HCRS for consideration in the 1981 Action Program. After public comment these issues will be correlated to form core issues. Many are still in the problem statement stage at this time. Some of the issues may continue through more than one Annual Action Program, with different aspects addressed in succeeding years. They are as follows:

1. *Strengthen employment-recreation linkages.* This issue deals with the response of park and recreation systems to longterm social problems like unemployment. How can training and placement opportunities be made available to disadvantaged workers in maintenance, rehabilitation and development projects for part and recreation facilities? What are possible linkages with youth, minority, refugee, delinquency, and other social concerns?

2. *Improve small community recreation program delivery.* How can we build onto existing institutional stuctures to increase small community capacities to use funds effectively for recreation?

3. *Develop effective health promotion strategies.* How can mutually cooperative strategies be developed to include health and physical fitness programs in park and recreation settings? How can activities for employees be encouraged during leisure time at the workplace and related to beneftis such as productivity and health?

4. *Elderly population recreation.* Demographics show that the retirement and elderly population is increasing. In what ways will this expanding recreation need be met?

5. *Safety in parks and recreation.* How can safety problems be corrected by recreation facility design and programming? Also, what policies should be developed to aid in determining the responsibilities of park and recreation managers in risk environments and activities?

6. *Issue-oriented research for decisionmakers.* How can research and information assist decisionmakers better? How can data bases (such as visitor use statistics) be made comparable to ensure maximum use and sharing of information? Timely research needs include: vacation patterns and leisure trends, budget cut impacts on park and recreation programs, recreation facility design and planning for energy development.

7. *Inadequate recreation funding.* Growing recreation demand is often not reflected in these budget areas: operation and maintenance, construction and development, and land acquisition. How can these funds be kept from being diminished at disproportionate rates compared to other budget items? What are ways that parks can fill the gap in funding for operation and maintenance? What are the impacts of regressive user fees?

8. *Water resources and recreation.* Has public access been adequately addressed in urban waterfront revitalization and improved water quality areas? Is lake, river and stream protection receiving priority consideration by all levels of government and the private sector?

9. *Handicapped access.* In what areas should accessible recreation for disabled persons receive further emphasis?

10. *Increase the amount of available recreation land where it is most needed.* What methods are available or should be developed to increase or ensure adequate recreation resources? How can Federal goals for open space and recreation be clarified to provide direction in land acquisition and guidelines for state planning? Several concerns are tied to the need for available and accessible land for recreation: closure of private lands to recreationists, and the need for preservation of open space around urban areas to provide close-to-home recreation.

11. *Maintain the quality of recreation lands.* How can the natural characteristics be kept intact on currently owned land resources? This is a large issue area which covers: Intensive use of wilderness and decline of the resource; pollution such as acid rain which can affect an entire biological community; protection of areas to perpetuate natural diversity; and land adjacency issues which are characterized by a lack of intergovernmental planning and coordination.

12. *Emphasize the public transportation role in meeting recreation demand in an energy-efficient manner.* What are the possibilities of the following concepts: Recreational transit service funding in certain Federal grants; development of incentive packages for transit services to recreation areas; and regional information/travel centers with intermodal transportation focal points?

DATE: Comments must be received by December 1, 1980.

ADDRESS: Send written comments to Shirley D. Patterson, Division Chief, Nationwide Recreation Planning, Heritage Conservation and Recreation Service, 440 G Street, N.W., Washington, D.C. 20243.

FOR FURTHER INFORMATION CONTACT:

Marcia Keener, Outdoor Recreation Planner, Division of Nationwide Recreation Planning, Department of the Interior, Heritage Conservation and Recreation Service, Washington, D.C. 20243 (202) 343–4317.

Dated: October 28, 1980.

Meg Maguire,

Acting Director, Heritage Conservation and Recreation Service.

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October 31, 1980

Part VII

Department of Health and Human Services

Public Health Service

Health Maintenance Organizations; Employees' Health Benefits Plans; Final Regulations

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

42 CFR Part 110

Health Maintenance Organizations; Employees' Health Benefits Plans

AGENCY: Public Health Service, HHS.
ACTION: Final Regulations.

SUMMARY: This rule amends the Public Health Service regulations by setting forth revised requirements for certain employers, States, and political subdivisions of States to include in any health benefits plans offered to their employees the option of membership in qualified health maintenance organizations (HMOs). These changes are made as a result of public comments received on the notice of proposed rulemaking (NPRM) published on July 18, 1979. Certain minor technical and editorial changes have also been made.

EFFECTIVE DATE: This rule is effective on December 1, 1980.

FOR FURTHER INFORMATION CONTACT: Howard R. Veit, Director, Office of Health Maintenance Organizations, Park Building—3rd Floor, 12420 Parklawn Drive, Rockville, Maryland 20857, 301/443–4106.

SUPPLEMENTARY INFORMATION: On July 18, an NPRM was published in the **Federal Register** (44 FR 42083–91) proposing changes to 42 CFR Part 110, Subpart H, issued under Title XIII of the Public Health Service Act, as amended (the Act). Section 1310 of the Act (42 U.S.C. 300e–9) requires certain employers, States, and political subdivisions of States to include in the health benefits plans offered their employees the option of membership in qualified health maintenance organizations (HMOs).

Interested persons were given an opportunity to submit comments on the proposed amendments by September 17, 1979. Forty-four comments were received by September 17, 1979, and three were received after that date. All comments received were considered in revising these regulations.

As an introductory note, the Department wishes to emphasize that to the extent that the employing entity (the collective term for employers, States and political subdivisions of States) and qualified HMOs can negotiate successfully the inclusion of the HMO option(s) in the employing entity's health benefits plan, it encourages such negotiation. However, in order for an HMO to maintain its status as a qualified HMO, it must provide services and be organized and operated in accordance with Subpart A of this Part ("Requirements for a Health Maintenance Organization"). Thus, in negotiating with a qualified HMO, an employing entity may not insist upon any terms which would require the HMO to violate any Subpart A requirements.

The comments received, responses thereto, and the changes made, if any, are summarized below:

1. Proposed § 110.803(a) defined when the request for inclusion by an HMO must be received by an employing entity in terms of the expiration or renewal date of certain contracts. Subparagraph (2)(ii) of that section stated that a collective bargaining agreement that is "for a fixed term in excess of one year and has provisions for periodically changing wages, hours, or conditions of employment * * *" is to be considered as either expired or renewable at the time provided by the agreement for discussion of these changes. Two commenters suggested that the term "periodically changing" was imprecise in that it covered both those provisions of the contract that changed automatically on a periodic basis without the need for discussion as well as those provisions that provided for a periodic discussion of changes. The Department notes that it intended for this provision to apply only when the contract contained the latter type of provision. It notes further that the section, as proposed, was also inadvertently broader than intended in that it referred to provisions for periodically changing "wages, hours, or conditions of employment." The Department intended that only provisions that provided for renegotiating health benefits should be considered in determining when the HMO should submit its request for inclusion. The Department believes that more precision is necessary in order to clarify both of these points. Accordingly, the phrase "* * * and provides that its terms regarding health benefits may be renegotiated during the term of the agreement * * *" has been substituted in § 110.803(a)(2)(ii) in place of the phrase "has provisions for periodically changing wages, hours, or conditions of employment." The same change has been made in § 110.807(a)(2), which relates to when the offer of the HMO option is to be raised in the collective bargaining process.

2. The purpose of § 110.803(c) is to require the HMO to furnish the employing entity with a broad description of the way the HMO is organized and operated, including sufficient information for it to determine whether it is subject to a request for inclusion by the HMO and, if so, and if there are competing HMOs, to determine which HMO(s) to offer. Section 110.803(c)(4) requires an individual practice association (IPA) type HMO to furnish to the employing entity a list of the IPA members by name, specialty, address, days and hours of operation and whether they are accepting new patients from the HMO membership, with the listing current within 90 days of the HMO's request for inclusion. One commenter requested that the HMO be required to list only the number of physicians in the IPA and another suggested that the HMO should list the telephone numbers of the IPA physicians instead of their days and hours of operation. The Department agrees that the proposed requirement is burdensome on the HMO and that employing entities do not need all of the information it would have required the HMO to provide. The Department believes that a more appropriate way to reduce the burden on the HMO is to delete the requirement that it include the addresses and days and hours of operation of the IPA physicians. Accordingly, § 110.803(c)(4) has been amended to require the HMO to list the IPA members by name, specialty, and whether they are accepting new patients from the HMO membership.

Other commenters noted the information required to be submitted about the IPA, as well as that required to be submitted by the non-IPA type HMOs under § 110.803(c)(5), could be inaccurate or out-of-date at the time of enrollment. The Department thinks that a listing current within 90 days of the HMO's request for inclusion is sufficient to meet the needs of the employing entity when the HMO makes this request. It emphasizes, however, that § 110.108(c) of Subpart A of this Part provides clearly that the HMO has the obligation to disclose fully and fairly information to prospective enrollees at the time of the offer of enrollment, including a general description of participating providers, as well as the locations and hours of service of the HMO.

3. Proposed § 110.803(c)(9) would have required the HMO to provide the employing entity with a report of the financial condition of the HMO consisting of its most current financial statements in addition to its most recently audited annual set of financial statements. One commenter opposed this requirement as being not only burdensome to the HMO, but also

potentially misleading to the employing entity in that the HMO's most current financial statements were not required to be audited. Other commenters suggested that the provision be revised to require the HMO to include a narrative description of its current financial position, as this would be more comprehensible to the layman. The Department agrees that this section should be changed in the interest of minimizing the burden on the HMO while at the same time providing that accurate, relevant information will be available to the employing entity. Accordingly, this section has been revised by deleting the requirement that the HMO must submit its most current financial statements. It now requires the HMO to provide only its most recently audited annual financial statements.

4. Proposed § 110.803(c)(12) would have required an HMO to provide the employing entity its proposed rates for basic and supplemental services to be charged by the HMO on the effective date of the HMO coverage. Under certain conditions, copayment levels and the corresponding premium rates were also required to be stated. A number of commenters requested clarification of this provision. In response to an inquiry as to which rating structures need to be included, the Department notes that, as a minimum, the HMO must provide its rates for an individual and for two or more persons. In response to an inquiry as to when, if ever, an HMO must furnish rates for supplemental health services and copayments, the offering of which are subject to negotiation (see discussion below in section 15), the Department notes that rates for the supplemental health services and copayments yet to be negotiated are not required to be provided to the employing entity at the time of the HMO's request for inclusion.

Additionally, a number of commenters were concerned that the HMO's statement of its proposed rates would be construed by the employing entity as a guarantee by the HMO that these would be its actual rates. These commenters felt that such an interpretation of the provision would be unfair because an HMO, at the time it requests inclusion, may not necessarily know: (a) The day on which the coverage for employees selecting the HMO option will begin; (b) the HMO's own cost experience in the interim before final rates are determined; and (c) the employing entity's preferred rating structure.

The Department notes that it did not intend to require the HMO to submit, at the time of its request, guaranteed rates. It agrees with the commenters that this interpretation of § 110.803(c)(12) would be unreasonable. It also believes that, because of the uncertainties inherent in estimating rates, HMOs should be given the option of stating their current rates (and the dates these rates become effective) instead of their estimated rates. Accordingly, the Department has revised the section. It now requires HMOs to state either (a) their current rates, including copayments, if any, for basic (and uniformly included supplemental) health services and the dates these rates became effective, or (b) their estimated rates for these services.

5. Proposed § 110.803(d) would have required the employing entity to respond, within 30 days of receipt of a request by an HMO for inclusion, with information enabling the HMO to determine whether the employing entity is required to offer the HMO option upon proper request.

The comments received by the Department as to this proposal and its responses thereto are as follows: (a) A number of commenters requested that the proposed 30 day response period be extended to assure that the employing entity had sufficient time to gather the necessary information. The Department agrees that a longer response period would be beneficial and has changed the 30 day response period to 60 days. The Department has extended similarly to 60 days the proposed 30 day period in § 110.803(e), which applies to the length of time the employing entity has to notify the HMO when it has concluded that the HMO's request is inadequate; (b) Two commenters recommended that since an employing entity is not subject to section 1310 of the Act unless 25 or more of its employees reside in the service area of the HMO, such an entity should be required to include information regarding its employees' health benefits plan only if it has 25 or more employees who reside within the service area of the HMO. The Department agrees with this comment and has incorporated this change into the regulation; (c) One commenter requested that, in order to inform the HMO more precisely, the employing entity should include, in addition to its contribution levels, the dates on which they became effective. The Department agrees that this information would be helpful to the HMO in deciding how to proceed with its request for inclusion in the employing entity's health benefits plan and has incorporated this requirement in the final regulations; and (d) One commenter requested that private employers, in addition to public entities, be required to furnish the HMO with a description of the health benefits that are required to be included in health benefits plans under State law or regulation. The Department notes that the reason that the regulation is limited to public entities is that there are laws or regulations in some States requiring certain benefits, including limitations and exclusions, that are applicable only to employees of public entities, in contrast with those laws or regulations requiring certain benefits that are applicable to all employees in a State. Since the Department believes that this latter, more general type of information is readily available to HMOs, it does not find it necessary to increase the burden on private employers by requiring them to furnish this information to the HMO.

6. Section 110.803(e) pertains to the notification of the HMO by the employing entity that the HMO's request for inclusion is inadequate. As noted above in section 5, the section has been modified, in response to public comment, to allow the employing entity 60 days to notify the HMO. Three commenters objected to this proposed section on the grounds that the HMO, and not the employing entity, should be responsible for submitting a valid request. The Department notes that the HMO is, of course, responsible for submitting an accurate request for inclusion. However, the Department believes that, if the employing entity intends to refuse to include the HMO alternative in its health benefits plan because it believes the HMO's request to be insufficient, it is only reasonable that the entity notify the HMO of the basis for its conclusion.

