contribution does not financially discriminate if the employer's or State's or political subdivision's method of determining the contributions on behalf of all employees is reasonable and is designed to assure employees a fair choice among health benefits plans.

(2) Each employer or State or political subdivision which provides payroll deductions as a means of paying employees' contributions for health benefits or which provides a health benefits plan to which an employee contribution is not required shall, with the consent of an employee who exercises option of membership in a qualified health maintenance organization, arrange for the employee's contribution for membership in the organization to be paid through payroll deductions.

(3) No employer or State or political subdivision shall be required to pay more for health benefits as a result of the application of this subsection than would otherwise be required by any prevailing collective bargaining agreement or other legally enforceable contract for the provision of health benefits between the employer or State or political subdivision and its employees.

(c) “Qualified health maintenance organization” defined

For purposes of this section, the term “qualified health maintenance organization” means (1) a health maintenance organization which has provided assurances satisfactory to the Secretary that it provides basic and supplemental health services to its members in the manner prescribed by section 300e(b) of this title and that it is organized and operated in the manner prescribed by section 300e(c) of this title, and (2) an entity which proposes to become a health maintenance organization and which the Secretary determines will when it becomes operational provide basic and supplemental health services to its members in the manner prescribed by section 300e(b) of this title and will be organized and operated in the manner prescribed by section 300e(c) of this title.

(d) Civil penalty; notice and presentation of views; review

(1) Any employer who knowingly does not comply with one or more of the requirements of paragraph (1) or (2) of subsection (b) of this section shall be subject to a civil penalty of not more than \$10,000. If such noncompliance continues, a civil penalty may be assessed and collected under this subsection for each thirty-day period such noncompliance continues. Such penalty may be assessed by the Secretary and collected in a civil action brought by the United States in a United States district court.

(2) In any proceeding by the Secretary to assess a civil penalty under this subsection, no penalty shall be assessed until the employer charged shall have been given notice and an opportunity to present its views on such charge. In determining the amount of the penalty, or the

amount agreed upon in compromise, the Secretary shall consider the gravity of the non-compliance and the demonstrated good faith of the employer charged in attempting to achieve rapid compliance after notification by the Secretary of a noncompliance.

(3) In any civil action brought to review the assessment of a civil penalty assessed under this subsection, the court shall, at the request of any party to such action, hold a trial de novo on the assessment of such civil penalty and in any civil action to collect such a civil penalty, the court shall, at the request of any party to such action, hold a trial de novo on the assessment of such civil penalty unless in a prior civil action to review the assessment of such penalty the court held a trial de novo on such assessment.

(e) "Employer" defined

For purposes of this section, the term "employer" does not include (1) the Government of the United States, the government of the District of Columbia or any territory or possession of the United States, a State or any political subdivision thereof, or any agency or instrumentality (including the United States Postal Service and Postal Regulatory Commission) of any of the foregoing, except that such term includes nonappropriated fund instrumentalities of the Government of the United States; or (2) a church, convention or association of churches, or any organization operated, supervised or controlled by a church, convention or association of churches which organization (A) is an organization described in section 501(c)(3) of title 26, and (B) does not discriminate (i) in the employment, compensation, promotion, or termination of employment of any personnel, or (ii) in the extension of staff or other privileges to any physician or other health personnel, because such persons seek to obtain or obtained health care, or participate in providing health care, through a health maintenance organization.

(f) Termination of payment for failure to comply

If the Secretary, after reasonable notice and opportunity for a hearing to a State, finds that it or any of its political subdivisions has failed to comply with paragraph (1) or (2) of subsection (b) of this section, the Secretary shall terminate payments to such State under sections 247b, 247c, and 300a of this title and notify the Governor of such State that further payments under such sections will not be made to the State until the Secretary is satisfied that there will no longer be any such failure to comply.

(July 1, 1944, ch. 373, title XIII, §1310, as added Pub. L. 93-222, §2, Dec. 29, 1973, 87 Stat. 930; amended Pub. L. 94-460, title I, §110(a), Oct. 8, 1976, 90 Stat. 1950; Pub. L. 95-559, §§8, 12(a)(1), Nov. 1, 1978, 92 Stat. 2135, 2140; Pub. L. 96-32, §2(f), July 10, 1979, 93 Stat. 82; Pub. L. 97-35, title IX, §§942(a)(3), (4), 946, Aug. 13, 1981, 95 Stat. 573, 577; Pub. L. 99-514, §2, Oct. 22, 1986, 100 Stat. 2095; Pub. L. 99-660, title VIII, §808, Nov. 14, 1986, 100 Stat. 3801; Pub. L. 100-517, §§4(b), 7(a)(1), (2), (b), Oct. 24, 1988, 102 Stat. 2578, 2580; Pub. L. 109-435, title VI, §604(f), Dec. 20, 2006, 120 Stat. 3242.)

AMENDMENTS

2006—Subsec. (e). Pub. L. 109-435 substituted "Postal Regulatory Commission" for "Postal Rate Commission".

