Public Law 94-460 94th Congress

An Act

To amend title XIII of the Public Health Service Act to revise and extend the program for the establishment and expansion of health maintenance organizations.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled.

SHORT TITLE : REFERENCE TO ACT

SECTION 1. (a) This Act may be cited as the "Health Maintenance Organization Amendments of 1976".

(b) Whenever in title I an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Public Health Service Act.

TITLE I-AMENDMENTS TO TITLE XIII OF THE PUBLIC HEALTH SERVICE ACT

SUPPLEMENTAL HEALTH SERVICES

SEC. 101. (a) Section 1301(b) (1) is amended by adding at the end the following: "A health maintenance organization may include a health service, defined as a supplemental health service by section 1302(2), in the basic health services provided its members for a basic health services payment described in the first sentence.".

(b) The first sentence of section 1301(b) (2) is amended by striking out "the organization shall provide" and all that follows in that sentence and substituting "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 1302(2)).".

(c) Section 1301(b)(4) is amended by striking out "and supplemental health services in the case of the members who have contracted therefor" and substituting "and only such supplemental health services as members have contracted for".

STAFFING

SEC. 102. (a) (1) The first sentence of section 1301(b) (3) is amended 42 USC 300e. (A) by striking out "or through" and by substituting "(b) is an ended by striking out "or groups) or" and substituting "(or groups), through an", and (C) by inserting after "(or associations)" the following: ", through health professionals who have contracted with the health maintenance organization for the provision of such services, or through any combination of such staff, medical group (or groups), individual practice association (or associations), or health professionals under contract with the organization".

(2) Section 1301(b)(3) is amended by adding after the first sentence the following: "A health maintenance organization may also, during the thirty-six month period beginning with the month follow-

Health Maintenance Organization Amendments of 1976. 42 USC 300e note.

42 USC 201 note.

42 USC 300e.

42 USC 300e-1.

Oct. 8, 1976

[H.R. 9019]

42 USC 300e-9. 42 USC 300e-1. ing the month in which the organization becomes a qualified health maintenance organization (within the meaning of section 1310(d)), provide basic and supplemental health services through an entity which but for the requirement of section 1302(4)(C)(i) would be a medical group for purposes of this title. 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. 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 this sentence does 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 1302(4)(C)(i) would be a medical group for purposes of this title. 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).".

42 USC 300e-1.

(b) (1) Section 1302(4) (C) is amended (A) by striking out clause (iv), (B) by redesignating clause (v) as clause (iv), and (C) by inserting "and" at the end of clause (iii).

(2) Section 1302(5) (B) is amended (A) by striking out clause (i), and (B) by redesignating clauses (ii) and (iii) as clauses (i) and (ii), respectively.

OPEN ENROLLMENT

42 USC 300e.

SEC. 103. (a) Section 1301(c) is amended by amending paragraph (4) to read as follows:

"(4) have an open enrollment period in accordance with the provisions of subsection (d);".

(b) Section 1301 is amended by adding at the end thereof the following:

"(d) (1) (A) A health maintenance organization which—

"(i) has for at least 5 years provided comprehensive health services on a prepaid basis, or

"(ii) has an enrollment of at least 50,000 members,

shall have at least once during each fiscal year next following a fiscal year in which it did not have a financial deficit an open enrollment period (determined under subparagraph (B)) during which it shall accept individuals for membership in the order in which they apply for enrollment and, except as provided in paragraph (2), without regard to preexisting illness, medical condition, or degree of disability.

"(B) An open enrollment period for a health maintenance organization shall be the lesser of—

"(i) 30 days, or

"(ii) the number of days in which the organization enrolls a number of individuals at least equal to 3 percent of its total net increase in enrollment (if any) in the fiscal year preceding the fiscal year in which such period is held. For the purpose of determining the total net increase in enrollment in a health maintenance organization, there shall not be included any individual who is enrolled in the organization through a group which had a contract for health care services with the health maintenance organization at the time that such health maintenance organization was determined to be a qualified health maintenance organization under section 1310.

"(2) Notwithstanding the requirements of paragraph (1) a health maintenance organization shall not be required to enroll individuals who are confined to an institution because of chronic illness, permanent injury, or other infirmity which would cause economic impairment to the health maintenance organization if such individual were enrolled.

"(3) A health maintenance organization may not be required to make the effective date of benefits for individuals enrolled under this subsection less than 90 days after the date of enrollment.