One commenter recommended that employing entities be allowed, as a condition of the HMO's participation in the health benefits plan, to make their own determinations as to the fiscal soundness of an HMO which has requested inclusion. The Department believes that this type of scrutiny of an HMO is unnecessary. It notes that federally qualified HMOs are required, under § 110.108(a) of the regulations, to have fiscally sound operations and that the Department monitors carefully their compliance with that requirement. Moreover, to permit each employing entity to make this determination as a requirement for the HMO's inclusion in the health benefits plan would lead to inconsistent determinations and would undermine the purposes of section 1310 by allowing the exclusion of HMOs that the Department has determined are eligible for inclusion.

7. Section 110.803(f) describes when an HMO must submit a new request for

inclusion in a health benefits plan of an employing entity. Four commenters recommended that, regardless of whether any employees enroll in the HMO during the initial offering, the entity should be required to continue to offer the HMO during the entire health benefits year so that new employees, transfers, and others who subsequently become eligible to enroll in the HMO (see § 110.806(e)(2) for a complete list) have the opportunity to do so. Other commenters took the opposite position; namely, that if the HMO does not get any enrollees during the initial offering period, it should have to submit a new request in order for any subsequently eligible employees to enroll. The Department believes that the former position reflects accurately the purposes of section 1310 of the Act in that it assures that more employees will be offered the option of membership in a qualified HMO. Accordingly, the regulation has been changed to require that the employees described in § 110.806(e)(2) be given the opportunity to enroll in the HMO during the entire health benefits year, regardless of whether any other employees of that entity have enrolled previously in the HMO.

8. Section 110.804 sets forth the details of how the HMO option is to be offered by the employing entity to its employees. One commenter suggested that, as a condition to the offering of the HMO, the HMO should be required to execute a contract with the employing entity binding the HMO to assure the delivery of health services to employees who subsequently enroll in the HMO. The Department notes that, in order to obtain Federal qualification, an HMO must provide assurances satisfactory to the Secretary that it will arrange for the provision of all medically necessary basic health services to its members. (See § 110.102(a)). Since the Department monitors, on an ongoing basis, the compliance of HMOs with their assurances, it does not believe that the contract suggested above between the employing entity and the HMO is necessary.

9. Section 110.805 describes which HMOs must be included in a health benefits plan. Paragraph (c) of this section, which is intended to promote competition among HMOs, describes alternate HMOs which may be offered by the employing entity instead of an HMO which made a timely request. A new section (c)(4) was proposed to limit the alternate HMOs which were otherwise eligible to be offered to those which were "included in the health benefits plan on terms no less favorable to the employing entity's employees (with regard to the employing entity's monetary contribution) than those on which the HMO submitting the timely request would have been included." A number of commenters objected to and suggested deletion of the proposed § 110.805(c)(4). They stated that the phrase "no less favorable" was ambiguous and could result in the offering of an alternate HMO that, even though the employer's monetary contribution was no less favorable to the employee, (a) underbid the timely HMO by offering employees a less favorable package of health benefits, or (b) was less favorable to employees in that it would cost them more out-of-pocket (e.g. for copayments).

The Department, while noting that § 110.805(c)(4) was intended to protect employees, acknowledges that the provision fails to contribute to that end because it does not protect employees in situations such as those described above. The Department has decided to delete this provision because of the difficulties inherent in trying to determine on a qualitative basis whether a plan is less favorable to an employee, and because it is not convinced that there is a problem with employer behavior in this regard. However, the Department is interested in receiving information from the public as to whether § 110.805(c) is being used in a manner that affects employees adversely. Upon receipt of such comments, it will reconsider what action, if any, is appropriate.

10. Section 110.806(a) requires that each employing entity provide each qualified HMO which is included in its health benefits plan with "fair and reasonable" access to eligible employees. The section then details what, at a minimum, this access shall include. While one commenter wanted the HMO's access to employees to be more flexible, others suggested that the term be defined in specific detail. The Department believes that the regulation adequately defines access by setting forth the minimum requirements for fair and reasonable access. It notes that an employing entity may, of course, agree to permit the HMO more favorable access than that required by the regulation.

11. Section 110.806(c), which sets forth the rules for the group enrollment period, requires the employing entity to have a group enrollment period with no waiting periods or exclusions or limitations based on health status as a condition of enrollment in the HMO or transfer to non-HMO coverage from an HMO. Two commenters recommended changing this section to allow a prospective HMO enrollee to remain with his original carrier if on the effective date of change to HMO coverage the enrollee is an inpatient and the original carrier responsibility continues through confinement. The Department notes that it has no authority to mandate the application of coordination of benefits agreements. However, as stated in § 110.806(c), nothing in these regulations prohibits voluntary agreements between HMOs and other carriers which are included in the health benefits plan, such as the one suggested above.

12. Section 110.806(d), as proposed, required the employing entity to "assure that employees selecting the option of HMO membership will not, because of this selection, lose their eligibility for other health benefits, such as dental or prescription drug coverage, for which they were previously eligible or would be eligible if selecting a non-HMO option and which are not included in the services provided by the HMO on a prepaid basis." This requirement, for convenience, will be referred to below as the "continued eligibility" requirement.

Twenty commenters addressed the continued eligibility requirement in their letters. The comments are summarized as follows: (a) One commenter urged the Department to retain the language as proposed, citing the requirement as critical for HMOs to compete in the marketplace; (b) one commenter, while approving the proposed regulation, urged its expansion to assure eligibility for any employment-related benefits; (c) five commenters objected to the provision, claiming it would unduly burden and result in additional administrative costs to employers; (d) eleven commenters felt the proposed regulation should be limited to "free-standing" or "self-contained" benefits, that is, benefits which are offered as a separate, discrete package and not integrated into a basic medical insurance policy or a major medical plan; many of these commenters requested clarification as to the level and scope of benefits the Department was proposing be subject to the requirement; and (e) four commenters urged that the requirement apply only to free-standing benefits, except that dental benefits should be extracted from a comprehensive package of indemnity benefits because the dental benefit is "significant."

The Department notes that the purpose of section 1310 and its implementing regulations is to assure that employees are given a true option

to choose among competing alternatives in health benefits plans, including HMOs. The continued eligibility requirement, which assures that employees who choose to enroll in an HMO are not penalized by that choice with respect to free-standing health benefits available to employees is, among other provisions, a means of achieving that statutory purpose.

In light of the public comments received, however, the Secretary has revised the regulation to require an employing entity, at the request of the HMO, to provide for continued eligibility only as to those benefits which are "free-standing" and not offered by the HMO to its members as part of the HMO benefit package. The term "free-standing" is defined at § 110.806(d)(2). Further, the provision at § 110.806(d) is applicable only when the HMO does not offer a particular health benefit in whole or in part. Because, in the experience of the Department, this is most likely to occur with respect to the offering of three distinct health benefits, prescription drugs, dental services, and optical services, the Department has limited the applicability of § 110.806(d) to these benefits. Should the public submit information regarding any other free-standing health benefits for which employees selecting the HMO option would be likely, in the absence of the continued eligibility requirement, to lose their eligibility, the Department will consider further rulemaking to broaden the requirement.

In view of the response that this proposed section elicited, the Department believes that it is appropriate to clarify this section by adding to the regulation specific examples of what the employing entity is, and is not, required to continue to make available to its employees selecting an HMO option. This addition to the regulations includes examples showing when the employing entity is required to continue to make available the free-standing benefits not available through the HMO to its employees because the HMO option being offered does not provide for any level of that particular benefit. The regulation also includes examples showing when the employing entity need not continue to make available the free-standing, non-HMO coverage to employees selecting the HMO option.

In addition, as noted in one of the examples under § 110.806(d), nothing in this regulation requires that the coverage for the free-standing benefit be made optional (or mandatory) for employees selecting the HMO option if coverage for the benefit is not optional (or mandatory) for employees selecting the non-HMO option.

The Department also notes that § 110.806(d) does not address whether the employing entity must continue to make available to employees who select the HMO option non-health related benefits, such as life or disability insurance. While the Department has decided not to include in these regulations a requirement that employing entities continue to make these non-health benefits available, it is concerned that any employing entity that does not do so may be acting in a manner inconsistent with other Federal statutes. The Department intends to report any discriminatory or anti-competitive conduct to the appropriate Federal agencies for monitoring in this regard. Moreover, it notes that under § 110.808(c), the employing entity may only exclude from its contribution to the HMO option those portions of the contribution allocable to benefits (either related to health or not) for which eligible employees continue to be covered notwithstanding selection of the HMO option.

Finally, the Department notes that, while it is now limiting this requirement to free-standing benefits, the HMO and employer may agree to give employees access to coverage for an "integrated" benefit.

13. Section 110.806(e)(2) specifies when the employng entity shall make available the opportunity to select among different existing alternatives within a health benefits plan outside of the group enrollment period. Proposed § 110.806(e)(2)(ii) specified that this opportunity must be provided, among others, to eligible employees who, "have been transferred or have changed their place of residence, resulting in * * * loss of membership in a qualified HMO in which they were previously enrolled." A commenter noted that this language would not have given an otherwise eligible employee the opportunity to select a new option if he or she transferred or moved out of the service area of the HMO in which he or she was enrolled and was allowed by that HMO to retain membership. While this employee would not have lost membership in a qualified HMO, the services of the HMO would not longer be readily available and accessible since the employee would reside outside the HMO's service area. In order to accommodate this situation, the Department has changed the phrase, "resulting in loss of membership in a qualified HMO in which they were previously enrolled" to "resulting in residence outside the service area of a qualified HMO in which they were previously enrolled."

14. Section 110.806(e)(2)(iii) requires the employing entity to make available the opportunity to select among different existing alternatives within a health benefits plan to eligible employees who are covered by any alternative which ceases operation. One commenter felt this requirement should be deleted since it placed an unreasonable burden on employing entities. Another commenter suggested that the provision be amended to allow for a reasonable period of time for the transition of these employees to a new health benefits option. Since the Department believes that the section as proposed is reasonable in light of the importance of assuring that all employees are provided the opportunity for continuous health care coverage, it has not changed this section.

15. Two different proposed sections addressed the determination of which supplemental health services were to be included with the required basic health services in the HMO's prepaid benefit package. Proposed § 110.806(f)(3) would have allowed the HMO to select, for all employees, the supplemental health services to be included as part of its prepaid benefit package. Proposed § 110.808(a)(3) would have allowed the HMO to add supplemental health services to its prepaid benefit package if the amount of the HMO's premium is less than the employing entity's contribution to the HMO alternative. A number of commenters objected to these proposed rules on the following grounds: (a) They would only only increase the cost of health care but also eliminate the potential cost savings of offering an HMO, which is a major reason for the attractiveness of HMOs to employing entities; and (b) The inclusion of supplementals is more properly a subject for the negotiation process; in fact, allowing the HMO to select supplemental defeats the provisions of § 110.806(f) (1) and (2), which give the employing entity the right either to negotiate the supplemental health services to be offerd through its collective bargaining process or to select them through the same decision-making process it uses with respect to the non-HMO alternatives in its health benefits plan.

The Department notes that the HMO Amendments of 1976 (Pub. L. 94–460) amended section 1301(b)(1) of the Act to allow HMOs to include supplemental health services in their basic health services provided to their members for a basic health service payment. The Conference Committee, in its report

adopting this provision as proposed by the House of Representatives, noted that the provision was necessary because "there are some States which require HMOs under State law to offer services which are not included among the defined basic health services." (H.R. Rep. #94–1513, 94th Cong., 2d Sess. 19 (1976)). The House Committee, in its report, explained its amendment by stating that "(It) would simplify the marketing of benefits by HMO's (sic) allowing them to choose a single benefits package which was competitive in the area which is served and to market that single package to all of its members. The present requirements (making the choice optional with members) have proved cumbersome for HMO's (sic) which find that each member, or group of members chooses a different set of supplemental health services for which to contract, with the result that the HMO must provide and administer a great variety of different benefit packages to its different groups of members." (H.R. Rep. #94–518, 94th Cong., 1st Sess. 16 (1975)).

Thus, the legislative history shows clearly that Congress intended to allow HMOs to determine on a non-negotiable basis which supplemental health services to include in their prepaid benefit packages, if those supplemental services are (a) required to be offered under State law or (b) included uniformly by the HMO in the prepaid benefit package offered to all of its members.

Given this background, the Department has concluded that it is inappropriate to provide that the offering of all supplemental health services by the HMO is subject to negotiation. However, it does believe that it is consistent with section 1301(b)(1) of the Act and its legislative history to limit the HMO's right to determine on a non-negotiable basic which supplemental health services to include to the two situations described above.

In addition, based on the revision to § 110.806(d) ("Continued availability of other health benefits") described in item #12 above, the Department has concluded that a conforming amendment to this provision is appropriate. Accordingly, the Department has added a third situation in which the HMO may require the offering of certain supplemental health services as part of its basic health services package: When coverage for the supplemental health service at issue is available through the non-HMO option and that coverage is not available to employees selecting the HMO option. For example, if the coverage is available in an integrated (i.e., not free-standing) health service benefit plan, and thus is not required by § 110.806(d) to be made available to employees selecting the HMO option, the HMO may require the offering of this supplemental health service as part of its prepaid health services package. This result would also occur if the HMO and the employer had mutually agreed that the continued availability requirement of § 110.806(d) would not be applied with respect to a given supplemental health service.