1988—Pub. L. 100-517, §7(b), amended section generally, substituting subsecs. (a) to (f) for former subsecs. (a) to (g).

Subsec. (b). Pub. L. 100-517, §§4(b), 7(a)(1)(A), in introductory provisions, substituted "or a State or political subdivision" for "subject to subsection (a) of this section", in par. (1), inserted "and provides at least 90 percent of such services through physicians described in section 300e(b)(3)(A) of this title", in par. (2), inserted "and provides no more than 10 percent of such services through physicians who are not described in section 300e(b)(3)(A) of this title", and in concluding provisions, substituted "employer or State or political subdivision pursuant" for "employer pursuant".

Subsec. (c). Pub. L. 100-517, §7(a)(1)(B), (2), substituted "No employer or State or political subdivision" for "No employer", "between the employer or State or political subdivision" for "between the employer", and "Each employer or State or political subdivision" for "Each employer", and inserted at end "If a health benefits plan offered by an employer or a State or political subdivision under subsection (a) of this section includes contributions for services offered under the plan, the employer or State or political subdivision shall make a contribution under the plan for services offered by a qualified health maintenance organization in an amount which does not financially discriminate against an employee who enrolls in such organization. For purposes of the preceding sentence, an employer's or a State's or political subdivision's contribution does not financially discriminate if the employer's or State's or political subdivision's method of determining the contributions on behalf of all employees is reasonable and is designed to assure employees a fair choice among health benefits plans."

1986—Subsec. (d). Pub. L. 99-660 struck out last sentence which read as follows: "Every two years (or such longer period as the Secretary may by regulation prescribe) after the date a health maintenance organization becomes a qualified health maintenance organization under this subsection, the health maintenance organization must demonstrate to the Secretary that it is qualified within the meaning of this subsection."

Subsec. (f). Pub. L. 99-514 substituted "Internal Revenue Code of 1986" for "Internal Revenue Code of 1954", which for purposes of codification was translated as "title 26" thus requiring no change in text.

1981—Subsec. (b)(1). Pub. L. 97-35, §942(a)(3)(A), substituted provisions respecting provision of more than one-half of the basic services provided by physicians, for provisions respecting provision of basic services.

Subsec. (b)(2). Pub. L. 97-35, §942(a)(3)(B), (4), inserted reference to provision by physicians, added cl. (B), and redesignated former cl. (B) as (C).

Subsec. (d). Pub. L. 97-35, §946(a), inserted provisions relating to demonstration of continued qualification of organization.

Subsec. (f)(1). Pub. L. 97-35, §946(b), inserted reference to United States nonappropriated fund instrumentalities.

1979—Subsec. (e)(1). Pub. L. 96-32 substituted "subsection (a), (b), or (c)" for "subsection (a)".

1978—Subsec. (b). Pub. L. 95-559, §8(b), substituted in par. (1) "through physicians or other health professionals who are members of the staff of the organization or a medical group (or groups)" for "(A) without the use of an individual practice association and (B) without the use of contracts (except for contracts for unusual or infrequently used services) with health professionals" and in par. (2) "(B) a combination of such association (or associations), medical group (or groups), staff, and individual physicians and other health professionals under contract with the organization" for "(B) health professionals who have contracted with the health maintenance organization for the provision of such services, or (C) a combination of such association (or associations) or health professionals under contract with the organization".

Subsec. (c). Pub. L. 95-559, §8(a), inserted provision that each employer which provides payroll deductions

as a means of paying employees' contributions for health benefits or which provides a health benefits plan to which an employee contribution is not required and which is required by subsection (a) of this section to offer his employees the option of membership in a qualified health maintenance organization shall, with the consent of an employee who exercises such option, arrange for the employee's contribution for such membership to be paid through payroll deductions.

Subsec. (h). Pub. L. 95-559, §12(a)(1), struck out subsec. (h) which provided that the duties and functions of the Secretary, insofar as they involve determinations as to whether an organization is a qualified health maintenance organization within the meaning of subsection (d) of this section, be administered through the Assistant Secretary for Health and in the Office of the Assistant Secretary for Health, and the administration of such duties and functions be integrated with the administration of section 300e-11(a) of this title.

1976—Subsec. (a). Pub. L. 94-460, §110(a)(1), substituted reference to each employer which is now or hereafter required for reference to each employer which is required, reference to basic health services in health maintenance organization service areas in which at least 25 of such employees reside for reference to basic and supplemental health services in the areas in which such employees reside, and inserted provisions requiring certain States and political subdivisions thereof to include in any health benefits plan the option of membership in qualified health maintenance organizations as a condition of payment to the State of funds under section 246(d), 247b, 247c, 300a, 300m-4, or 300p-3 of this title, and that the offer of membership in such an organization be first made to the employees' representative, if any, and then be made to each employee if the offer is accepted by the representative.