"(4) The Secretary may waive the requirements of this subsection Waiver. for a health maintenance organization which demonstrates that compliance with the provisions of this subsection would icopardize its economic viability in its service area.".

DEFINITION OF SERVICES

SEC. 104. (a) (1) Paragraph (1) (H) of section 1302 is amended to 42 USC 300e-1. read as follows:

"(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 eve and ear examinations conducted to determine the need for vision and hearing correction).".

(2) Paragraph (1) of section 1302 is amended by striking out "or podiatrist" each place it occurs and substituting "podiatrist, or other health care personnel".

(b) Paragraph (2) of such section is amended-

(1) by striking out "under paragraph (1) (A) or (1) (H)" in subparagraphs (B) and (C); (2) by striking out "and" at the end of subparagraph (E), by

striking out the period at the end of subparagraph (F) and substituting "; and", and by adding after subparagraph (F) the following:

"(G) other health services which are not included as basic health services and which have been approved by the Secretary for delivery as supplemental health services.";

(3) by striking out "or podiatrist" each place it occurs and substituting "podiatrist, or other health care personnel".

COMMUNITY RATING

SEC. 105. (a) (1) Section 1301(b)(1) is amended by adding at the end thereof the following new sentence: "In the case of an entity which before it became a qualified health maintenance organization (within the meaning of section 1310(d)) 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.".

42 USC 300e-9.

42 USC 300e.

90 STAT. 1948

42 USC 300e.

42 USC 300e-9.

42 USC 300e-5.

(2) The last sentence of section 1301(b)(2) is amended by inserting before the period the following: "except that, in the case of an entity which before it became a qualified health maintenance organization

(within the meaning of section 1310(d)) 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) Section 1306(b) is amended (A) by striking out "and" at the end of paragraph (6), (B) by redesignating paragraph (7) as paragraph (8), and (C) by inserting after paragraph (6) the following new paragraph:

"(7) 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 1301(b) respecting the fixing of basic health services pavments and supplemental health services payments under a community rating system; and"

(b) Section 1302(8)(A) is amended by inserting "differences in marketing costs and" after "reflect".

(c) Subparagraph (B) of section 1302(8) is redesignated as subparagraph (C) and the following new subparagraph is inserted after subparagraph (A):

"(B) 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.".

MEDICAL GROUP REQUIREMENTS

42 USC 300e-1.

SEC. 106. (a) Section 1302(4) (C) is amended by striking out "(i) as their principal professional activity and as a group responsibility engage in the coordinated practice of their profession for a health maintenance organization" and substituting "(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".

(b) Section 1302(4)(C)(ii) is amended by striking out "plan" and substituting "similar plan unrelated to the provision of specific health services".

(c) 1302(4) (C) (as amended by section 102(b)(1)) is amended by—

(1) striking "and" before "(iv)", and

(2) striking the period at the end of subparagraph (C) and substituting "; 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.".

INCREASE IN LIMITS ON ASSISTANCE FOR FEASIBILITY SURVEYS, PLANNING, INITIAL DEVELOPMENT, AND INITIAL OPERATION

42 USC 300e-2.

42 USC 300e-3.

SEC. 107. (a) Section 1303(e) is amended by striking "\$50,000" and substituting "\$75,000".

(b) (1) Section 1304(f) (1) (A) is amended by striking "\$125,000"

and substituting "\$200,000". (2) Section 1304(f)(2)(A) is amended by inserting after "\$1,000,000" the following: "or, in the case of a project for a health maintenance organization which will provide services to an additional

42 USC 300e-1.

service area (as defined by the Secretary) or which will provide services in one or more areas which are not contiguous, \$1,600,000".

(c) Section 1305(a) is amended by striking out "first thirty-six 42 USC 300e-4. months" each place it occurs and substituting "first sixty months".

LOAN GUARANTEES FOR PRIVATE ENTITIES

SEC. 108. (a) Section 1304(a) (2) is amended to read as follows: "(2) guarantee to non-Federal lenders payment of the principal of and the interest on loans made to-

"(A) nonprofit private entities for planning projects for the establishment or expansion of health maintenance organizations, or

²⁷(B) other private entities for such projects for health maintenance organizations which will serve medically underserved populations.".