A supplemental health service which did not fall in any of the three categories described above would properly be the subject of negotiation between the employing entity and the HMO, as well as the collective bargaining process, if any. The Department believes that this approach not only furthers the legislative intent by reducing the administrative burden on HMOs, but also does not interfere unduly with the employing entity's collective bargaining or other decision-making processes. Accordingly, § 110.806(f)(3) has been modified to reflect this approach.

Further, in light of the analysis set forth above, the Department has reconsidered the appropriateness of proposed § 110.808(a)(3) (which would have allowed HMOs to add prepaid supplemental health services so as to raise its premium up to the amount of the employing entity's contribution to the non-HMO alternative). Consistent with the revision to § 110.806(f)(3), proposed § 110.808(a)(3) has been deleted.

16. Section 110.808(a) sets forth the general principles for determining the employing entity's contribution to the HMO option. Proposed subparagraph (2) of that section stated that the amount of this contribution shall be equal, in terms of dollars, "to the largest amount of contribution per employee paid to any other option which is available to all eligible employees included in the health benefits plan * * *" (up to the amount of the HMO's premium). A number of commenters noted that using "all eligible employees" as a standard for determining contribution was not only inequitable but also would have an inflationary impact on those companies which determine their contributions based on the earning levels of each particular employee. Since the Department agrees with these commenters, it has changed § 110.808(a)(2) to require contribution by the employing entity based on the largest amount of contribution "for that individual employee".

17. Proposed § 110.808(a)(4) (now § 110.808(a)(3)) required the employing entity to increase the amount of its contribution for the HMO option whenever its contribution to other alternatives in its health benefits plan increases (up to the amount of the HMO premium). A number of commenters objected to this provision because they believe it to be inflationary and likely to be detrimental to the relationship between HMOs and employers. They also pointed out that applying this requirement in the middle of the health benefits year might result in altering an employing entity's contribution which was fixed by a contract with the HMO. Other commenters suggested that the Department add that the employing entity has the right to decrease the amount of its contribution for the HMO option whenever its contribution to other health plan alternatives decreases.

The Department believes that these comments have merit with respect to the proposed rule's applicability to the case where the employing entity's contribution to the HMO option is fixed by contract. Accordingly, the Department had decided to modify the provision. The employing entity is now required to increase its contribution to the HMO option during the health benefits year unless (a) the employing entity's contribution is fixed by contract or other arrangement with the HMO, or (b) the employing entity and HMO come to any other agreement on this issue. Of course, if the employing entity's contribution to the non-HMO alternative is to be revised only prospectively for the following health benefits year, then this revised contribution is to be used in determining the employing entity's contribution for the HMO premium. (See § 110.808(g)(1).) The Department also notes that while nothing in the statute or regulations prohibits an employing entity from decreasing its contribution to the HMO option at the time that its contribution to its other alternatives decreases, the parties may, of course, provide otherwise.

Finally, the Department encourages HMOs and employing entities to make provisions in advance on the subject of adjustments to the contribution rate in the event that the employing entity's contribution to other alternatives in its health benefits plan changes midterm during the health benefits year. It believes that agreement in advance on this issue would be beneficial to the relationship between HMOs and employing entities.

18. At the same time that the proposed subpart H rules were published, § 110.809 was promulgated as a final

regulation. (44 FR 42082, July 18, 1979). This section sets forth the conditions under which an employer must arrange for its employees' contributions for membership in a qualified HMO to be paid through payroll deductions. Although § 110.809 was effective immediately, it was also included in the NPRM, and the Department requested comments on it as well as on the proposed amendments to subpart H. The Department received the following comments on this provision: (a) A recommendation for deletion on the basis that the cost of setting up payroll deductions for a number of small HMOs would be prohibitive; (b) a suggestion that a grace period of one year be allowed for an employer to implement a payroll deduction system where one does not presently exist; and (c) a suggestion that a minimum number of enrollees in the HMO be required before the employing entity had to offer a payroll deduction. The Department notes that neither the statute (section 1310(c)) nor the regulation requires an employing entity to institute a payroll deduction system for HMO enrollees if it doesn't already provide such a system for paying employees' contributions for other options in the health benefits plans. The first and second suggestions are therefore not appropriate. The Department cannot adopt the suggestion in the third comment because it is inconsistent with section 1310(c).

19. The Department has also made certain minor technical and editorial changes.

The Assistant Secretary for Health of the Department of Health and Human Services, with the approval of the Secretary of Health and Human Services, amends 42 CFR Part 110, Subpart H, as set forth below.

Dated: June 30, 1980.

Julius B. Richmond,

Assistant Secretary for Health.

Approved: October 21, 1980.

Patricia Roberts Harris,

Secretary.

Subpart H—Employees' Health Benefits Plans

Sec.

Authority: Sec. 215, 58 Stat. 690 (42 U.S.C. 216); secs. 1301–1318, as amended, 92 Stat. 2131–2141 (42 U.S.C. 300e–300e–17)

Subpart H—Employees' Health Benefits Plans

§ 110.801 Definitions.

In addition to the terms defined in § 110.101 and 110.602, as used in this subpart:

"Bargaining representative" means a representative designated or selected for the purposes of collective bargaining under the National Labor Relations Act, as amended, (29 U.S.C. 151 *et seq.*) or under the Railway Labor Act, as amended, (45 U.S.C. 151 *et seq.*) or under a public entity collective bargaining agreement, or under the laws of any State or political subdivison thereof, or other employee representative designated or selected under any law.

"Carrier" means a voluntary association, corporation, partnership, or other organization which is engaged in providing, paying for, or reimbursing all or part of the cost of health benefits under group insurance policies or contracts, medical or hospital service agreements, membership or subscription contracts, or similar group arrangements, in consideration of premiums or other periodic charges payable to the carrier.

"Collective bargaining agreement" means an agreement entered into between an employing entity and the bargaining representative of its employees, and includes agreements entered into on behalf of groups of employing entities with the bargaining representative of their employees in accordance with the provisions of the National Labor Relations Act, as amended (29 U.S.C. 151 *et seq.*), or the Railway Labor Act, as amended, (45 U.S.C. 151 *et seq.*) or the laws of any State or political subdivision thereof.

"Designee" means any person or entity authorized to act on behalf of an employing entity or a group of employing entities to offer the option of membership in a qualified health maintenance organization to their eligible employees.

"Eligible employee" means an employee who is eligible to participate in a health benefits plan.

"Employee" means any individual employed by an employer or public entity on a full- or part-time basis.

"Employer" shall have the meaning given that term in Section 3(d) of the Fair Labor Standards Act of 1938, as amended, (29 U.S.C 203(d), 203(x)), except that 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 (i) is an organization described in section 501(c)(3) of the Internal Revenue Code of 1954, and (ii) does not discriminate (A) in the employment, compensation, promotion, or termination of employment of any personnel, or (B) 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 an HMO.

"Employing entity" means an employer or public entity.

"Employing entity-employee contract" means a legally enforceable agreement (other than a collective bargaining agreement) between an employing entity and its employees for the provision of, or payment for, health benefits for its employees, or for its employees and their eligible dependents.

"Group enrollment period" means the period of at least 10 working days each calendar year during which each eligible employee is given the opportunity to select among the alternatives included in a health benefits plan.

"Health benefits" means health benefits and services.

"Health benefits contract" means a contract or other agreement between an employing entity or a designee and a carrier for the provision of, or payment for, health benefits to eligible employees or to eligible employees and their eligible dependents.

"Health benefits plan" means any arrangement for the provision of, or payment for, any of the basic and supplemental health benefits described in §§ 110.102 and 110.103 of this Part offered to eligible employees, or to eligible employees and their eligible dependents, by or on behalf of an employing entity.

"Public entity" means a State as defined by section 2(f) of the Public Health Service Act (42 U.S.C. 201(f)), a political subdivision of a State, or any agency or instrumentality of the foregoing. "Political subdivision" includes counties, parishes, townships,

cities, municipalities, towns, villages, and incorporated villages.

"To offer a health benefits plan" means to make participation in a health benefits plan available to eligible employees, or to eligible employees and their eligible dependents, and to make a financial contribution to the plan whether the financial contribution by the employing entity on behalf of these employees is made directly or indirectly, (e.g. through payments on any basis into a health and welfare trust fund).

§ 110.802 Applicability.

The regulations of this subpart apply in each calendar year to:

(a) Each employer which was required during any calendar quarter of the previous calendar year to pay its employees the minimum wage specified by Section 6 of the Fair Labor Standards Act of 1938 (or would have been required to pay its employees the minimum wage but for Section 13(a) of that Act) and which during any calendar quarter of the previous calendar year employed an average of not less than 25 employees; and

(b) Each public entity, as a condition of the payment to the State of funds under Sections 314(d), 317, 318, 1002, 1525, or 1610 of the Public Health Service Act, which during any calendar quarter of the previous calendar year employed an average of not less than 25 employees, if the employer or public entity:

(1) Offers, or if there is offered on behalf of the employer or public entity, in the calendar year beginning after any calendar quarter of the previous calendar year in which the employer or public entity employed an average of not less than 25 employees, a health benefits plan to its eligible employees; and

(2) Has received a written request for inclusion in the employer's or public entity's health benefits plan (which request meets the requirements of § 110.803) from one or more qualified HMOs which provide basic health services in an HMO service area in which at least 25 employees of the employer or the public entity, respectively, reside.

§ 110.803 Requirements for a request for inclusion of the HMO option in a health benefits plan; employing entity response.

(a) *Time limitations.* (1) Unless otherwise agreed to by the HMO and the employing entity or designee, an HMO's request for inclusion in an employing entity's health benefits plan must be received by the employing entity or designee no more than 365 days and not less than 180 days before the expiration or renewal date of a health benefits contract or employing entity-employee contract, and no more than 365 days and not less than 180 days before the expiration date of a collective bargaining agreement, or in the case of a public entity, such longer period as may be prescribed by State law.

(2) For the purposes of this paragraph:

(i) A collective bargaining agreement that is automatically renewable or without fixed term shall be treated as having an expiration or renewal date on the earliest anniversary date of the collective bargaining agreement.

(ii) A collective bargaining agreement that is for a fixed term in excess of one year and provides that its terms regarding health benefits may be renegotiated during the term of the agreement shall be treated as having an expiration or renewal date at the time provided by the agreement for discussion of these changes.

(b) *To whom the written request is to be directed.* The request for inclusion must be in writing and (1) in the case of an employer, be directed specifically to the employer's managing official at the employer site being solicited or to the employer's designee; and (2) in the case of a public entity, be directed to the Chief Executive Officer of the public entity, or to the public entity's designee.

(c) *Information which the request must include.* The request must (1) Provide evidence that the Secretary has determined that the HMO is a qualified HMO in accordance with section 1310(d) of the Act and Subpart F of this part;

(2) Describe the HMO's service area or proposed service area and give the dates basic and supplemental health services will be provided in the area or areas;

(3) Indicate whether the services of health professionals which are provided as basic health services are provided through health professionals who are (i) members of the staff of the organization, or (ii) members of a medical group(s), or (iii) members of an individual practice association(s), or (iv) health professionals who have contracted with the HMO for the provision of these services or (v) any combination of the above;

(4) If the HMO provides health services through an individual practice association(s), provide a listing of member physicians by name, specialty, and whether they are accepting new patients from the HMO membership. This listing must be current within 90 days of the date of the request for inclusion;

(5) If the HMO provides health services other than through an individual practice association, provide for each ambulatory care facility the facility's address, days and hours of operation, a statement whether it is accepting new patients from the HMO membership, and the names and specialities of the facility's providers of basic and supplemental health services. This information must be current within 90 days of the date of the request for inclusion;

(6) List the hospitals where HMO members will be provided basic and supplemental health services;

(7) Identify (i) the nature of the HMO entity, i.e., for profit or non-profit, public or private, sole proprietorship, partnership, or stock or non-stock corporation, , (ii) the members of the HMO's policymaking body, and (iii) the principal managing officer of the HMO;

(8) Provide a statement of the HMO's capacity to enroll new members and the likelihood of any future limitations on enrollment;

(9) Provide the HMO's most recently audited annual financial statements;

(10) Provide proposed implementing agreements between the HMO and the employer, public entity, or designee for the HMO offering;

(11) Provide sample copies of solicitation brochures and membership literature which will be used in the offer of the HMO alternative to employees;

(12) State either (i) the HMO's current rates, including copayments, if any, for basic (and uniformly included supplemental) health services and the dates these rates became effective, or (ii) the HMO's estimated rates for these services.

(d) *Employing entity response.* An employing entity or designee shall respond in writing to an HMO's request for inclusion no later than 60 days after the receipt of the request and shall state whether the employing entity has 25 or more employees who reside within the service area of the HMO. If so, the employing entity or designee shall also state the expiration or renewal dates of its health benefits contracts, employer-employee contracts, and public entity-employee contracts covering these employees, the amount of the employing entity's current contribution (and, where applicable, the employee's contribution) for health benefits, including the dates those contribution levels became effective, and the expiration dates of any collective bargaining agreements covering these employees. In addition, in this response, a public entity or its designee shall furnish the HMO with a description of health benefits, including limitations and exclusions, required under State law or regulation for health benefits plans for employees of the public entity.

(e) *Effect of inadequate request.* If the request for inclusion does not meet the requirements of paragraphs (a)–(c) of this section, the employing entity is not required to include the HMO alternative in its employees' health benefits plan under § 110.805 until the HMO makes its request in accordance with those paragraphs. In such a case, the employing entity or its designee shall, within 60 days after receipt of the request, notify the HMO in writing of the basis for its conclusion that the request does not meet the requirements of paragraphs (a)–(c) of this section.