Subsec. (b)(1). Pub. L. 94-460, §110(a)(2), substituted "(A) without the use of an individual practice association and (B) without the use of contracts (except for contracts for unusual or infrequently used services) with health professionals" for "through professionals who are members of the staff of the organization or a medical group (or groups)".

Subsec. (b)(2). Pub. L. 94-460, §110(a)(2), substituted "basic health services through (A) an individual practice association (or associations), (B) health professionals who have contracted with the health maintenance organization for the provision of such services, or (C) a combination of such association (or associations) or health professionals under contract with the organization" for "such services through an individual practice association (or associations)".

Subsec. (c). Pub. L. 94-460, §110(a)(3), struck out provision that failure of any employer to comply with the requirements of subsection (a) of this section be considered a willful violation of section 215 of title 29.

Subsecs. (e) to (h). Pub. L. 94-460, §110(a)(4), added subsecs. (e) to (h).

EFFECTIVE DATE OF 1988 AMENDMENT

Section 7(b) of Pub. L. 100-517 provided that the amendment made by section 7(b) is effective 7 years after Oct. 24, 1988.

EFFECTIVE DATE OF 1986 AMENDMENT

Amendment by Pub. L. 99-660 effective Oct. 1, 1985, see section 815(a) of Pub. L. 99-660, set out as an Effective and Termination Dates of 1986 Amendment note under section 300e-1 of this title.

EFFECTIVE DATE OF 1981 AMENDMENT

Section 942(a)(5) of Pub. L. 97-35 provided that: "The amendment made by paragraph (3)(A) [amending this section] shall apply with respect to the offering of a health maintenance organization in accordance with section 1310(b)(1) of the Public Health Service Act [subsec. (b)(1) of this section] after four years after the date the organization becomes a qualified health maintenance organization for purposes of section 1310 of such

Act [this section] if the health maintenance organization provides assurances satisfactory to the Secretary that upon the expiration of such four years it will provide more than one half of its basic health services which are provided by physicians through physicians or other health professionals who are members of the staff of the organization or a medical group (or groups)."

EFFECTIVE DATE OF 1976 AMENDMENT

Amendment by section 110(a)(1), (2) of Pub. L. 94-460 applicable with respect to calendar quarters which began after Oct. 8, 1976, and amendment by section 110(a)(3), (4) of Pub. L. 94-460 applicable with respect to failures of employers to comply with section 300e-9 of this title after Oct. 8, 1976, see section 118 of Pub. L. 94-460, set out as a note under section 300e of this title.

COLLECTIVE BARGAINING AGREEMENTS IN EFFECT ON OCTOBER 24, 1988, UNAFFECTED

Section 7(a)(3) of Pub. L. 100-517 provided that: "Nothing in section 1310 of the Public Health Service Act (42 U.S.C. 300e-9), as amended by this Act, shall be construed to supersede any provision of a collective bargaining agreement in effect on the date of enactment of this Act [Oct. 24, 1988]."

§ 300e-10. Restrictive State laws and practices

(a) Entities operating as health maintenance organizations

In the case of any entity—

(1) which cannot do business as a health maintenance organization in a State in which it proposes to furnish basic and supplemental health services because that State by law, regulation, or otherwise—

(A) requires as a condition to doing business in that State that a medical society approve the furnishing of services by the entity,

(B) requires that physicians constitute all or a percentage of its governing body,

(C) requires that all physicians or a percentage of physicians in the locale participate or be permitted to participate in the provision of services for the entity,

(D) requires that the entity meet requirements for insurers of health care services doing business in that State respecting initial capitalization and establishment of financial reserves against insolvency, or

(E) imposes requirements which would prohibit the entity from complying with the requirements of this subchapter, and

(2) for which a grant, contract, loan, or loan guarantee was made under this subchapter or which is a qualified health maintenance organization for purposes of section 300e-9 of this title (relating to employees' health benefits plans),

such requirements shall not apply to that entity so as to prevent it from operating as a health maintenance organization in accordance with section 300e of this title.

(b) Advertising

No State may establish or enforce any law which prevents a health maintenance organization for which a grant, contract, loan, or loan guarantee was made under this subchapter or which is a qualified health maintenance organization for purposes of section 300e-9 of this title (relating to employees' health benefits plans),

from soliciting members through advertising its services, charges, or other nonprofessional aspects of its operation. This subsection does not authorize any advertising which identifies, refers to, or makes any qualitative judgement concerning, any health professional who provides services for a health maintenance organization.

(c) Digest of State laws, regulations, and practices; legal consultative assistance

The Secretary shall, within 6 months after October 8, 1976, develop a digest of State laws, regulations, and practices pertaining to development, establishment, and operation of health maintenance organizations which shall be updated at least annually and relevant sections of which shall be provided to the Governor of each State annually. Such digest shall indicate which State laws, regulations, and practices appear to be inconsistent with the operation of this section. The Secretary shall also insure that appropriate legal consultative assistance is available to the States for the purpose of complying with the provisions of this section.