(b) Section 1304(b) (1) (B) is amended to read as follows:

"(B) guarantee to non-Federal lenders payment of the principal of and the interest on loans made to-

"(i) nonprofit private entities for projects for the initial development of health maintenance organizations, or

"(ii) other private entities for such projects for health maintenance organizations which will serve medically underserved populations.".

(c) Section 1305(a) (3) is amended to read as follows:

"(3) guarantee to non-Federal lenders payment of the principal of and the interest on loans made to-

"(A) nonprofit private health maintenance organizations for the amounts referred to in paragraph (1) or (2), or

"(B) other private health maintenance organizations for such amounts but only if the health maintenance organiza-

tion will serve a medically underserved population.". (d) (1) Section 1304(d) is amended by adding at the end the following new sentence: "In considering applications for loan guaran-

tees under this section, the Secretary shall give special consideration to applications for projects for health maintenance organizations which will serve medically underserved populations.".

(2) Section 1305 is amended by adding at the end thereof the following new subsection :

"(f) 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.".

MISCELLANEOUS AMENDMENTS

SEC. 109. (a) (1) Section 1305(a) is amended by striking out "in the period of" in paragraphs (1) and (2) and substituting "during a period not to exceed".

(2) The last sentence of 1305(b)(1) is amended to read as follows: Limitation. "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.".

Special consideration.

42 USC 300e-4.

42 USC 300e-4.

42 USC 300e-3.

42 USC 300e-6.

(b) (1) Section 1307(e) is amended—

(A) by inserting "for a private health maintenance organization (other than a private nonprofit health maintenance organization)" after "may be made", and

(B) by inserting "for private health maintenance organizations (other than private nonprofit health maintenance organizations)" after "guaranteed".

42 USC 300e-7.

(2) Section 1308(c) is amended by adding after paragraph (4) the following new paragraph:

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

(c) (1) Section 1308(a)(1)(A) is amended by striking out "for similar loans" and substituting "for loans with similar maturities, terms, conditions, and security".

(2) Section 1308(b)(2)(D) is amended by striking out "loans guaranteed under this title" and substituting "marketable obligations of the United States of comparable maturities, adjusted to provide for appropriate administrative charges".

(d)(1) The last sentence of section 1303(i) is amended-

(A) by striking "the fiscal year ending June 30, 1974, or

June 30, 1975," and substituting "any fiscal year"; and (B) by striking "for projects other than those described in clause (1) of such sentence" and substituting "for any project, with priority being given to projects described in clause (1) of such sentence".

(2) The last sentence of section 1304(k)(1) is amended—

(A) by striking "the fiscal year ending June 30, 1974, or June 30, 1975," and substituting "any fiscal year"; and

(B) by striking "for projects other than those described in clause (A) of such sentence" and substituting "for any project, with priority being given to projects described in clause (A) of such sentence".

(3) The last sentence of section 1304(k) (2) is amended-

(A) by striking "the fiscal year ending June 30, 1974, or in either of the next two fiscal years" and substituting "any fiscal year"; and

(B) by striking "for projects other than those described in clause (Å) of such sentence" and substituting "for any project, with priority being given to projects described in clause (A) of such sentence".

(e) Section 1304(b)(2)(D) is amended by striking out "for such an organization" and substituting "who will engage in practice principally for the health maintenance organization".

EMPLOYEE HEALTH BENEFITS PLANS

42 USC 300e-9.

SEC. 110. (a) Section 1310 is amended-

(1) by amending subsection (a) to read as follows:

"SEC. 1310. (a) (1) In accordance with regulations which the Secretary shall prescribe-

"(A) each employer-"(i) which is now or hereafter required during any calendar quarter to pay its employees the minimum wage prescribed by section 6 of the Fair Labor Standards Act of 1938 (or would be required to pay its employees such wage but for section 13(a) of such Act), and

42 USC 300e-3.

42 USC 300e-2.

29 USC 206. 29 USC 213.

"(ii) which during such calendar quarter employed an average number of employees of not less than 25, shall include in any health benefits plan, and

"(B) 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 the payment to the State of funds under section 314(d), 317, 318, 1002, 1525, or 1613, shall include in any health benefits plan,

offered to such employees in the calendar year beginning after such calendar quarter the option of membership in qualified health maintenance organizations which are engaged in the provision of basic health services in health maintenance organization service areas in which at least 25 of such employees reside.