(f) *New request for inclusion.* If an employing entity includes the HMO alternative in a health benefits plan in accordance with a request meeting the requirements of paragraphs (a)–(c) of this section, the employing entity shall offer the HMO alternative to the employees described in § 110.806(e)(2) during the entire health benefits year. However, if no employees enroll during the health benefits year, the HMO seeking inclusion in the health benefits plan for subsequent enrollment periods shall submit a new request in accordance with paragraphs (a)–(c) of this section.

(g) *Discretionary offering of HMO alternative.* Nothing in this subpart prevents the employing entity or designee from offering the HMO alternative at any time by mutual agreement with the HMO.

§ 110.804 Offer of HMO option to employees.

(a) *Inclusion of HMO option.* An employing entity subject to § 110.802 shall, at the time a health benefits plan is offered to its eligible employees, include in the plan the option of membership in qualified HMOs in accordance with this section.

(b) *Employees to whom the HMO option must be offered.* Each employing entity subject to this subpart shall offer the option of membership in a qualified HMO to each eligible employee, or to each eligible employee and his or her eligible dependents, who reside within the service area of the qualified HMO being offered.

(c) *Manner of offering the HMO option.* (1) For the employees of an employing entity subject to this subpart who are represented by a bargaining representative, the offer of membership in a qualified HMO (i) must first be made to the bargaining representative, and (ii) if the offer is accepted by the representative, must then be made to each represented employee.

(2) For those employees not represented by a bargaining representative, the offer must be made directly to those employees in accordance with this subpart.

§ 110.805 HMOs which must be included in a health benefits plan.

(a) *HMOs providing basic health services through varying arrangements with health professionals.* If more than one qualifed HMO engaged in the provision of basic health services in an area in which eligible employees of an employing entity subject to this subpart reside has requested inclusion in the employer's or public entity's health benefits plan as provided by § 110.802(a)(2)(ii), and if:

(1) One or more of these organizations provides basic health services through physicians or other health professionals who are members of the staff of the organization or a medical group (or groups), and

(2) One or more of these organizations provides basic health services through (i) an individual practice association (or associations), or (ii) a combination of such an association (or associations), medical group (or groups), staff, and individual physicians and other health professionals under contract with the organization, then, of the qualified HMOs included under this section in a health benefits plan of an employing entity subject to this subpart, at least one shall be an organization which provides basic health services as described in subparagraph (1) of this paragraph and at least one shall be an organization which provides basic health services as described in subparagraph (2) of this paragraph. For purposes of this paragraph, individual physicians and other health professionals who have contracted with the HMO do not include health professionals who are members of the HMO's staff, of medical groups, or of entities which would be medical groups but for the requirements of subparagraph (3)(i) of the definition of medical group in § 110.101.[1]

(b) *Additional HMOs which must be included.* An employing entity subject to this subpart shall offer the option of membership in additional qualified HMOs to its eligible employees, described in subparagraphs (1) and (2) of this paragraph, if the additional qualified HMOs demonstrate that their service areas include the place of residence of at least 25 employees of the employing entity:

(1) Who do not reside in the service area of qualified HMOs already included in the employing entity's health benefits plan; or

(2) To whom membership in qualified HMOs already included in the health benefits plan is not available because these HMOs have closed their enrollment of additional eligible employees of the employing entity.

(c) *Alternate HMOs which may be included.* An employing entity subject to this subpart is not required to include in the health benefits plan offered to eligible employees the option of membership in the specific qualified HMO which initiated the request for inclusion in the health benefits plan if (1) the employing entity or designee includes in the health benefits plan the option of membership in one or more other qualified HMOs that may not have made a request within the time limit of § 110.803(a) but are willing to be included, (2) these latter HMOs are of the same type (i.e., as described in paragraph (a)(1) or (2) of this section) as the HMO which submitted the timely request, and (3) all of the employees of the employing entity residing in the service area of the HMO submitting the timely request reside in areas served by these latter HMOs.

§ 110.806 How the HMO option is to be included in the health benefits plan.

(a) *HMO access to employees.* The employing entity shall provide each qualified HMO which is included in its health benefits plan with fair and reasonable access, not less than 30 days prior to and during the group enrollment period, to employees referred to in § 110.804(b) for purposes of presenting and explaining its program in accordance with § 110.108(c) of this Part. This access shall include, at a minimum, the opportunity for the distribution of educational literature, brochures, announcements of meetings, and other relevant printed materials meeting the requirement of § 110.108(c) to each employee referred to in § 110.804(b). In no event shall the employing entity provide qualified HMOs access to eligible employees which is more restrictive or less favorable than the access it provides other offerors of alternatives included in the health benefits plan, whether or not these offerors elect to avail themselves of that access.

(b) *Review of HMO offering materials.* The HMO shall give the employing entity or designee the opportunity to review, revise, and approve HMO educational and offering materials before distribution. Revisions shall be limited to correcting factual

[1] These requirements are that the members of the medical group "as their principal professional activity (over 50 percent individually) engage in the coordinated practice of their profession and as a group responsibility have substantial responsibility (over 35 percent in the aggregate of their professional activity) for the delivery of health services to members of an HMO."

errors and misleading or ambiguous statements, unless otherwise agreed to by the HMO and the employer or public entity or designee, or as may be required by law. The employing entity or designee shall complete promptly any of these revisions in the offering material so as not to delay or otherwise interfere with the group enrollment period.

(c) *Group enrollment period; prohibition of waiting periods, exclusions, and limitations.* An employing entity or designee including the option of membership in a qualified HMO under this subpart as part of the health benefits plan offered to its eligible employees shall provide for a group enrollment period, prior to the effective date of the HMO coverage established under paragraph (g) of this section, without application of waiting periods or exclusions or limitations based on health status as a condition of enrollment in the HMO or transfer to non-HMO coverage from an HMO. Nothing in this subpart precludes the uniform application of coordination of benefits agreements between the HMOs and the other carriers which are included in the health benefits plan.

(d) *Continued availability of other health benefits.* (1) At the request of a qualified HMO, the employing entity or its designee shall provide that employees selecting the option of HMO membership will not, because of this selection, lose their eligibility for free-standing dental, optical, or prescription drug benefits for which they were previously eligible or would be eligible if selecting a non-HMO option and which are not included in the services provided by the HMO to its members as part of the HMO prepaid benefit package.

(2) For purposes of this paragraph, the term "free-standing" refers to a benefit which (i) is not integrated or incorporated into a basic health benefits package or major medical plan, and (ii) is either (A) offered by a carrier other than the one offering the basic health benefits package or major medical plan, or (B) subject to a separate premium from the premium for the basic health benefits package or major medical plan.

Illustrative Examples: Set forth below are examples of the employing entity's obligation with respect to the continued eligibility of employees selecting the HMO option for these free-standing health benefits:

1. The health benefits plan includes a free-standing dental benefit. The HMO does not offer any dental coverage as part of its health services provided to members on a prepaid basis. The employing entity must provide for the continued eligibility of those employees selecting the HMO option for dental coverage.

Note: If the dental coverage is not optional for employees selecting the non-HMO option, nothing in this regulation requires that the coverage be made optional for employees selecting the HMO option. Conversely, if this coverage is optional for employees selecting the non-HMO option, nothing in this regulation requires that the coverage be mandatory for employees selecting the non-HMO option.

2. If the non-HMO option provides free-standing coverage for optical services (such as refraction and the provision of eye glasses), and the HMO does not, the employing entity must provide for the continued eligibility for those employees selecting the HMO option for optical coverage.

3. The non-HMO option includes dental coverage in its major medical package, with a common deductible applied to dental as well as non-dental benefits. The HMO provides no dental coverage as part of its prepaid health services. Because the dental coverage is not free-standing, the employing entity is not required to provide for the continued eligibility for dental coverage for those employees selecting the HMO option, although it is free to do so.

(e) *Affirmative written selections.* (1) During the group enrollment period in which the alternative of membership in any particular qualified HMO is offered to an eligible group of employees for the first time, the employing entity or designee shall present the health benefits plan alternatives to each eligible employee residing in the service area of the HMO with the requirement that an affirmative written selection be made among the different alternatives included in the health benefits plans. In subsequent group enrollment periods, it shall make available a selection among the alternatives; however, a written selection is required only when the eligible employee elects to change from one alternative to another.

(2) In addition to the group enrollment period, the employing entity or designee shall make available the opportunity to select among different existing alternatives within a health benefits plan to eligible employees who: (i) Are new employees, (ii) have been transferred or have changed their place of residence, resulting in eligibility for membership in a qualified HMO for which they were not previously eligible by place of residence, or resulting in residence outside the service area of a qualified HMO in which they were previously enrolled, or (iii) are covered by any alternative which ceases operation. At the time these employees are eligible to participate in the health benefits plan, the employing entity or designee shall make available, without waiting periods or exclusions or limitations based on health status as a condition, the opportunity to enroll in an alternative HMO or transfer to a non-HMO coverage from an HMO, and shall require these employees to make an affirmative written selection among the different alternatives included in the health benefits plan.

(f) *Determination of copayment levels and supplemental health services.* The selection of a copayment level and of supplemental health services to be contracted for is to be made as follows:

(1) For those employees represented by a collective bargaining representative, the selection of copayment levels and supplemental health services is subject to the collective bargaining process.

(2) For those employees not represented by a bargaining representative, the selection of copayment levels and supplemental health services to be offered to eligible employees is subject to the same decisionmaking process used by the employing entity with respect to the non-HMO alternatives in its health benefits plan.

(3) In all cases, the HMO has the right to include with its basic health services provided to its members for a basic health services payment, on a non-negotiable basis, those supplemental health services (i) that are required to be offered under State law, or (ii) that are included uniformly by the HMO in its prepaid benefit package, or (iii) coverage for which is available to employees selecting the non-HMO option but not available to employees selecting the HMO option.

(g) *Effective date of coverage.* Unless otherwise agreed to by the employing entity, or designee, and the HMO, the effective date of coverage by the HMO for employees selecting the HMO option shall begin on the day the non-HMO coverage expires or is renewed without lapse.

§ 110.807 When the HMO is to be offered to employees.

The employing entity or designee shall offer eligible employees the option of membership in a qualified HMO at the earliest date permitted under the terms of existing collective bargaining agreements, employer-employee or public entity-employee contracts, or contracts for health benefits. Should the HMO's request for inclusion in a health benefits plan be received at a time when these existing contracts or agreements do not provide for including a qualified HMO in the health benefits plan, the inclusion of the HMO in the health benefits plan shall occur at the time that new agreements or contracts are offered or negotiated and shall be consistent with the following paragraphs:

(a) Unless mutually agreed otherwise, if a collective bargaining agreement is in

force at the time the request for inclusion in the health benefits plan is made by the HMO to the employing entity or designee, the request shall be raised in the collective bargaining process (1) when a new agreement is negotiated, (2) if the agreement is for a fixed term in excess of one year and provides that its terms regarding health benefits may be renegotiated during the term of the agreement, at the times provided by the agreement for discussion of these changes, or (3) in accordance with a specific process to review HMO offers.

(b) Unless mutually agreed otherwise, for those employees not covered by a collective bargaining agreement, the employing entity or designee shall include the HMO option in any health benefits plan offered to eligible employees when the existing employer-employee contract or public entity-employee contract is renewed or when a new health benefits contract or other arrangement is negotiated. If an employer-employee or public entity-employee contract or a health benefits contract has no fixed term or has a term in exess of one year, the contract shall be treated as renewable on its earliest anniversary date. If the employing entity or designee is self-insured, the budget year shall be treated as the term of the existing contract.

(c) Unless mutually agreed otherwise, for employing entities with multiple contracts or other arrangements included as part of the health benefits plan which may have different expiration or renewal dates, the employing entity shall include the HMO option, in accordance with paragraphs (a) and (b) of this section, for each contract or arrangement at the time the contract or arrangement is renewed or reissued or the benefits provided under the contract or arrangement are offered to employees.

§ 110.808 Contributions for HMO option.

(a) *General principles.* (1) The employing entity or designee shall include the HMO option in the health benefits plan on terms no less favorable, with respect to the employing entity's monetary contribution or designee's cost for health benefits calculated in dollars and cents, than those on which the other alternatives in the health benefits plan are included. However, the employing entity or designee is not required to pay more for health benefits as a result of offering the option of membership in a qualified HMO than it would otherwise be required to pay for health benefits by a collective bargaining agreement or other employer-employee contract or public entity-employer contract in effect at the time the HMO is included in the health benefits plan.

(2) An employing entity or designee which calculates the health benefits contribution on a per employee earnings level basis must apply that same calculation to the HMO contribution. The amount of the employing entity's or designee's contribution per employee for the HMO option must be equal, in terms of dollars and cents, to the largest amount of the contribution that would be paid for that individual employee to any other alternative which is included in the health benefits plan, but shall not be required to exceed the amount of the HMO premium.

(3) The employing entity or designee shall increase the amount of its contribution for the HMO option at the time the contribution to other alternatives in the health benefits plan increases (up to the amount of the HMO premium), unless (i) the employing entity's or designee's contribution is fixed by a contract or other arrangement between the employing entity or designee and the HMO, or (ii) otherwise agreed to by the employing entity or designee and the HMO.