(July 1, 1944, ch. 373, title XIII, §1311, as added Pub. L. 93-222, §2, Dec. 29, 1973, 87 Stat. 931; amended Pub. L. 94-460, title I, §114, Oct. 8, 1976, 90 Stat. 1954; Pub. L. 99-660, title VIII, §809, Nov. 14, 1986, 100 Stat. 3801; Pub. L. 100-517, §8, Oct. 24, 1988, 102 Stat. 2583.)

PRIOR PROVISIONS

A prior section 1311 of act July 1, 1944, was classified to section 211a of this title prior to repeal by Pub. L. 93-222, §7(b).

AMENDMENTS

1988—Subsec. (a)(1)(E). Pub. L. 100-517 added subpar. (E).

1986—Subsec. (c). Pub. L. 99-660 substituted “annually” for “quarterly” after “at least”.

1976—Subsec. (c). Pub. L. 94-460 added subsec. (c).

EFFECTIVE DATE OF 1986 AMENDMENT

Amendment by Pub. L. 99-660 effective Oct. 1, 1985, see section 815(a) of Pub. L. 99-660, set out as an Effective and Termination Dates of 1986 Amendment note under section 300e-1 of this title.

EFFECTIVE DATE OF 1976 AMENDMENT

Amendment by Pub. L. 94-460 effective Oct. 8, 1976, see section 118 of Pub. L. 94-460, set out as a note under section 300e of this title.

§ 300e-11. Continued regulation of health maintenance organizations

(a) Determination of deficiency

If the Secretary determines that an entity which received a grant, contract, loan, or loan guarantee under this subchapter as a health maintenance organization or which was included in a health benefits plan offered to employees pursuant to section 300e-9 of this title—

(1) fails to provide basic and supplemental services to its members,

(2) fails to provide such services in the manner prescribed by section 300e(b) of this title, or

(3) is not organized or operated in the manner prescribed by section 300e(c) of this title,

the Secretary may take the action authorized by subsection (b) of this section.

(b) Action by Secretary upon determination

(1) If the Secretary makes, with respect to any entity which provided assurances to the Secretary under section 300e-9(d)(1)¹ of this title, a determination described in subsection (a) of this section, the Secretary shall notify the entity in writing of the determination. Such notice shall specify the manner in which the entity has not complied with such assurances and direct that the entity initiate (within 30 days of the date the notice is issued by the Secretary or within such longer period as the Secretary determines is reasonable) such action as may be necessary to bring (within such period as the Secretary shall prescribe) the entity into compliance with the assurances. If the entity fails to initiate corrective action within the period prescribed by the notice or fails to comply with the assurances within such period as the Secretary prescribes, then after the Secretary provides the entity a reasonable opportunity for reconsideration of his determination, including, at the entity's election, a fair hearing (A) the entity shall not be a qualified health maintenance organization for purposes of section 300e-9 of this title until such date as the Secretary determines that it is in compliance with the assurances, and (B) each employer which has offered membership in the entity in compliance with section 300e-9 of this title, each lawfully recognized collective bargaining representative or other employee representative which represents the employees of each such employer, and the members of such entity shall be notified by the entity that the entity is not a qualified health maintenance organization for purposes of such section. The notice required by clause (B) of the preceding sentence shall contain, in readily understandable language, the reasons for the determination that the entity is not a qualified health maintenance organization. The Secretary shall publish in the Federal Register each determination referred to in this paragraph.

(2) If the Secretary makes, with respect to an entity which has received a grant, contract, loan, or loan guarantee under this subchapter, a determination described in subsection (a) of this section, the Secretary may, in addition to any other remedies available to him, bring a civil action in the United States district court for the district in which such entity is located to enforce its compliance with the assurances it furnished respecting the provision of basic and supplemental health services or its organization or operation, as the case may be, which assurances were made in connection with its application under this subchapter for the grant, contract, loan, or loan guarantee.

(July 1, 1944, ch. 373, title XIII, §1312, as added Pub. L. 93-222, §2, Dec. 29, 1973, 87 Stat. 931; amended Pub. L. 94-460, title I, §111, Oct. 8, 1976, 90 Stat. 1952; Pub. L. 95-559, §12(a)(2), Nov. 1, 1978, 92 Stat. 2140; Pub. L. 97-35, title IX, §949(a), Aug. 13, 1981, 95 Stat. 578.)

REFERENCES IN TEXT

Section 300e-9(d)(1) of this title, referred to in subsec. (b)(1), was redesignated section 300e-9(c)(1) of this title by Pub. L. 100-517, §7(b), Oct. 24, 1988, 102 Stat. 2580.

¹ See References in Text note below.

PRIOR PROVISIONS

A prior section 1312 of act July 1, 1944, was classified to section 212a of this title prior to repeal by Pub. L. 93-222, §7(b).

AMENDMENTS

1981—Subsec. (b)(1). Pub. L. 97-35 inserted provisions relating to opportunity for reconsideration of determination of Secretary.