"(2) If any of the employees of an employer or State or political subdivision thereof described in paragraph (1) are represented by a collective bargaining representative or other employee representative designated or selected under any law, offer of membership in a qualified health maintenance organization required by paragraph (1) to be made in a health benefits plan offered to such employees (A) shall first be made to such collective bargaining representative or other employee representative, and (B) if such offer is accepted by such representative, shall then be made to each such employee."; (2) by amending paragraphs (1) and (2) of subsection (b)

to read as follows:

"(1) one or more of such organizations provides basic health services (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

"(2) one or more of such organizations provides 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,"

(3) by striking out the last sentence of subsection (c); and

(4) by adding after subsection (d) the following new subsections:

"(e) (1) Any employer who knowingly does not comply with one or more of the requirements of subsection (a) 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 noncompliance 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

42 USC 246, 247b, 247c, 300a, 300m-4, 300p-3.

Civil penalty.

Notice.

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.

"Employer."

26 USC 501.

Notice and hearing.

42 USC 246, 247b, 247c, 300a, 300m-4 300p-3.

Administration.

42 USC 300e-11.

"Qualified health maintenance carrier." 42 USC 300e-9.

42 USC 300e-11.

Determination, notification. a prior civil action to review the assessment of such penalty the court held a trial de novo on such assessment. "(f) 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 Rate Commission) of any of the foregoing; 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 the Internal Revenue Code of 1954, 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. "(g) If the Secretary, after reasonable notice and opportunity for hearing to a State, finds that it or any of its political subdivisions has failed to comply with one or more of the requirements of subsection (a), the Secretary shall terminate payments to such State under sections 314(d), 317, 318, 1002, 1525, and 1613 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.

"(h) The duties and functions of the Secretary, insofar as they involve making determinations as to whether an organization is a qualified health maintenance organization within the meaning of subsection (d), shall 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 shall be integrated with the administration of section 1312(a)."

(b) Section 8902 of title 5, United States Code, relating to Federal employee health insurance, is amended by adding at the end thereof the following new subsection:

"(1) The Commission shall contract under this chapter for a plan described in section 8903(4) of this title with any qualified health maintenance carrier which offers such a plan. For the purpose of this subsection, 'qualified health maintenance carrier' means any qualified carrier which is a qualified health maintenance organization within the meaning of section 1310(d)(1) of title XIII of the Public Health Service Act (42 U.S.C. 300c-9(d))."

ENFORCEMENT REQUIREMENTS

SEC. 111. (a) Section 1312(a) is amended by striking out all of the section following paragraph (3) and substituting the following: "the Secretary may take the action authorized by subsection (b)."

(b) Section 1312(b) is amended to read as follows:

"(b) (1) If the Secretary makes, with respect to any entity which provided assurances to the Secretary under section 1310(d)(1), a determination described in subsection (a), 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 Notification. corrective action within the period prescribed by the notice or fails to comply with the assurances within such period as the Secretary prescribes (A) the entity shall not be a qualified health maintenance organization for purposes of section 1310 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 1310, 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 title, a determination described in subsection (a), 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 title for the grant, contract. loan, or loan guarantee.".

(c) Section 1312 is amended by adding at the end the following new subsection :

"(c) The Secretary, acting through the Assistant Secretary for Health, shall administer subsections (a) and (b) in the Office of the Assistant Secretary for Health.".

HMO'S AND FEDERAL HEALTH BENEFITS PROGRAMS.

SEC. 112. Section 1307(d) is amended by adding after and below paragraph (2) the following new sentence: "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, United States Code, may be considered as a health maintenance organization for purposes of receiving assistance under this title if with respect to its other members it provides health services in accordance with section 1301(b) and is organized and operated in the manner prescribed by section 1301(c).".

EXTENSIONS AND AUTHORIZATIONS

SEC. 113. (a) Section 1304(j) is amended (1) by striking out "September 30, 1976" and substituting "September 30, 1978", and (2) by striking out "September 30, 1977" and substituting "September 30, 1979"

(b) Subsection (d) of section 1305 is amended to read as follows: (d) No loan may be made or guaranteed under this section after September 30, 1980."

42 USC 300e-9.

Publication in Federal Register.