(b) *Administrative expenses.* The employing entity or designee may not consider administrative expenses incurred in connection with offering any alternative in the health benefits plan in determining the amount of its contribution to the HMO. However, if the employing entity or designee has special requirements for other than standard solicitation brochures and membership literature, it shall determine and distribute any administrative costs attributable to these requirements, in the case of the offering of the HMO option, in a manner consistent with its method of determining and distributing these costs for the non-HMO alternatives.

(c) *Exclusion for contribution for certain benefits.* In determining the amount of the employing entity's contribution or designee's cost for the HMO option, the employing entity or designee may exclude those portions of the contribution allocable to benefits (e.g., life insurance or insurance for supplemental health benefits) for which eligible employees or eligible employees and their eligible dependents will be covered notwithstanding selection of membership in an HMO, and which are not offered on a prepaid basis by the HMO to the employing entity's employees.

(d) *Contributions determined by collective bargaining agreements or by other contracts or by law.* Where the specific amount of the employing entity's contribution for health benefits is fixed by a collective bargaining agreement, by an employer-employee or public entity-employee contract, or by law, the amount so determined shall constitute the employing entity's obligation for contribution toward the HMO premiums on behalf of eligible employees or eligible employees and their eligible dependents.

(e) *Allocation of portion of a contribution determined by a collective bargaining agreement.* Where the employing entity's contribution for health benefits is determined by a collective bargaining agreement, but the amount so fixed includes contribution for benefits in addition to health benefits, the employing entity shall determine, or shall instruct its designee to determine, the portion of its contribution applicable to health benefits in accordance with paragraph (g) of this section.

(f) *Contributions not determined by collective bargaining agreements or by other contracts or by law.* For employees not covered by a collective bargaining agreement, employer-employee or public entity-employee contract, or by a law specifying the contribution for health benefits, the employing entity's contribution to the HMO on behalf of eligible employees or eligible employees and their eligible dependents shall be determined in accordance with paragraphs (a), (b), (c), and (g) of this section on the basis of the total cost of providing the health benefits offered to the employees for the most recent period for which experience is available.

(g) *Calculation of cost.* An employing entity's contribution or designee's cost for alternatives other than the qualified HMO, included in the health benefits plan shall be determined in the following manner, unless otherwise agreed to by the HMO and the employing public entity or designee:

(1) *Prospective calculation.* If the employing entity's contribution or designee's cost for non-HMO alternative health benefits is determined solely on the basis of a fixed prospective amount (not subject to retrospective adjustment) then the amount of the prospective payment made by or on behalf of the employing entity to the non-HMO alternative for the provision of health benefits to eligible employees or to eligible employees and their eligible dependents shall constitute the employing entity's contribution toward the HMO premium.

(2) *Retrospective calculation.* If the employing entity's contribution or designee's cost for non-HMO alternative health benefits is determined by a contract with a carrier on any form of retrospective experience rating basis,

including any determination of current premiums which reflects, takes into account, or is otherwise based on any form of supplementation or any rebate, refund or other redistribution of premiums collected in any previous year for which experience is available, any billing contract arrangement, any plan of self-insurance, any direct service plan provided by the employing entity or designee, or any other form of health benefits plan wherein the actual cost to the employing entity or designee is determined retrospectively, an estimated cost shall be used to determine the obligation for contribution toward the HMO premium. The employing entity or designee shall determine this estimated cost based on consideration of the following factors: (i) The employing entity's or designee's cost experience for the non-HMO alternatives with respect to the most recent benefit period for which the experience is available at the time when the employing entity's prospective contribution or designee's obligation to the HMO is to be determined; (ii) a reasonable allowance for inflation based on historical cost trends and the anticipated future costs increases; (iii) where applicable and consistently applied, cost differences experienced in the provision of health benefits for separate regional or local areas of employment; (iv) anticipated changes in the composition and experience of the covered population actually being served by the non-HMO alternatives attributable to the shift of enrollment to the HMO; (v) any changes in health benefits to be provided by the non-HMO alternatives during the period for which the estimated contribution is to be determined; (vi) any other anticipated material change in the experience rating basis under any health benefits contract for the benefits period.

(h) *Retention of data.* An employing entity or designee shall retain the data used to compute its level of contribution to the alternatives included in the health benefits plan for three years. The Secretary may review this data either on her own initiative or in response to a request to the Secretary from an HMO or an employee of the employing entity which sets forth reasonable grounds supporting the request to determine whether the level of contributions determined by the employing public entity or designee complies with this subpart.

§ 110.809 Payroll deductions.

Each employing entity 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 § 110.802(a) to offer its employees the option of membership in a qualified HMO, shall, with the consent of an employee who exercises this option, arrange for the employee's contribution, if any, for HMO membership to be paid through payroll deductions.

§ 110.810 Relationship of Section 1310 of the Public Health Service Act to the National Labor Relations Act, as amended, and the Railway Labor Act, as amended.

The obligation of an employing entity subject to this subpart to include the option of membership in a qualified HMO in any health benefits plan offered to its eligible employees shall be carried out consistently with the obligations imposed on that employing entity under the National Labor Relations Act, the Railway Labor Act, and other laws of similar effect.

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Part VIII

Department of Health and Human Services

Public Health Service

Requirements for a Health Maintenance Organization; Final Regulations

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 110

Health Maintenance Organizations; Requirements for a Health Maintenance Organization

AGENCY: Public Health Service, HHS.

ACTION: Final regulations.

SUMMARY: This rule amends the Public Health Service regulations by setting forth revised requirements for the organization and operation of federally qualified health maintenance organizations (HMOs). These amendments are made as a result of (1) public comments on the interim regulations published on July 18, 1979, and (2) public comments on the notice of proposed rulemaking (NPRM) governing relationships between federally qualified HMOs and other parties, also published on July 18, 1979.

EFFECTIVE DATE: This rule is effective on December 1, 1980.

FOR FURTHER INFORMATION CONTACT: Howard R. Veit, Director, Office of Health Maintenance Organizations, Park Building, 3rd Floor, 12420 Parklawn Drive, Rockville, Maryland 20857, 301/443–4106.

SUPPLEMENTARY INFORMATION: On July 18, 1979, interim regulations were published in the **Federal Register** (44 FR 42060–71) to amend 42 CFR Part 110, Subpart A, issued under Title XIII of the Public Health Service Act (the Act). Interested persons were given an opportunity to submit comments concerning these regulations by September 17, 1979. Fifteen persons submitted comments on the interim final regulations. Also on July 18, 1979, an NPRM was published in the **Federal Register** (44 FR 41838–41) concerning the relationships between federally qualified HMOs and other parties. The Secretary invited comments by September 17, 1979, and stated that after the public comments were received, the policies would be revised as warranted and incorporated into regulations or set forth as interpretive rulings, as appropriate. Ten persons submitted comments on the NPRM.

The following are summarized below: (1) The comments received, responses thereto, and the changes made, if any, on the Subpart A interim final regulations; (2) the comments received, responses thereto, and the changes made, if any, in the policies stated in the NPRM on relationships between federally qualified HMOs and other parties, including which of these policies have been added, and where, to the Subpart A regulations; and (3) the changes made to correct technical problems in the regulations.

The Department also notes that on April 29, 1980, at 45 FR 28654–63, it published in the **Federal Register** a series of informational questions and answers based on the interim regulations for Subpart A. The Department refers the public to that document for further information on the requirements of Subpart A. It notes that the document will be amended as appropriate in the near future to reflect the revisions made to the Subpart A regulations by this notice.

Subpart A Interim Final Regulations

1. Section 110.102 addresses the required health benefits for basic health services, including short-term rehabilitation and physical therapy. Several commenters requested clarification of the duration of these "short-term" services. The regulations have been changed to specify that short-term rehabilitation services and physical therapy must be provided if the HMO determines that the provision of these services can be expected to result in significant improvement of a member's condition within a period of two months. The physical therapy requirement has been moved from § 110.102(a)(2)(ii) to § 110.102(a)(2)(iii) to clarify that short-term physical therapy is required on both an outpatient and inpatient basis.

2. Section 110.102(a)(5)(ii), pertaining to referral services for the abuse of or addiction to alcohol and drugs, has been amended to indicate that prolonged rehabilitation services for alcohol or drug abuse or addiction in a specialized inpatient or residential facility need not be offered by an HMO as a basic health service. The Department notes, however, that an HMO may choose to offer prolonged rehabilitation services as a supplemental health service. This change is in response to a request by a commenter that this information, which was included in the preamble of the interim regulations, be incorporated into the final regulations.

3. Section 110.102(d) lists the permissible exclusions from the required basic health services. Section 110.102(d)(9) has been modified at the request of a commenter who noted that the exclusion of vision and hearing care as a basic health service failed to take into consideration that some vision and hearing services may be a part of physician services, such as care for diseases of the eye and ear, as well as preventive health services, as in the case of eye and ear examinations for children through age 17 to determine the need for vision or hearing correction. The exclusion for vision and hearing care has been clarified to indicate that this care need not be provided as a basic health service except as required by sections 1302(1)(A) and 1302(1)(H)(vi) of the Act and §§ 110.102(a)(1) and 110.102(a)(8) of these regulations.

4. Section 110.104(a)(2), pertaining to non-conforming medical groups, has been changed and is now § 110.104(a)(3). This revised section clarifies that after the four-year period which follows the month in which the HMO was qualified, the HMO may provide services through a non-conforming medical group if it meets the definition of medical group as set forth in § 110.101 or if the Secretary has determined that the entity meets the conditions set forth in § 110.104(a)(3)(ii). A suggestion to permit the four-year period allowed for the use of a non-conforming medical group to commence from the date of the HMO's contract with the group has been rejected because section 1301(b)(3)(B)(ii) of the Act indicates that the four-year period is to be calculated from the month after the HMO's qualification date.

5. One commenter requested clarification of the requirements that apply to the HMO's contracts for health services under § 110.104(c). In response, the Department has separated this paragraph into two subparagraphs to delineate clearly the difference between the requirements for (1) contracts between the HMO and medical groups or IPAs, and (2) direct service contracts between the HMO and health professionals. Section 110.104(c)(1) now lists the requirements for the former type of contract and § 110.104(c)(2) clarifies that the contract between the HMO and its health professionals must include provisions for appropriate continuing education in addition to four of the provisions which an HMO must include in its contracts with medical groups or IPAs: a description of the responsibilities of the parties to the contract; the agreed upon compensation for services; an agreement that the contracting parties will look solely to the HMO for compensation for services provided to HMO members; and a provision specifically requiring participation by health professionals in the quality assurance activities which the HMO is required to have under § 110.108(j).

6. Section 110.105(e) states that HMOs may charge a late payment penalty on accounts receivable which are in arrears. The Department has not adopted the suggestion that the regulations require 30 days written notice or limit the HMO's late payment

penalty charges to amounts which are not in dispute. These limitations are not properly within the scope of the Act. Of course, an HMO may agree to these limitations.

7. Section 110.108(a)(1) requires an HMO to have a fiscally sound operation. In the preamble to the interim final regulations, the Secretary expressed the intention of using a ratio of current assets to current liabilities of at least one-to-one as a benchmark in administering the cash flow requirement of § 110.108(a)(1)(ii). A commenter noted that current liabilities may exceed current assets at any given date, because the former may include a significant amount of prepaid dues (deferred income) and the latter a relatively low amount for receivables. Further, the proposed ratio test was cited as an inappropriate benchmark for evaluating adequacy of cash flow because cash flow is dynamic and the ratio test is a static measure of liquidity. The Department agrees with these comments and notes that the adequacy of cash flow will now be examined on a case-by-case basis to assure that the HMO can meet its obligations as they become due. Accordingly, the requirement at § 110.108(a)(1)(ii) has been changed to require an HMO to provide evidence of its ability to meet its obligations as they become due, as determined by sufficient cash flow and by adequate liquidity. The evaluation of the maintenance of adequate liquidity will start with the ratio test of current assets to current liabilities of at least one-to-one, but will allow for valid deviations such as the situation noted in this paragraph.

8. The Department received a number of inquiries as to the scope of § 110.108(a)(2)(i), which sets out the standards for the satisfactory administrative and managerial arrangements with respect to the HMO's policymaking body. In particular, the inquiries have focused on the requirement that the policymaking body *"exercises oversight and control* over the HMO's policy and personnel to assure that management actions are in the best interest of the HMO and its membership" (Emphasis added). In order to determine whether the HMO's policymaking body has the capability to and does in fact carry out these responsibilities and thus meets the requirements of § 110.108(a)(2)(i), the Department requires the HMO to demonstrate that its policymaking body has the appropriate skills (e.g., planning, financial management and evaluation skills) to perform these oversight and control functions.

9. The Department has received a number of questions as to whether it is permissible for federally qualified HMOs to expel or refuse to reenroll their members who have reached age 65. The Department's position has always been that the expulsion of such persons by an HMO is inconsistent with Title XIII of the Act. (The expulsion of the aged by HMOs receiving Federal financial assistance may also violate the Age Discrimination Act of 1975, as amended. (42 U.S.C. 6101 *et seq.))* In order to avoid confusion in this regard, the Department has decided to incorporate this prohibition expressly into the regulations. Accordingly, § 110.108(f), which prohibits an HMO from expelling or refusing to reenroll any member, as well as from refusing to enroll individual members of a group, on the basis of the health status or health care needs of the member or individual, has been modified by adding age as an impermissible basis for such actions by the HMO. It is still permissible, of course, for HMOs to require that, as a condition of continued eligiblility for membership, dependents of a subscriber, upon reaching a specified age, convert to nongroup membership in accordance with § 110.108(g).