1978—Subsec. (c). Pub. L. 95-559 struck out subsec. (c) which provided that the Secretary, acting through the Assistant Secretary for Health, administer subsections (a) and (b) of this section in the Office of the Assistant Secretary for Health.

1976—Subsec. (a). Pub. L. 94-460, §111(a), substituted “the Secretary may take the action authorized by subsection (b) of this section” for “the Secretary may, in addition to any other remedies available to him, bring a civil action in the United States district court for the district in which such entity is located to enforce its compliance with any assurances it furnished him respecting the provision of basic and supplemental health services or its organization or operation, as the case may be, which assurances were made under section 300e-9 of this title or when application was made under this subchapter for a grant, contract, loan, or loan guarantee”.

Subsecs. (b), (c). Pub. L. 94-460, §111(b), (c), added subsec. (b), redesignated former subsec. (b) as (c), and substituted “acting through the Assistant Secretary for Health, shall administer subsections (a) and (b) of this section” for “through the Assistant Secretary for Health, shall administer subsection (a) of this section”.

EFFECTIVE DATE OF 1976 AMENDMENT

Amendment by Pub. L. 94-460 applicable with respect to determinations of the Secretary of Health, Education, and Welfare described in subsec. (a) of this section and made after Oct. 8, 1976, see section 118 of Pub. L. 94-460, set out as a note under section 300e of this title.

§ 300e-12. Limitation on source of funding for health maintenance organizations

No funds appropriated under any provision of this chapter (except as provided in sections 254b¹ and 254b of this title) other than this subchapter may be used—

(1) for grants or contracts for surveys or other activities to determine the feasibility of developing or expanding health maintenance organizations or other entities which provide, directly or indirectly, health services to a defined population on a prepaid basis;

(2) for grants or contracts, or for payments under loan guarantees, for planning projects for the establishment or expansion of such organizations or entities;

(3) for grants or contracts, or for payments under loan guarantees, for projects for the initial development or expansion of such organizations or entities; or

(4) for loans, or for payments under loan guarantees, to assist in meeting the costs of the initial operation after establishment or expansion of such organizations or entities or in meeting the costs of such organizations in acquiring or constructing ambulatory health care facilities.

(July 1, 1944, ch. 373, title XIII, §1313, as added Pub. L. 93-222, §2, Dec. 29, 1973, 87 Stat. 932; amended Pub. L. 95-559, §5(b), Nov. 1, 1978, 92

Stat. 2133; Pub. L. 95-626, title I, §107, Nov. 10, 1978, 92 Stat. 3562; Pub. L. 107-251, title VI, §601(a), Oct. 26, 2002, 116 Stat. 1664; Pub. L. 108-163, §2(m)(2), Dec. 6, 2003, 117 Stat. 2023.)

REFERENCES IN TEXT

The reference to section 254b of this title the first place appearing in text was in the original a reference to section 329, meaning section 329 of act July 1, 1944, which was omitted in the general amendment of subpart I (§254b et seq.) of part D of this subchapter by Pub. L. 104-299, §2, Oct. 11, 1996, 110 Stat. 3626.

AMENDMENTS

2003—Pub. L. 108-163 substituted “254b and 254b” for “254b, 254c, and 254b(h)” in introductory provisions.

2002—Pub. L. 107-251 substituted “254b(h)” for “256” in introductory provisions.

1978—Pub. L. 95-626 inserted “(except as provided in sections 254b, 254c, and 256 of this title)” after “under any provision of this chapter” in provisions preceding par. (1).

Par. (4). Pub. L. 95-559 inserted “or in meeting the costs of such organizations in acquiring or constructing ambulatory health care facilities” after “or entities”.

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by Pub. L. 108-163 deemed to have taken effect immediately after the enactment of Pub. L. 107-251, see section 3 of Pub. L. 108-163, set out as a note under section 233 of this title.

§ 300e-13. Repealed. Pub. L. 97-35, title IX, § 949(b), Aug. 13, 1981, 95 Stat. 578

Section, acts July 1, 1944, ch. 373, title XIII, §1314, as added Dec. 29, 1973, Pub. L. 93-222, §2, 87 Stat. 932; amended Oct. 8, 1976, Pub. L. 94-460, title I, §115, 90 Stat. 1954; Nov. 1, 1978, Pub. L. 95-559, §13, 92 Stat. 2140, required the Comptroller General to: (a) evaluate the operations, particularly, specified aspects of the operations, of at least ten or one-half, whichever is greater, of the health maintenance organizations for which assistance was provided under sections 300e-2, 300e-3, and 300e-4 of this title, and which, by Dec. 31, 1976, were designated by the Secretary under section 300e-9(d) of this title as qualified health maintenance organizations, to Congress by June 30, 1978; (b) conduct a study of the economic effects on employers resulting from their compliance with the requirements of section 300e-9 of this title and report to Congress not later than 36 months after Dec. 29, 1973; (c) evaluate the operations of health maintenance organizations in comparison with others in distinct categories, in comparison with alternative forms of health care delivery, and their impact on the health of the public and report to Congress not later than 36 months after Dec. 29, 1973; and (d) evaluate the adequacy and effectiveness of the policies and procedures of the Secretary for the management of the grant and loan programs established by this subchapter and the adequacy of the amounts of assistance available under these programs and report to Congress not later than May 1, 1979.