42 USC 300e-11. Administration.

42 USC 300e-6.

5 USC 8901 et seq.

42 USC 300e.

42 USC 300e-3.

42 USC 300e-4.

42 USC 300e-8.

(c) Section 1309(a) is amended—

thereof is amended to read as follows:

Such report shall contain findings-".

following new section:

(1) by striking out "and" after "1975,",

(2) by inserting after "1976" the following: ", \$45,000,000 for the fiscal year ending September 30, 1977, and \$45,000,000 for the fiscal year ending September 30, 1978",

(3) by striking out "ending June 30, 1977" and substituting "ending September 30, 1977", and (4) by striking out "\$85,000,000" the first time it occurs and

substituting "\$40,000,000", and by striking out "\$85,000,000" the second time it occurs and substituting "\$50,000,000".

RESTRICTIVE STATE LAWS

42 USC 300e-10. Digest.

SEC. 114. Section 1311 is amended by adding at the end the following new subsection:

(c) The Secretary shall, within 6 months after the date of the enactment of this subsection, 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 quarterly 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."

PROGRAM EVALUATION BY THE COMPTROLLER GENERAL SEC. 115. So much of section 1314(a) as precedes paragraph (1)

"SEC. 1314. (a) The Comptroller General shall evaluate the operations of at least ten or one-half (whichever is greater) of the health maintenance organizations for which assistance was provided under

sections 1303, 1304, and 1305, and which, by December 31, 1976, have

been designated by the Secretary under section 1310(d) as qualified

health maintenance organizations. The Comptroller General shall report to the Congress the results of the evaluation by June 30, 1978.

42 USC 300e-13.

42 USC 300e-2-300e-4. Report to Congress.

> ADMINISTRATION OF PROGRAMS SEC. 116. Title XIII is amended by adding after section 1315 the

"ADMINISTRATION OF PROGRAM

42 USC 300e-15. 42 USC 300e-9,

"SEC. 1316. The Secretary shall administer this title (other than sections 1310 and 1312) through a single identifiable administrative unit of the Department.".

CONFORMING AMENDMENTS

SEC. 117. (a) Section 1532(c) is amended by adding the following sentence at the end thereof: "The criteria established by any health systems agency or State Agency under paragraph (8) shall be consistent with the standards and procedures established by the Secretary under section 1306(c) of this Act.".

300e-11.

42 USC 300n-1.

42 USC 300e-5.

(b) (1) Paragraph (6) of section 1302 is amended to read as follows: "(6) The term 'health systems agency' means an entity which is designated in accordance with section 1515 of this Act.".

(2) Paragraph (7) of section 1302 is amended by-

(A) striking "section 314(a) State health planning agency whose section 314(a) plan" and substituting "State health planning and development agency which"; and

(B) striking "section 314(b) areawide health planning agency whose section 314(b) plan", and substituting "health systems agency designated for a health service area which".

(3) Paragraph (1) of section 1303(b) is amended by striking "sec- 42 USC 300e-2. tion 314(b) areawide health planning agency (if any) whose section 314(b) plan" and substituting "each health systems agency designated for a health service area which".

(4) Paragraph (1) of section 1304(c) is amended by striking "sec- 42 USC 300e-3. tion 314(b) areawide health planning agency (if any) whose section 314(b) plan" and substituting "each health systems agency designated for a health service area which".

(5) Section (b) (5) of section 1306 is amended to read as follows: "(5) 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 :".

(6) Subsection (c) of section 1306 is amended by striking "section 314(b) areawide health planning agencies and section 314(a) State health planning agencies" and substituting "health systems agencies".

EFFECTIVE DATES

SEC. 118. (a) Except as provided in subsection (b), the amendments made by this title shall take effect on the date of the enactment of this Act.

(b) (1) The amendments made by sections 101, 102, 103, 104, and 106 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 for fiscal years beginning after September 30, 1976, (B) apply with respect to health benefit plans offered under section 1310 of such Act after such date, and (C) for purposes of section 1312 take effect October 1, 1976.

(2) Subsection (d) of section 1301 of the Public Health Service Act (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.

(3) The amendments made by section 107 shall apply with respect to grants, contracts, loans, and loan guarantees made under sections 1303, 1304, and 1305 of the Public Health Service Act for fiscal years beginning after September 30, 1976.

(4) The amendments made by sections 109(a)(1) and 109(c) shall apply with respect to loan guarantees made under section 1305 of the Public Health Service Act after September 30, 1976.

(5) The amendment made by section 109(e) shall apply with respect to projects assisted under section 1304 of the Public Health Service Act after September 30, 1976.