10. Section 110.108(g) had required an HMO to offer conversion privileges to subscribers leaving a group "on the same terms and conditions as are available to a nongroup subscriber." Because this requirement was phrased in terms of "subscribers," a number of commenters expressed confusion as to the conversion privileges which the HMO is required to offer "members" who would otherwise lose their eligibility for HMO membership. Since the language was inadvertently narrower than intended, the regulation has been changed to require an HMO to offer membership on the same terms and conditions as are available to a nongroup subscriber to:

(1) Each subscriber (and enrolled dependents) leaving a group; and

(2) Each member who would otherwise cease to be eligible for HMO membership because of his or her age or the death or divorce of a subscriber.

11. Section 110.108(k) pertains to certification of providers. The Department agrees with a comment that it is not necessary to require non-institutional providers to be certified by Medicare or Medicaid. It notes that the requirements of this section are intended to insure that HMO institutional providers are certified in accordance with Federal or national certification standards. Since individual providers are required to meet State licensure requirements, and since certification of certain health professionals under Title XVIII or Title XIX of the Social Security Act is for reimbursement purposes only, the requirements have been changed to require that the HMO offer institutional services only through institutional providers that maintain such certification. Hospitals, however, may satisfy the "certification" requirement either by certification under Title XVIII or by accreditation by the Joint Commission on Accreditation of Hospitals. The requirements as to clinical laboratories through which the HMO provides services (except for laboratories exempted from section 353 of the Public Health Service Act, "Licensing of Laboratories," by paragraphs (d)(2), (i) or (1) of that section), must either be certified under Medicare or Medicaid or be licensed under section 353. The Department notes that these regulations do not apply to the HMO's own laboratory, although the laboratory may otherwise be subject to the requirements of section 353 or Medicare or Medicaid.

12. Section 110.108(o) covers reporting and disclosure requirements for HMOs and § 110.108(o)(1) requires HMOs to furnish specific reports to the general public upon request. One commenter inquired where a request by the public for information which an HMO has reported to the Department under § 110.108(o)(1) should be directed. The Department notes that requests regarding information reported under this subsection may be directed to the HMO, in accordance with the HMO's reporting procedure, or to the Department's Office of Health Maintenance Organizations.

13. A number of commenters noted that § 110.108(o)(2)(ii), which sets out which transactions between an HMO and a party in interest must be disclosed to the Secretary, imposed a heavy reporting burden on HMOs. Accordingly, the section has been changed. It would require the reporting only of *significant* business transactions between the HMO and a party in interest, instead of the previous requirement that *all* such business transactions be reported. The term "significant business transaction" is adapted from the Department's Medicare-Medicaid regulations at 42 CFR 420.201, which govern the disclosure of ownership and control information by providers, intermediaries, and carriers. For purposes of § 110.108(o)(2)(ii), the term is defined (see § 110.101) as "any business transaction or series of transactions during any one fiscal year

of the HMO, the total value of which exceeds the lesser of $25,000 or five percent of the total operating expenses of the HMO."

14. Section 110.108(o)(2)(ii)(B) requires an HMO to disclose, among other items, certain transactions between itself and a party in interest for the furnishing of services. A commenter suggested that since the ordinary employee-employer relationship does not constitute a suspect or potentially abusive transaction, services provided by employees of the HMO in the normal course of their employment should be excluded from services which are subject to disclosure. The Secretary agrees with this comment and has changed § 110.108(o)(2)(ii)(B) to exclude transactions for these services from those subject to disclosure.

NPRM on Relationships Between Federally Qualified HMOs and Other Parties

The NPRM addressed issues that arose under five general headings: (1) The legal structure of an HMO, (2) the HMO's conduct of other activities, (3) the activities of providers affiliated with the HMO, (4) arrangements for HMO contract services, and (5) maximizing HMO enrollment. The Secretary has decided to finalize the policies which were detailed in the NPRM as follows: (1) Certain of the policies set forth in the NPRM, as clarified in response to comments, are now incorporated into the subpart A regulations, as detailed in the first section below, and (2) the remainder of the policies set forth in the NPRM, as clarified in response to comments, are summarized in the second section below. These latter policies have been adopted as official policies of the Department and are set forth in the informational document referred to above (45 FR 28654–63).

Third Party Policies Incorporated Into the Subpart A Regulations

1. Section 110.104(a) addresses the requirements for providers of basic and supplemental health services. A new § 110.104(a)(2) has been added, which modifies the policy set forth in the NPRM that would have permitted sharing of physicians by alternative model HMOs, but only to the extent that the physicians the IPA shares with the alternative model HMO (i.e., either a staff or medical group model) constituted less than 50 percent of the physicians participating in the IPA. Two commenters, citing a lack of statutory authority, objected to this requirement and questioned the basis for the 50 percent limitation. The Department notes that the purpose behind the enactment of section 1310(b), which requires employers in certain circumstances to offer their employees the option of membership in different model HMOs, is to encourage competition among different model HMOs (as well as between HMOs (as well as between HMOs and other health care providers) by providing employees with real "alternatives from which to choose for their care." (H.R. Rep. #93–451, 93rd Cong., 1st Sess. p. 39). If alternative model HMOs were to offer services to HMO members through the same physicians, the result would defeat the essential purpose of section 1310(b) by limiting genuine consumer choice. Accordingly, the Department believes a limitation is necessary to assure that the purpose of section 1310(b) is fulfilled. However, it agrees that a 50 percent limitation, in the absence of other information, may not be appropriate. Therefore, the regulation at § 110.104(a)(2) permits physician sharing between an IPA and medical group or staff HMO of 50 percent or more, but only if this sharing is approved by the Secretary as being consistent with the purposes of section 1310(b). The Secretary will, on a case-by-case basis, review the characteristics of those HMOs which share physicians in excess of the 50 percent limitation, taking into account the following factors: (1) The total number of practicing physicians in the service area of each HMO which proposes to share physicians with another HMO, (2) the number of physicians to be shared as a percentage of the IPA's total pool, (3) the specialties of the shared physicians, (4) the overlap of the service areas of the HMOs which propose sharing, (5) the practice location of the shared physicians in relation to the location of the other HMO physician providers, and (6) such other factors as the Secretary may consider necessary in determining whether the sharing of physicians enables the HMOs to meet the purpose of section 1310(b).

The Department notes that there is no limitation of physician sharing by competing IPAs or by competing IPA model HMOs, since the purpose of encouraging different model HMOs to compete with each other is not applicable in these situations. All HMOs must, of course, assure the accessibility and availability of services to their members.

2. Section 110.108(a)(1), which requires the HMO to have a fiscally sound operation, has been expanded to incorporate the policy set out in the NPRM that all HMOs shall maximize their enrollment.

Although the NPRM invited the public to suggest standards to determine whether on HMO is maximizing its enrollment, none of the four comments received suggested any such standards. For example, one commenter, noting that flexible indicators were preferable to standards, suggested that the Department meet with representatives of the HMO industry to develop such indicators. Another commenter suggested standards for determining whether an HMO has failed, as opposed to succeeded, in maximizing its enrollment. Noting that none of the comments received suggested for determining whether an HMO is maximizing its enrollment, the Department has determined that it is not feasible to set such uniformly applicable standards. Rather, is has decided that it is more appropriate to implement this policy by requiring (at § 110.108(a)(1)(vii)), that each HMO submit a plan to maximize its enrollment. The Department notes that it will only examine the extent to which the HMO has maximized its enrollment as it relates to the HMO's continued fiscal soundness.

The Department also notes that while membership growth is essential to the development and maintenance of a financially viable HMO, HMOs must monitor their growth in the context of per member per month revenues and costs. Accordingly, the HMO's efforts to maximize enrollment must be consistent with sound management.

3. Section 110.108(h)(1) sets forth the requirement that at least one-third of the HMO's policymaking body must be members of the HMO. This section has been modified to incorporate the policy set forth in the NPRM that the one-third of the policymaking body who are members of the HMO must reside in or in proximity to the HMO's service area. This policy is based on the clear Congressional intent to require member participation in the HMO policymaking body in order to assure that input is available from individuals who represent the viewpoint of users of the HMO's services.

The Department received a request to clarify this requirement with respect to (1) an HMO with regional components and one overall policy body, and (2) different HMOs with policymaking bodies consisting of the same members. The regulation now specifies that the one-third member portion of the policymaking body shall consist of individuals who live in or in proximity to the service area of at least one regional component of the HMO or at least one of the HMOs, respectively.

4. The NPRM reiterated the policy that an HMO may not offer prepaid health benefits which do not meet the requirements of the Act. This prohibition is already included in the regulations, at § 110.102(e), which prohibits an HMO from offering to provide or arrange for the provision of prepaid basic health services which do not meet the requirements of § 110.102(a).

5. A new § 110.109, *Prohibited Activities,* has been added. This section prohibits an HMO, including its employees in the normal course of their employment, from selling, marketing, or promoting, directly or through arrangements with other entities, health insurance or health service benefit plans for health benefits which are included in the health benefits package offered by the HMO to an individual or a group. Thus, for any individual or group, the HMO may not sell, market, or promote health insurance or a health service benefit plan for a benefit for which the member is eligible to receive services under his or her prepaid benefit package. In the NPRM, the Department had proposed to prohibit the "promotion or sale" by an HMO of "competing health insurance." Two commenters, noting that this prohibition could be evaded by the sale of competing health insurance through the marketing staff of an HMO who are licensed as individuals, suggested that the prohibition be extended to selling, promoting, or marketing through the HMO's employees or through other arrangements (such as by an arrangement with another entity). Another commenter noted that the phrase "competing health insurance" was vague and imprecise. Since the Department agrees with these comments, it has structured the prohibition to (1) apply to an HMO and to its employees, (2) encompass marketing as well as selling or promoting, and (3) apply to health insurance and health service benefit plans, instead of competing health insurance. However, the Department has limited the prohibition, as to any individual or group, to benefits which the HMO includes in the prepaid health benefit package offered to that individual or group. Thus, for example, if an HMO does not include dental services in the prepaid benefit package it offers to an individual, it would not be prohibited from offering that individual coverage for dental services through an indemnity insurance or health service benefit plan.

Five commenters opposed the proposed restrictions on an HMO's activities. These commenters suggested that the Secretary did not have the statutory authority to limit the HMO's activities. They also characterized the proposed policy as anti-competitive and as detrimental to HMOs, on the basis that an HMO would be prohibited from engaging in certain activities while similar restrictions were not placed on its competitors. The Department believes that the restriction is consistent with the statute. The Department notes that the purpose of Congress in enacting Title XIII of the Act was to foster competition by making HMOs available as a genuine alternative health delivery system, rather than to foster entities which sell, promote or market health insurance or health service benefits plans which compete with the HMO's benefit package. (See S. Rep. No. 93–129, 93rd Cong., 1st Sess. pp. 7, 8 (1973) and H.R. Rep. No. 93–451, 93rd Cong., 1st Sess. p. 8 (1973).) The Department notes that permitting an HMO or its employees to engage in the activities prohibited by § 110.109 would defeat the purpose of Title XIII because it would reduce the incentives for the HMO to offer its qualified prepaid health benefits package in a competitive manner, which might then threaten the fiscal soundness of the HMO. Accordingly, the Department views this limited prohibition as being within the scope of its authority under Title XIII and necessary for its proper implementation.

As to the comments suggesting that the proposed restriction was anti-competitive, the Department believes that the limitation which it has added to § 110.109 has addressed these concerns. Because the HMO is not prohibited from offering indemnity insurance or health service benefit plan coverage for services it does not include in its prepaid health benefit plan, it would be free to respond to a competitive situation by doing so. The HMO would, of course, have the alternative option of offering the services at issue on a prepaid basis as part of its prepaid health benefit package. In the Department's view, this array of options available to the HMO enhances the HMO's competitive posture.

The former §§ 110.109 and 110.110 have been renumbered as §§ 110.110 and 110.111, respectively.

One commenter inquired whether it is permissible for an HMO to own or control a subsidiary that is a separate legal entity and, if so, whether there are any prohibitions on the activities of an HMO's subsidiaries. Nothing in the Act prohibits an HMO from having a subsidiary that is a separate legal entity. Furthermore, at this time there are no prohibitions on the activities of an HMO's subsidiaries. For example, the prohibition at § 110.109 applies to the HMO entity only; it does not apply to subsidiaries of HMOs.

The Department is, however, currently collecting data on the activities of HMO subsidiaries. In particular, the Department is evaluating whether HMO subsidiaries are (1) offering to provide or arrange for prepaid services which do not meet the requirements of Title XIII, or (2) selling, marketing, or promoting, directly or through arrangements with other entities, health insurance or health service benefit plans in the manner prohibited (as to the HMO itself) by the new § 110.109. The Department intends to analyze these data to determine what prohibitions, if any, should be applicable to the activities of HMO subsidiaries. If it appears that some prohibitions might be appropriate, the Department will issue a notice of proposed rulemaking setting forth its proposed policies, invite public comments, and finalize the policies and incorporate them into regulations or set them forth as interpretive rulings, as appropriate.

Other Third Party Policies

1. As set forth in the NPRM, an HMO is required to be a separate legal entity; it may not be a cost center or separate line of business of a sponsor organization. However, an HMO may be a subsidiary of another legal entity as long as the HMO is itself a legal entity with its own policymaking body.

Three commenters, concerned about the requirement noted in the NPRM that each HMO must b a separate legal entity, suggested an exemption from this requirement for public HMOs. Section 1301(a) of the Act and § 110.101 of these regulations, which include in the definition of an HMO the requirement that it be a legal entity, do not distinguish between public and private HMOs. However, the Secretary notes that a public HMO may be administered by a cost center or a department of a public entity, as long as the HMO is the legal entity.