§ 300e-14. Annual report

(a) The Secretary shall periodically review the programs of assistance authorized by this subchapter and make an annual report to the Congress of a summary of the activities under each program. The Secretary shall include in such summary—

(1) a summary of each grant, contract, loan, or loan guarantee made under this subchapter in the period covered by the report and a list of the health maintenance organizations which during such period became qualified health maintenance organizations for purposes of section 300e-9 of this title;

¹ See References in Text notes below.

(2) the statistics and other information reported in such period to the Secretary in accordance with section 300e(c)(11)¹ of this title;

(3) findings with respect to the ability of the health maintenance organizations assisted under this subchapter—

(A) to operate on a fiscally sound basis without continued Federal financial assistance,

(B) to meet the requirements of section 300e(c) of this title respecting their organization and operation,

(C) to provide basic and supplemental health services in the manner prescribed by section 300e(b) of this title,

(D) to include indigent and high-risk individuals in their membership, and

(E) to provide services to medically underserved populations; and

(4) findings with respect to—

(A) the operation of distinct categories of health maintenance organizations in comparison with each other,

(B) health maintenance organizations as a group in comparison with alternative forms of health care delivery, and

(C) the impact that health maintenance organizations, individually, by category, and as a group, have on the health of the public.

(b) The Office of Management and Budget may review the Secretary's report under subsection (a) of this section before its submission to the Congress, but the Office may not revise the report or delay its submission, and it may submit to the Congress its comments (and those of other departments or agencies of the Government) respecting such report.

(July 1, 1944, ch. 373, title XIII, §1315, as added Pub. L. 93-222, §2, Dec. 29, 1973, 87 Stat. 933.)

REFERENCES IN TEXT

Section 300e(c)(11) of this title, referred to in subsec. (a)(2), was redesignated section 300e(c)(9) of this title by Pub. L. 97-35, title IX, §942(d)(1), Aug. 13, 1981, 95 Stat. 574, and redesignated section 300e(c)(8) of this title by Pub. L. 100-517, §5(b), Oct. 24, 1988, 102 Stat. 2579.

§ 300e-14a. Health services for Indians and domestic agricultural migratory and seasonal workers

The Secretary of Health and Human Services, in connection with existing authority (except section 254b¹ of this title) for the provisions of health services to domestic agricultural migratory workers, to persons who perform seasonal agricultural services similar to the services performed by such workers, and to the families of such workers and persons, is authorized to arrange for the provision of health services to such workers and persons and their families through health maintenance organizations. In carrying out this section the Secretary may only use sums appropriated after December 29, 1973.

(Pub. L. 93-222, §6(b), Dec. 29, 1973, 87 Stat. 936; Pub. L. 95-626, title I, §102(b)(2), Nov. 10, 1978, 92

Stat. 3551; Pub. L. 96-88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695.)

REFERENCES IN TEXT

Section 254b of this title, referred to in text, was in the original a reference to section 329 of the Public Health Service Act, act July 1, 1944, which was omitted in the general amendment of subpart I (§254b et seq.) of part D of subchapter II of this chapter by Pub. L. 104-299, §2, Oct. 11, 1996, 110 Stat. 3626. Section 2 of Pub. L. 104-299 enacted a new section 330 of act July 1, 1944, which is classified to section 254b of this title.

CODIFICATION

Section was enacted as part of the Health Maintenance Organization Act of 1973, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

1978—Pub. L. 95-626 substituted “section 254b” for “section 247d”.

CHANGE OF NAME

“Secretary of Health and Human Services” substituted for “Secretary of Health, Education, and Welfare” in text, pursuant to section 509(b) of Pub. L. 96-88 which is classified to section 3508(b) of Title 20, Education.

§ 300e-15. Repealed. Pub. L. 97-35, title IX, § 949(b), Aug. 13, 1981, 95 Stat. 578

Section, act July 1, 1944, ch. 373, title XIII, §1316, as added Oct. 8, 1976, Pub. L. 94-460, title I, §116, 90 Stat. 1954, related to administration of programs.

§ 300e-16. Training and technical assistance

(a) National Health Maintenance Organization Intern Program

(1) The Secretary shall establish a National Health Maintenance Organization Intern Program (hereinafter in this subsection referred to as the “Program”) for the purpose of providing training to individuals to become administrators and medical directors of health maintenance organizations or to assume other managerial positions with health maintenance organizations. Under the Program the Secretary may directly provide internships for such training and may make grants to or enter into contracts with health maintenance organizations and other entities to provide such internships.

(2) No internship may be provided by the Secretary and no grant may be made or contract entered into by the Secretary for the provision of internships unless an application therefor has been submitted to and approved by the Secretary. Such an application shall be in such form and contain such information, and be submitted to the Secretary in such manner, as the Secretary shall prescribe. Section 300e-5 of this title does not apply to an application submitted under this section.