(6) The amendments made by paragraphs (1) and (2) of section 110(a) shall apply with respect to calendar quarters which begin after the date of the enactment of this Act.

42 USC 300e-1. "Health systems agency." 42 USC 3001-4.

42 USC 300e-5.

42 USC 300e note.

42 USC 300e-2-300e-4.

42 USC 300e-9.

42 USC 300e-11.

42 USC 300e.

42 USC 300e-9.

42 USC 300e-11. (7) The amendments made by paragraphs (3) and (4) of section 110 shall apply with respect to failures of employers to comply with section 1310(a) of the Public Health Service Act after the date of the enactment of this Act.

(8) The amendment made by section 111 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 and made after the date of the enactment of this Act.

TITLE II-AMENDMENTS TO SOCIAL SECURITY ACT

MEDICARE AMENDMENTS

42 USC 1395mm. "Health maintenance organization."

42 USC 1395x.

42 USC 300e.

"Basic health services."

Administration.

SEC. 201. (a) Section 1876(b) of the Social Security Act is amended to read as follows:

"(b) (1) The term 'health maintenance organization' means a legal entity which provides health services on a prepayment basis to individuals enrolled with such organizations and which—

"(A) provides to its enrollees who are insured for benefits under parts A and B of this title or for benefits under part B alone, through institutions, entities, and persons meeting the applicable requirements of section 1861, all of the services and benefits covered under such parts (to the extent applicable under subparagraph (A) or (B) of subsection (a) (1)) which are available to individuals residing in the geographic area served by the organization;

⁷⁷(B) provides such services in the manner prescribed by section 1301(b) of the Public Health Service Act, except that solely for the purposes of this section—

"(i)" the term 'basic health services' and references thereto shall be deemed to refer to the services and benefits included under parts A and B of this title;

"(ii) the organization shall not be required to fix the basic health services payment under a community rating system;

"(iii) the additional nominal payments authorized by section 1301(b)(1)(D) of such Act shall not exceed the limits applicable under subsection (g) of this section; and

^{*a}(iv) payment for basic health services provided by the organization to its enrollees under this section or for services such enrollees receive other than through the organization shall be made as provided for by this title;

"(C) is organized and operated in the manner prescribed by section 1301(c) of the Public Health Service Act, except that solely for the purposes of this section—

"(i) the term 'basic health services' and references thereto shall be deemed to refer to the services and benefits included under parts A and B of this title;

"(ii) the organization shall not be reimbursed for the cost of reinsurance except as permitted by subsection (i) of this section; and

"(iii) the organization shall have an open enrollment period as provided for in subsection (k) of this section.

"(2) (A) The duties and functions of the Secretary, insofar as they involve making determinations as to whether an organization is a 'health maintenance organization' within the meaning of paragraph (1), shall 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 shall be integrated with the administration of section 1312 (a) and (b) of the Public Health Service Act.

"(B) Except as provided in subparagraph (A), the Secretary shall administer the provisions of this section through the Commissioner of Social Security.".

(b) Section 1876(h) of such Act is amended to read as follows: 42 USC

"(h) (1) Except as provided in paragraph (2), each health mainte- 1395mm. nance organization with which the Secretary enters into a contract under this section shall have an enrolled membership at least half of which consists of individuals who have not attained age 65.

"(2) The Secretary may waive the requirement imposed in para- Waiver. graph (1) for a period of not more than three years from the date a health maintenance organization first enters into an agreement with the Secretary pursuant to subsection (i), but only for so long as such organization demonstrates to the satisfaction of the Secretary by the submission of its plan for each year that it is making continuous efforts and progress toward compliance with the provisions of paragraph (1) within such three-year period.".

(c) Section 1876(i)(6)(B) of such Act is amended by striking out "(other than those with respect to out-of-area services)" and inserting in lieu thereof "(other than costs with respect to out-of-area services and, in the case of an organization which has entered into a risksharing contract with the Secretary pursuant to paragraph (2)(A), the cost of providing any member with basic health services the aggregate value of which exceeds \$5,000 in any year)".

(d) Section 1876 is amended by adding at the end thereof the following-

"(k) Each health maintenance organization with which the Secretary enters into a contract under this section shall have an open enrollment period at least every year under which it accepts up to the limits period. of its capacity and without restrictions, except as may be authorized in regulations, individuals who are eligible to enroll under subsection (d) in the order in which they apply for enrollment (unless to do so would result in failure to meet the requirements of subsection (h)) or would result in enrollment of enrollees substantially nonrepresentative, as determined in accordance with regulations of the Secretary, of the population in the geographic area served by such health maintenance organization.".