2. The policy that officers, directors, and employees of a sponsoring organization may be included in the non-member portion of the HMO's policymaking body remains as described in the NPRM.

3. The policy that the Department does not intend to regulate the scope of the activities in which a medical group may engage when it is not providing services to members of its affiliated HMO remains as stated in the NPRM. In response to a comment, the Secretary notes that this policy applies to the non-

HMO activities of an individual practice association as well.

4. The policies as to the extent to which HMOs may contract with other parties to perform certain administrative functions which the HMO elects not to perform itself remains as stated in the NPRM. (See 44 FR 41840, section 4).

Technical Changes

1. Section § 110.104(b) has been changed to clarify that payments made by an HMO for physician services from a non-conforming medical group that meets the requirements set forth in § 110.104(a)(3)(ii) will not be counted against the 15 percent limitation on contracting which applies to an HMO four years following the month after its qualification.

2. Section § 110.104(c)(1)(vi) (formerly § 110.104(c)(4)) has been corrected to indicate that the requirement for professional liability coverage applies to medical groups and IPAs *or* the health professionals associated with them, rather than to medical groups, IPAs *and* health professionals associated with them. The interim final regulations contained the correct language in the preamble; however, there was a typographical error in the regulation itself.

3. Section § 110.108(a)(1)(iii) requires that certain HMOs, in order to demonstrate that they have a fiscally sound operation, submit a financial plan. With the publication on April 9, 1980, at 45 FR 24352–7, of regulations implementing section 1305A of the Act ("Loans and Loan Guarantees for Acquisition and Construction of Ambulatory Health Care Facilities"), the Department will soon be initiating the process of making these awards. Accordingly, § 110.108(a)(1)(iii) has been amended to require an HMO seeking a Federal loan or loan guarantee under section 1305A, as well as certain other HMOs, to submit a financial plan to the Secretary.

4. Section § 110.108(a)(v), which requires the HMO to procure and maintain in force a fidelity bond or bonds in an amount not less than $100,000, has been changed to clarify that the $100,000 minimum is applicable to "each" individual who is entrusted with the handling of the HMO's funds.

5. Sections § 110.108(o)(2)(i) and (3) of the interim regulations required an HMO to furnish to the Secretary the information required to be disclosed under the regulations implementing Sections 1124 and 1902(a)(38) of the Social Security Act, at 42 CFR 420.206 and 42 CFR 455.104, respectively. (These references have been changed to reflect the correct citations.) In the interim regulations, the requirements for the disclosure of this information were inadvertently different: While the Section 1124 information was required to be reported to the Secretary annually, the Section 1902(a)(38) information was required to be reported to the Secretary within 35 days of a request and to HMO members upon reasonable request. In order to treat similarly all of the information required to be disclosed under these provisions of the Social Security Act, the provision in former § 110.108(o)(3) has been combined with § 110.108(o)(2)(i). Section 110.108(o)(2) now requires that the information described above (in addition to the information about significant business transactions with parties in interest) be reported annually to the Secretary and be available to members upon reasonable request. The rest of § 110.108(o) has been renumbered accordingly.

The Assistant Secretary for Health of the Department of Health and Human Services, with the approval of the Secretary of Health and Human Services, amends 42 CFR Part 110, Subpart A, as set forth below.

Dated: June 6, 1980.

Julius B. Richmond,

Assistant Secretary for Health.

Approved: October 21, 1980.

Patricia Roberts Harris,

Secretary.

Subpart A is revised to read as follows:

Subpart A—Requirements for a Health Maintenance Organization

Sec.

Authority: Sec. 215 of the Public Health Service Act, as amended, 58 Stat. 690 (42 U.S.C. 216); secs. 1301–1318 of the Public Health Service Act, as amended, 92 Stat. 2131–2141 (42 U.S.C. 300e–300e–17).

Subpart A—Requirements for a Health Maintenance Organization

§ 110.101 Definitions.

As used in this part: "Act" means the Public Health Service Act.

"Basic health services" means health services described in § 110.102(a).

"Community rating system" means a system of fixing rates of payments for health services which meets the requirements of § 110.105(a)(3).

"Comprehensive health services" means as a minimum the following services which may be limited as to time and cost:

(1) Physician services (§ 110.102(a)(1));

(2) Outpatient services and inpatient hospital services (§ 110.102(a)(2));

(3) Medically necessary emergency health services (§ 110.102(a)(3)); and

(4) Diagnostic laboratory and diagnostic and therapeutic radiologic services (§ 110.102(a)(6)).

"Direct service contract" means a contract for the provision of basic or supplemental health services or both between an HMO and (1) a health professional other than a member of the staff of the HMO, or (2) an entity other than a medical group or an IPA.

"Full-time student" means a student who is enrolled for a sufficient number of credit hours in a semester or other academic term to enable the student to complete the course of study within not more than the number of semesters or other academic terms normally required to complete that course of study on a full-time basis at the school in which the student is enrolled.

"Health maintenance organization" (HMO) means a legal entity which provides or arranges for the provision of basic and supplemental health services to its members in the manner prescribed by, is organized and operated in the manner prescribed by, and otherwise meets the requirements of, section 1301 of the Act and the regulations of this subpart.

"Health professionals" means physicians (doctors of medicine and doctors of osteopathy), dentists, nurses, podiatrists, optometrists, physicians' assistants, clinical psychologists, social workers, pharmacists, nutritionists, occupational therapists, physical therapists, and other professionals engaged in the delivery of health services who are licensed, practice under an institutional license, are certified, or practice under authority of the HMO, a medical group, individual practice association, or other authority consistent with State law.

"Individual practice association" (IPA) means a partnership, association, corporation, or other legal entity:

(1) Which delivers or arranges for the delivery of health services and which has entered into a written services arrangement or arrangements with health professionals, a majority of whom are licensed to practice medicine or osteopathy. The written services arrangement shall provide:

(i) That these health professionals shall provide their professional services in accordance with a compensation arrangement established by the entity; and

(ii) To the extent feasible:

(A) For the sharing by these health professionals of health (including medical) and other records, equipment, and professional, technical, and administrative staff; and

(B) For the arrangement and encouragement of the continuing education of these health professionals in the field of clinical medicine and related areas.

"Medical group" means a partnership, association, corporation, or other group:

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

(2) A majority of the members of which are licensed to practice medicine or osteopathy; and

(3) The members of which:

(i) As their principal professional activity (over 50 percent individually) engage in the coordinated practice of their profession and as a group responsibility have substantial responsibility (over 35 percent in the aggregate of their professional activity) for the delivery of health services to members of an HMO;

(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 health (including medical) 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 health professionals employed by 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.

"Medical group members" means (1) a health professional engaged as a partner, associate, or shareholder in the medical group, or (2) any other health professional employed by the group who may be designated as a medical group member by the medical group.

"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. The Secretary will designate these areas as described in § 110.203(d).

"Member," when used in connection with an HMO, means an individual who has entered into a contractual relationship with the HMO or on whose behalf a contractual arrangement has been entered into with the HMO by a subscriber under which the HMO assumes the responsibility for the provision to the member of basic health services and such supplemental health services as may be contracted for.

"Non-conforming medical group" means an entity which would be a medical group for the purposes of this part but for its failure to satisfy the requirements in paragraph (3)(i) of the definition in this section of "medical group" that the members of a medical group: (1) Spend over 50 percent of their professional time in the coordinated practice of their profession and (2) as a group have substantial responsibility (over 35 percent in the aggregate of their professional time) for the delivery of health services to members of an HMO. Except for purposes of § 110.104(a), regarding the providers of basic health services which an HMO may use, a "non-conforming medical group" shall be considered as a "medical group" for purposes of this subpart.

"Nonmetropolitan area" means an area no part of which is within a standard metropolitan statistical area as designated by the Office of Management and Budget and which does not contain a city whose population exceeds 50,000 individuals.

"Party in interest" means: (1) Any director, officer, partner, or employee of an HMO, any person who is directly or indirectly the beneficial owner of more than 5 percent of the equity of the HMO, any person who is the beneficial owner of a mortgage, deed of trust, note, or other interest secured by, and valuing more than 5 percent of the assets of the HMO, and, in the case of an HMO organized as a nonprofit corporation, an incorporator or member of the corporation under applicable State corporation law;

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

(i) Is an officer or director;

(ii) Is a partner (if the entity is organized as a partnership);

(iii) Has directly or indirectly a beneficial interest of more than 5 percent of the equity; or

(iv) Has a mortgage, deed of trust, note, or other interest valuing more than 5 percent of the assets of such entity;

(3) Any member of the immediate family of an individual described in paragraph (1).

"Policymaking body" of an HMO means a board of directors, governing body, or other body of individuals which has the authority to establish policy for the HMO.

"Qualified HMO" means an HMO found by the Secretary to be qualified within the meaning of Section 1310 of the Act and Subpart F of this part.

"Rural area" means any area not listed as a place having a population of 2,500 or more in Document #PC(1)A, "Number of Inhabitants," Table VI, "Population of Places," and not listed as an urbanized area in Table XI, "Population of Urbanized Areas" of the same document (1970 Census or most recent update of this document, Bureau of Census, U.S. Department of Commerce).

"Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

"Service area" means the geographic area as defined through zip codes, census tracts, or other geographic subdivisions, found by the Secretary to be the area within which the HMO provides or arranges for basic and supplemental health services that are available and accessible to its members as required by section 1301(b)(4) of the Act.

"Significant business transaction" means any business transaction or series of transactions during any one fiscal year of the HMO, the total value of which exceeds the lesser of $25,000 or 5 percent of the total operating expenses of the HMO.

"Staff of the HMO" means health professionals who are employees of the HMO and who:

(1) Provide services to HMO members at an HMO facility subject to the staff policies and operational procedures of the HMO;

(2) Engage in the coordinated practice of their profession and provide to members of the HMO the health services which the HMO has contracted to provide;

(3) Share medical and other records, equipment, and professional, technical, and administrative staff of the HMO;

(4) Participate in continuing education in their professional field as provided or arranged for by the HMO; and

(5) Provide their professional services in accordance with a compensation arrangement, other than fee-for-service, established by the HMO. This arrangement may include, but is not limited to, fee-for-time, retainer or salary.

"Subscriber" means a member who has entered into a contractual relationship with the HMO or who is responsible for making payments for basic health services (and contracted for supplemental health services) to the HMO or on whose behalf these payments are made.

"Supplemental health services" means the health services described in § 110.103(a).

"Unusual or infrequently used health services" means: (1) Those health services which are projected to involve fewer than 1 percent of the encounters per year for the entire HMO membership, or,

(2) Those health services the provision of which, given the enrollment projection of the HMO and generally accepted staffing patterns, is projected will require less than 0.25 full time equivalent health professionals.

§ 110.102 Health benefits plan: Basic health services.

(a) An HMO shall provide or arrange for the provision of basic health services to its members as needed and without limitations as to time and cost other than those prescribed in the Act and these regulations, as follows:

(1) Physician services (including consultant and referral services by a physician), which shall be provided by a licensed physician, or if a service of a physician may also be provided under applicable State law by other health professionals, an HMO may provide the service through these other health professionals;

(2)(i) Outpatient services, which shall include diagnostic services, treatment services and x-ray services, for patients who are ambulatory and may be provided in a non-hospital based health care facility or at a hospital; (ii) inpatient hospital services, which shall include but not be limited to, room and board, general nursing care, meals and special diets when medically necessary, use of operating room and related facilities, use of intensive care unit and services, x-ray services, laboratory, and other diagnostic tests, drugs, medications, biologicals, anesthesia and oxygen services, special duty nursing when medically necessary, radiation therapy, inhalation therapy, and administration of whole blood and blood plasma; (iii) outpatient services and inpatient hospital services shall include short-term rehabilitation services and physical therapy, the provision of which the HMO determines can be expected to result in the significant improvement of a member's condition within a period of two months;

(3) Instructions to its members on procedures to be followed to secure medically necessary emergency health services both in the service area and out of the service area;

(4) Twenty outpatient visits per member per year, as may be necessary and appropriate for short-term evaluative or crisis intervention mental health services, or both;

(5) Diagnosis, medical treatment and referral services (including referral services to appropriate ancillary services) for the abuse of or addiction to alcohol and drugs:

(i) Diagnosis and medical treatment for the abuse of or addiction to alcohol and drugs shall include detoxification for alcoholism or drug abuse on either an outpatient or inpatient basis, whichever is medically determined to be appropriate, in addition to the other required basic health services for the treatment of other medical conditions;

(ii) Referral services may be either for medical or for nonmedical ancillary services. Medical services shall be a part of basic health services; nonmedical ancillary services (such as vocational rehabilitation and employment counseling) and prolonged rehabilitation services in a specialized inpatient or residential facility need not be a part of basic health services;

(6) Diagnostic laboratory and diagnostic and therapeutic radiologic services in support of basic health services;

(7) Home 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 HMO; and

(8) Preventive health services, which shall be made available to members and shall include at least the following:

(i) A broad range of voluntary family planning services;

(ii) Services for infertility;

(iii) Well-child care from birth;

(iv) Periodic health evaluations for adults;

(v) Eye and ear examinations for children through age 17, to determine the need for vision and hearing correction; and

(vi) Pediatric and adult immunizations, in accord with accepted medical practice.

(b) In addition, an HMO may include a health service described in § 110.103 as a supplemental health service in the basic health services which it provides or arranges for its members for a basic health services payment.