(3) Internships under the Program shall provide for such stipends and allowances (including travel and subsistence expenses and dependency allowances) for the recipients of the internships as the Secretary deems necessary. An internship provided an individual for training at a health maintenance organization or any other entity shall also provide for payments to be made to the organization or other entity for the cost of

¹ See References in Text note below.

¹ See References in Text note below.

support services (including the cost of salaries, supplies, equipment, and related items) provided such individual by such organization or other entity. The amount of any such payments to any organization or other entity shall be determined by the Secretary and shall bear a direct relationship to the reasonable costs of the organization or other entity for establishing and maintaining its training programs.

(4) Payments under grants under the Program may be made in advance or by way of reimbursement, and at such intervals and on such conditions, as the Secretary finds necessary.

(b) Technical assistance

The Secretary shall provide technical assistance (1) to entities intending to become a qualified health maintenance organization within the meaning of section 300e-9(d)¹ of this title, and (2) to health maintenance organizations. The Secretary may provide such technical assistance through grants to public and nonprofit private entities and contracts with public and private entities.

(c) Amounts provided in advance in appropriation acts

The authority of the Secretary to enter into contracts under subsections (a) and (b) of this section shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance by appropriation Acts.

(July 1, 1944, ch. 373, title XIII, §1317, as added Pub. L. 95-559, §7(a), Nov. 1, 1978, 92 Stat. 2134; amended Pub. L. 99-660, title VIII, §803(b)(4), Nov. 14, 1986, 100 Stat. 3800.)

REFERENCES IN TEXT

Section 300e-9(d) of this title, referred to in subsec. (b), was redesignated section 300e-9(c) of this title by Pub. L. 100-517, §7(b), Oct. 24, 1988, 102 Stat. 2580.

AMENDMENTS

1986—Subsec. (b). Pub. L. 99-660 redesignated cls. (2) and (3) as (1) and (2), respectively, and struck out former cl. (1) which read as follows: “to entities in connection with projects for which assistance is being provided under section 300e-2 or 300e-3 of this title.”

EFFECTIVE DATE OF 1986 AMENDMENT

Amendment by Pub. L. 99-660 not applicable to any grant made or contract entered into under this subchapter before Oct. 1, 1985, see section 803(c) of Pub. L. 99-660, set out as a note under section 300e-5 of this title.

Amendment by Pub. L. 99-660 effective Oct. 1, 1985, see section 815(a) of Pub. L. 99-660, set out as an Effective and Termination Dates of 1986 Amendment note under section 300e-1 of this title.

EFFECTIVE DATE

Section 7(c) of Pub. L. 95-559 provided that: “The amendments made by this section [enacting this section and amending section 300e-8 of this title] shall only be effective for fiscal years beginning on or after October 1, 1978.”

§ 300e-17. Financial disclosure

(a) Financial information reported to Secretary

Each health maintenance organization shall, in accordance with regulations of the Secretary,

report to the Secretary financial information which shall include the following:

(1) Such information as the Secretary may require demonstrating that the health maintenance organization has a fiscally sound operation.

(2) A copy of the report, if any, filed with the Centers for Medicare & Medicaid Services containing the information required to be reported under section 1320a-3 of this title by disclosing entities and the information required to be supplied under section 1396a(a)(38) of this title.

(3) A description of transactions, as specified by the Secretary, between the health maintenance organization and a party in interest. Such transactions shall include—

(A) any sale or exchange, or leasing of any property between the health maintenance organization and a party in interest;

(B) any furnishing for consideration of goods, services (including management services), or facilities between the health maintenance organization and a party in interest, but not including salaries paid to employees for services provided in the normal course of their employment and health services provided to members by hospitals and other providers and by staff, medical group (or groups), individual practice association (or associations), or any combination thereof; and

(C) any lending of money or other extension of credit between a health maintenance organization and a party in interest.

The Secretary may require that information reported respecting a health maintenance organization which controls, is controlled by, or is under common control with, another entity be in the form of a consolidated financial statement for the organization and such entity.

(b) “Party in interest” defined

For the purposes of this section the term “party in interest” means:

(1) any director, officer, partner, or employee responsible for management or administration of a health maintenance organization, any person who is directly or indirectly the beneficial owner of more than 5 per centum of the equity of the organization, any person who is the beneficial owner of a mortgage, deed of trust, note, or other interest secured by, and valuing more than 5 per centum of the health maintenance organization, and, in the case of a health maintenance organization organized as a nonprofit corporation, an incorporator or member of such corporation under applicable State corporation law;

(2) any entity in which a person described in paragraph (1)—

(A) is an officer or director;

(B) is a partner (if such entity is organized as a partnership);

(C) has directly or indirectly a beneficial interest of more than 5 per centum of the equity; or

(D) has a mortgage, deed of trust, note, or other interest valuing more than 5 per centum of the assets of such entity;

¹ See References in Text note below.