(e) The amendments made by this section shall be effective with Effective date. respect to contracts entered into between the Secretary and health 42 USC maintenance organizations under section 1876 of the Social Security 1395mm note. Act on and after the first day of the first calendar month which begins more than 30 days after the date of enactment of this Act.

MEDICAID AMENDMENTS

SEC. 202. (a) Section 1903 of the Social Security Act is amended by 42 USC 1396b. adding at the end thereof the following new subsection:

"(m) (1) (A) The term 'health maintenance organization' means a legal entity which provides health services to individuals enrolled in such organization and which-

"(i) provides to its enrollees who are eligible for benefits under this title the services and benefits described in paragraphs (1),

(2), (3), (4) (C), and (5) of section 1905, and, to the extent 42 USC 1396d. required by section 1902(a)(13)(A)(ii) to be provided under a 42 USC 1396a. State plan for medical assistance, the services and benefits described in paragraph (7) of section 1905(a);

42 USC 300e-11.

Open enrollment

"Health maintenance organization."

"Basic health services." 42 USC 300e.

42 USC 1396d. 42 USC 1396a. "(ii) provides such services and benefits in the manner prescribed in section 1301(b) of the Public Health Service Act (except that, solely for purposes of this paragraph, the term 'basic health services' and references thereto, when employed in such section, shall be deemed to refer to the services and benefits described in paragraphs (1), (2), (3), (4)(C), and (5) of section 1905(a), and, to the extent required by section 1902(a) (13) (A) (ii) to be provided under a State plan for medical assistance, the services and benefits described in paragraph (7) of section 1905 (a)); and

"(iii) is organized and operated in the manner prescribed by section 1301(c) of the Public Health Service Act (except that solely for purposes of this paragraph, the term 'basic health services' and references thereto, when employed in such section shall be deemed to refer to the services and benefits described in section 1905(a)(1),(2),(3),(4)(C), and (5), and to the extent required by section 1902(a)(13)(A)(ii) to be provided under a State plan for medical assistance, the services and benefits described in paragraph (7) of section 1905(a)).

"(B) The duties and functions of the Secretary, insofar as they involve making determinations as to whether an organization is a health maintenance organization within the meaning of subparagraph (A), shall 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 shall be integrated with the administration of section 1312 (a) and (b) of the Public Health Service Act.

"(2) (A) Except as provided in subparagraphs (B) and (C), no payment shall be made under this title to a State with respect to expenditures incurred by it for payment for services provided by any entity—

"(i) which is responsible for the provision of-

"(I) inpatient hospital services and any other service described in paragraph (2), (3), (4), (5), or (7) of section 1905(a), or

"(II) any three or more of the services described in such paragraphs,

when payment for such services is determined under a prepaid capitation risk basis or under any other risk basis;

i'(ii) which the Secretary (or the State as authorized by paragraph (3)) has not determined to be a health maintenance organization as defined in paragraph (1); and

"(iii) more than one-half of the membership of which consists of individuals who are insured under parts A and B of title XVIII or recipients of benefits under this title.

"(B) Subparagraph (A) does not apply with respect to payments under this title to a State with respect to expenditures incurred by it for payment for services provided by an entity which—

for payment for services provided by an entity which— "(i) (I) received a grant of at least \$100,000 in the fiscal year ending June 30, 1976, under section 319(d) (1) (A) or 330(d) (1) of the Public Health Service Act, and (II) for the period beginning July 1, 1976, and ending on the expiration of the period for which payments are to be made under this title has been the recipient of a grant under either such section; and

42 USC 300e-11.

Administration.