(3) any person directly or indirectly controlling, controlled by, or under common control with a health maintenance organization; and

(4) any spouse, child, or parent of an individual described in paragraph (1).

(c) Information availability

Each health maintenance organization shall make the information reported pursuant to subsection (a) of this section available to its enrollees upon reasonable request.

(d) Evaluation of transactions

The Secretary shall, as he deems necessary, conduct an evaluation of transactions reported to the Secretary under subsection (a)(3) of this section for the purpose of determining their adverse impact, if any, on the fiscal soundness and reasonableness of charges to the health maintenance organization with respect to which they transpired. The Secretary shall evaluate the reported transactions of not less than five, or if there are more than twenty health maintenance organizations reporting such transactions, not less than one-fourth of the health maintenance organizations reporting any such transactions under subsection (a)(3) of this section.

(e) Repealed. Pub. L. 99-660, title VIII, § 810, Nov. 14, 1986, 100 Stat. 3801

(f) Rates

Nothing in this section shall be construed to confer upon the Secretary any authority to approve or disapprove the rates charged by any health maintenance organization.

(g) Annual financial statement

Any health maintenance organization failing to file with the Secretary the annual financial statement required in subsection (a) of this section shall be ineligible for any Federal assistance under this subchapter until such time as such statement is received by the Secretary and shall not be a qualified health maintenance organization for purposes of section 300e-9 of this title.

(h) Penalties

Whoever knowingly and willfully makes or causes to be made any false statement or representation of a material fact in any statement filed pursuant to this section shall be guilty of a felony and upon conviction thereof shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

(July 1, 1944, ch. 373, title XIII, §1318, as added Pub. L. 95-559, §9(a), Nov. 1, 1978, 92 Stat. 2135; amended Pub. L. 97-35, title IX, §948, Aug. 13, 1981, 95 Stat. 577; Pub. L. 99-660, title VIII, §810, Nov. 14, 1986, 100 Stat. 3801; Pub. L. 108-173, title IX, §900(e)(2)(E), Dec. 8, 2003, 117 Stat. 2372.)

AMENDMENTS

2003—Subsec. (a)(2). Pub. L. 108-173 substituted “Centers for Medicare & Medicaid Services” for “Health Care Financing Administration”.

1986—Subsec. (e). Pub. L. 99-660 struck out subsec. (e) which read as follows: “The Secretary shall file an annual report with the Congress on the operation of this section. Such report shall include—

“(1) an enumeration of standards and norms utilized to make the evaluations required under subsection (d) of this section;

“(2) an assessment of the degree of conformity or nonconformity of each health maintenance organization evaluated by the Secretary under subsection (d) of this section with such standards and norms;

“(3) what action, if any, the Secretary considers necessary under section 300e-11 of this title with respect to health maintenance organizations evaluated under subsection (d) of this section.”

1981—Subsec. (a). Pub. L. 97-35, §948(a), (b), in par. (2) inserted reference to copy of the report, if any, filed with the Health Care Financing Administration, and in par. (3)(B) reorganized excluding provisions and, among revisions, inserted salaries paid to employees for services.

Subsec. (b)(1). Pub. L. 97-35, §948(c), inserted “responsible for management or administration” after “employee”.

Subsec. (b)(4). Pub. L. 97-35, §948(d), substituted “spouse, child, or parent” for “member of the immediate family”.

EFFECTIVE DATE OF 1986 AMENDMENT

Amendment by Pub. L. 99-660 effective Oct. 1, 1985, see section 815(a) of Pub. L. 99-660, set out as an Effective and Termination Dates of 1986 Amendment note under section 300e-1 of this title.

SUBCHAPTER XII—SAFETY OF PUBLIC WATER SYSTEMS

PART A—DEFINITIONS

§ 300f. Definitions

For purposes of this subchapter:

(1) The term “primary drinking water regulation” means a regulation which—

(A) applies to public water systems;

(B) specifies contaminants which, in the judgment of the Administrator, may have any adverse effect on the health of persons;

(C) specifies for each such contaminant either—

(i) a maximum contaminant level, if, in the judgment of the Administrator, it is economically and technologically feasible to ascertain the level of such contaminant in water in public water systems, or

(ii) if, in the judgment of the Administrator, it is not economically or technologically feasible to so ascertain the level of such contaminant, each treatment technique known to the Administrator which leads to a reduction in the level of such contaminant sufficient to satisfy the requirements of section 300g-1 of this title; and

(D) contains criteria and procedures to assure a supply of drinking water which dependably complies with such maximum contaminant levels; including accepted methods for quality control and testing procedures to insure compliance with such levels and to insure proper operation and maintenance of the system, and requirements as to (i) the minimum quality of water which may be taken into the system and (ii) siting for new facilities for public water systems.

At any time after promulgation of a regulation referred to in this paragraph, the Administrator may add equally effective quality control and testing procedures by guidance published in the Federal Register. Such procedures shall be treated as an alternative for