42 USC 247d, 254c. "(II) provides to its enrollees, on a prepaid capitation risk basis or on any other risk basis, all of the services and benefits described in paragraphs (1), (2), (3), (4) (C), and (5) of section 1905(a) and, to the extent required by section 1902(a)(13)(A)(ii) to be provided under a State plan for medical assistance, the services and benefits described in paragraph (7) of such section; or

"(ii) is a nonprofit primary health care entity located in a rural area (as defined by the Appalachian Regional Commission)—

"(I) which received in the fiscal year ending June 30, 1976, at least \$100,000 (by grant, subgrant, or subcontract) under the Appalachian Regional Development Act of 1965, and

"(II) for the period beginning July 1, 1976, and ending on the expiration of the period for which payments are to be made under this title either has been the recipient of a grant, subgrant, or subcontract under such Act or has provided services under a contract (initially entered into during a year in which the entity was the recipient of such a grant, subgrant, or subcontract) with a State agency under this title on a prepaid capitation risk basis or on any other risk basis; or

"(iii) which has contracted with the single State agency for the provision of services (but not including inpatient hospital services) to persons eligible under this title on a prepaid risk basis prior to 1970.

"(C) Subparagraph (A) (iii) shall not apply with respect to payments under this title to a State with respect to expenditures incurred by it for payment for services by an entity during the three-year period beginning on the date of enactment of this subsection or beginning on the date the entity enters into a contract with the State under this title for the provision of health services on a prepaid risk basis, whichever occurs later, but only if the entity demonstrates to the satisfaction of the Secretary by the submission of plans for each year of such three-year period that it is making continuous efforts and progress toward achieving compliance with subparagraph (A) (iii).

"(3) A State may, in the case of an entity which has submitted an application to the Secretary for determination that it is a health maintenance organization within the meaning of paragraph (1) and for which no such determination has been made within 90 days of the submission of the application, make a provisional determination for the purposes of this title that such entity is such a health maintenance organization. Such provisional determination shall remain in force until such time as the Secretary makes a determination regarding the entity's qualification under paragraph (1)."

(b) The amendment made by subsection (a) shall apply with respect to payments under title XIX of the Social Security Act to States for services provided—

(1) after the date of enactment of subsection (a) under contracts under such title entered into or renegotiated after such date, or

(2) after the expiration of the 1-year period beginning on such date of enactment, whichever occurs first.

42 USC 1396d. 42 USC 1396a.

40 USC app. 1.

PUBLIC LAW 94-460-0CT. 8, 1976

TITLE III—MISCELLANEOUS AMENDMENTS

CENTER FOR HEALTH SERVICES POLICY ANALYSIS

42 USC 242c.

SEC. 301. Section 305(d)(1) of the Public Health Service Act is amended (1) by striking out "two national special emphasis centers" and substituting "three national special emphasis centers", (2) by striking out "and one" and substituting "one", and (3) by inserting before the last close parenthesis a semicolon and the following: "and one of which (to be designated as the Health Services Policy Analysis Center) shall focus on the development and evaluation of national policies with respect to health services, including the development of health maintenance organizations and other forms of group practice, with a view toward improving the efficiencies of the health services delivery system".

HOME HEALTH EXTENSION

42 USC 1395x note.

SEC. 302. (a) Section 602(a) (5) of Public Law 94-63 is amended by inserting ", \$2,000,000 for the period July 1, 1976, through September 30, 1976, \$8,000,000 for the fiscal year ending September 30, 1977" after "1976".

(b) Section 602(b) (4) of Public Law 94-63 is amended by inserting ", \$1,000,000 for the period July 1, 1976, through September 30, 1976, and \$4,000,000 for the fiscal year ending September 30, 1977" after "1976".

EXTENSION OF REPORTING DATE

42 USC 289k-2 note.

SEC. 303. Section 603(b) of Public Law 94-63 is amended by striking "Within one year" and substituting "Not later than 2 years".

TECHNICAL

21 USC 360d.

SEC. 304. Section 514(a) of the Federal Food, Drug, and Cosmetic Act is amended by redesignating paragraphs (4) and (5) as paragraphs (3) and (4), respectively.

Approved October 8, 1976.

LEGISLATIVE HISTORY:

HOUSE REPORTS: No. 94-518 (Comm. on Interstate and Foreign Commerce) and No. 94-1513 (Comm. of Conference).

SENATE REPORT No. 94-844 accompanying S. 1926 (Comm. on Labor and Public Welfare).

CONGRESSIONAL RECORD:

Vol. 121 (1975): Nov. 7, considered and passed House.

Vol. 122 (1976): June 14, considered and passed Senate, amended, in lieu of S. 1926.

Sept. 16, Senate agreed to conference report.

Sept. 23, House agreed to conference report. WEEKLY COMPILATION OF PRESIDENTIAL DOCUMENTS: Vol. 12, No. 42 (1976): Oct. 9, Presidential statement.