(c) To the extent that a natural disaster, war, riot, civil insurrection, epidemic or any other emergency or similar event not within the control of an HMO results in the facilities, personnel, or financial resources of an HMO being unavailable to provide or arrange for the provision of a basic or supplemental health service in accordance with the requirements of this subpart, the HMO is required only to make a good-faith effort to provide or arrange for the provision of the service, taking into account the impact of the event. For purposes of this paragraph, an event is not within the control of an HMO if the HMO cannot exercise influence or dominion over its occurrence.

(d) The following are not required to be provided as basic health services:

(1) Corrective appliances and artificial aids;

(2) Mental health services, except as required under section 1302(1)(D) of the Act and paragraph (a)(4) of this section;

(3) Cosmetic surgery, unless medically necessary;

(4) Prescribed drugs and medicines incidental to outpatient care;

(5) Ambulance services, unless medically necessary;

(6) Care for military service connected disabilities for which the member is legally entitled to services and for which facilities are reasonably available to this member;

(7) Care for conditions that State or local law requires be treated in a public facility;

(8) Dental services;

(9) Vision and hearing care except as required by sections 1302(1)(A) and 1302(1)(H)(vi) of the Act and paragraphs (a)(1) and (a)(8) of this section;

(10) Custodial or domiciliary care;

(11) Experimental medical, surgical, or other experimental health care procedures, unless approved as a basic health service by the policymaking body of the HMO;

(12) Personal or comfort items and private rooms, unless medically necessary during inpatient hospitalization;

(13) Whole blood and blood plasma;

(14) Long-term physical therapy and rehabilitation;

(15) Durable medical equipment for home use (such as wheel chairs, surgical beds, respirators, dialysis machines); and

(16) Health services which are unusual and infrequently provided and not necessary for the protection of individual health, as approved by the Secretary upon application by the HMO.

(e) An HMO may not offer to provide or arrange for the provision of basic health services on a prepayment basis which do not include all the basic health services set forth in paragraph (a) of this section or which are limited as to time and cost except in a manner prescribed by this part.

§ 110.103 Health benefits plan: supplemental health services.

(a) Each HMO may provide to its members any of the following health services, which may be limited as to time and cost:

(1) Services of facilities for intermediate and long-term care;

(2) Vision and hearing care not included as a basic health service;

(3) Dental services;

(4) Mental health services not included as a basic health service;

(5) Long-term physical medicine and rehabilitative services (including physical therapy);

(6) Prescription drugs prescribed in the course of the provision by the HMO of basic outpatient or supplemental health services; and

(7) Other health services which are not included as basic health services.

(b) An HMO shall determine the level and scope of supplemental health services included with basic health services provided to its members for a basic health services payment or those services offered to its members as supplemental health services.

(c) An HMO is authorized, in connection with the prescription or provision of prescription drugs, to: (1) Maintain, review, and evaluate a drug use profile of its members receiving these services, (2) evaluate patterns of drug utilization to assure optimum drug therapy, and (3) provide for instruction of its members and of health professionals in the use of prescription and non-prescription drugs. Each HMO providing these services shall insure that:

(i) The program is developed jointly by the physicians and pharmacists associated with the HMO;

(ii) The objectives of the program are explained to all health professionals and members of the HMO;

(iii) Individual rights are protected and that all information regarding and identifying an individual is available only to appropriate health professionals of the HMO and to the individual member at his request;

(iv) The primary thrust of the program is optimum drug therapy for the individual member of the HMO; and

(v) The information obtained in drug utilization review is utilized in educational programs for health professionals and members of the HMO.

§ 110.104 Providers of basic and supplemental health services.

(a)(1) The HMO shall provide that the services of health professionals which are provided as basic health services will, except as provided in paragraph (e) of this section, be provided or arranged for through (i) health professionals who are staff of the HMO, (ii) a medical group or groups, (iii) an IPA or IPAs, (iv) physicians or other health professionals under direct service contracts with the HMO for the provision of these services, or (v) any combination of staff, medical group or groups, IPA or IPAs, or physicians or other health professionals under direct service contracts with the HMO.

(2) A staff or medical group model HMO may have as providers of basic health services physicians who have also entered into written services arrangements with an IPA or IPAs, but only if either (i) these physicians number less than 50 percent of the physicians who have entered into arrangements with the IPA or IPAs, or (ii) if the sharing is 50 percent or greater, the Secretary approves the sharing as being consistent with the purposes of section 1310(b) of the Act.

(3) Within the 4 year period beginning with the month following the month in which an HMO becomes a qualified HMO, physician services which are basic health services may also be provided by a non-conforming medical group. After this 4 year period, the HMO may use this entity to provide physician services which are basic health services only if (i) the entity meets the definition of medical group in § 110.101, or (ii) the Secretary determines that the principal professional activity (over 50 percent individually) of the entity's members is the coordinated practice of their profession, and if the HMO has demonstrated to the satisfaction of the Secretary that the entity is committed to the delivery of medical services on a prepaid group practice basis by either:

(A) Presenting a reasonable time-phased plan for the entity to achieve compliance with the "substantial responsibility" requirement of Subparagraph (3)(i) of the definition of "medical group" in § 110.101. The HMO shall update the plan annually and shall demonstrate to the satisfaction of the Secretary that the entity is making continuous efforts and progress towards compliance with the requirements of the definition of "medical group," or,

(B) Demonstrating that compliance by the entity with the "substantial responsibility" requirement is unreasonable or impractical because *(1)* the HMO serves a non-metropolitan or rural area as defined in § 110.101, or *(2)* the entity is a multi-specialty group which provides medical consultation upon referral on a regional or national basis, or *(3)* the majority of the residents of the HMO's service area are not eligible for employer-employee health benefits plans and the HMO has an insufficient number of members to require utilization of at least 35 percent of the entity's services.

(b) After the expiration of the first fiscal years of an HMO beginning after the month in which it become a qualified HMO, the HMO may not, in any fiscal year, enter into contracts for basic and supplemental health services with physicians other than members of staff, medical groups, of IPAs if the amounts paid under these contracts exceed (1) 15 percent of the total estimated amount to be paid in that fiscal year by the HMO to physicians for the provision of basic and supplemental health services by physicians, or (2) if the HMO principally serves a rural area, 30 percent of that amount. However, this paragraph does not apply to payments under a contract for the purchase of physician services from a non-conforming medical group that meets the conditions set forth in § 110.104(a)(3)(ii).

(c) HMOs shall include: (1) In their contracts with medical groups or IPAs for the provision of basic and supplemental health services at least the following:

(i) A description of responsibilities of the parties to the contract;

(ii) The agreed upon compensation for services;

(iii) An agreement that the medical group or IPA, its members and the health professionals contracting with it, will look solely to the HMO for compensation for services provided to the HMO's members. This agreement shall not extend to copayments or payments for supplemental health services on other than a prepaid basis, but the contracting party shall not assert any claim for compenstion against members in excess of these copayments or payments for these supplemental health services;

(iv) Provisions requiring participation by health professionals in quality assurance activities;

(v) A description of mechanisms, such as risk sharing, financial incentives, or other incentives, to be applied to monitor utilization and to control costs

of basic and supplemental health services and to achieve utilization goals; and

(vi) Assurances that medical groups and IPAs, or the health professionals associated with them, will be protected by professional liability coverage, either through insurance or self-insurance;

(2) In their contracts with health professionals for the provision of basic and supplemental health services (except for unusual or infrequently used services) at least the following:

(i) The provisions described in paragraphs (c)(1)(i), (ii), (iii), and (iv) of this section; and

(ii) Provisions requiring appropriate continuing education.

(d) Staff model HMOs shall have effective procedures to monitor utilization and to control cost of basic and supplemental health services, and to achieve utilization goals.

(e) Paragraph (a) of this section does not apply to the provision of the services of a physician—

(1) Which the HMO determines are unusual or infrequently used services; or

(2) Which, because of an emergency, it was medically necessary to provide to the member other than as required by paragraph (a) of this section; or

(3) Which are provided as part of the inpatient hospital services by employees or staff of a hospital or provided by staff of other entities such as community mental health centers, home health agencies, visiting nurses' associations, independent laboratories, or family planning agencies.

(f) Supplemental health services shall be provided or arranged for by the HMO and need not be provided by providers of basic health services under contract with the HMO.

(g) Each HMO shall:

(1) Pay the provider, or reimburse its members for the payment of reasonable charges for basic health services (or supplemental health services which the HMO agreed to provide on a prepayment basis) for which its members have contracted, which were medically necessary and immediately required to be obtained other than through the HMO because of an unforeseen illness, injury, or condition, as determined by the HMO;

(2) Adopt procedures to review promptly all claims from members for reimbursement for the provision of health services described in paragraph (g)(1) of this section, including a procedure for the determination of the medical necessity for obtaining the services other than through the HMO; and

(3) Provide instructions to its members on procedures to be followed to secure these health services.

§ 110.105 Payment for basic health services.

(a) *Basic health services payment.* Each HMO shall provide or arrange for the provision of basic health services for a basic health services payment which:

(1) Is to be paid on a periodic basis without regard to the dates these services are provided;

(2) Is fixed without regard to the frequency, extent, or kind of basic health services actually furnished;

(3) Except as provided in paragraph (c) of this section, is fixed under a community rating system, as described in paragraph (b) of this section; and

(4) May be supplemented by nominal copayments which may be required for the provision of specific basic health services. Each HMO may establish one or more copayment options calculated on the basis of a community rating system.

(i) An HMO may not impose copayment charges that exceed 50 percent of the total cost of providing any single service to its members, nor in the aggregate more than 20 percent of the total cost of providing all basic health services.

(ii) To insure that copayments are not a barrier to the utilization of health services or membership in the HMO, an HMO may not impose copayment charges on any subscriber (or members covered by the subscriber's contract with the HMO) in any calendar year, when the copayments made by the subscriber (or members) in that calendar year total 100 percent of the total annual premium cost which that subscriber (or members) would be required to pay if he (or they) were enrolled under an option with no copayments. This limitation applies only if the subscriber (or members) demonstrates that copayments in that amount have been paid in that year.

(b) *Community rating system.* Under a community rating system, rates of payment for health services may be determined on a per-person or per-family basis and may vary with the number of persons in a family. Except as otherwise authorized in this paragraph, these rates must be equivalent for all individuals and for all families of similar composition. Rates of payment may be based on either a schedule of rates charged to each subscriber group or on a per-member-per-month (or per-subscriber-per-month) revenue requirement for the HMO. In the former event, rates may vary from group to group if the projected total revenue from each group in substantially equivalent to the revenue which would be derived if the schedule of rates were uniform for all groups. In the latter event, the payments from each group of subscribers shall be calculated to yield revenues substantially equivalent to the product of the total number of members (or subscribers) expected to be enrolled from the group and the per-member-per-month (or per-subscriber-per-month) revenue requirement for the HMO. In addition, a community rating system must meet the following requirements:

(1) Rates of payment may not vary because of actual or anticipated utilization of services by individuals associated with any specific group of subscribers. These provisions do not preclude changes in the rates of payment which are established for new enrollments or reenrollments and which do not apply to existing contracts until the renewal of these contracts.

(2) Rates of payment shall reflect differences in benefits and copayment requirements.

(3) The following differentials may be established under a community rating system.

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

(A) Individual (nongroup) subscribers (including their families),

(B) Small groups of subscribers (100 subscribers or fewer),

(C) Large groups of subscribers (over 100 subscribers).

(ii) Differentials in rates may be established for subscribers enrolled in a HMO: (A) Under a contract with a governmental authority under section 1079 ("Contracts for Medical Care for Spouses and Children: Plans") or section 1086 ("Contracts for Health Benefits for Certain Members, Former Members and their Dependents") of Title 10 ("Armed Forces"), United States Code; or (B) under any other governmental program (other than the health benefits program authorized by chapter 89 ("Health Insurance") of Title 5 ("Government Organization and Employees"), United States Code; or (C) under any health benefits program for employees of States, political subdivision of States, and other public entities.

(iii) an HMO may establish a separate community rate for separate regional components of the organization upon satisfactory demonstration to the Secretary of the following:

(A) Each regional component is geographically distinct and separate from any other regional component; and

(B) Each regional component provides substantially the full range of basic health services to its members, without extensive referral between components of the organization for these services, and without substantial utilization by any two components of the same health care facilities. The separate community rate for each regional component of the HMO must be based on the different costs of providing health services in the respective regions.

(c) *Exceptions to community rating requirement.* (1) In the case of an HMO which provided comprehensive health services on a prepaid basis before it became a qualifed HMO, the requirement of community rating shall not apply to the HMO during the forty-eight month period beginning with the month following the month in which it became a qualifed HMO.

(2) The requirement of community rating does not apply to the basic health services payment for basic health services provided a member who is a full-time student at an accredited institution of higher education.

(d) *Charges for benefits covered by workers' compensation law or insurance policy.* The requirements respecting the basic health services payment do 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 workers' compensation law or an insurance policy, but only to the extent these benefits apply to these services.

(1) For the provision of services for an illness or injury for which a member is entitled to benefits under a workers' compensation law, the HMO may, if authorized by this law, charge or authorize the provider of the services to charge, in accordance with the charges allowed under the law: (i) The insurance carrier, employer, or other entity which under the law is to pay for the provision of the services, or (ii) the member, to the extent that the member has been paid under the law for the services.

(2) For the provision of services for an illness or injury for which a member is entitled to benefits under an insurance policy, an HMO may charge or authorize the provider of the services to charge: (i) The insurance carrier under the policy, or (ii) the member, to the extent that the member has been paid under the policy for the services.

(e) *Late payment penalty.* HMOs may charge a late payment penalty on accounts receivable which are in arrears.

§ 110.106 Payment for supplemental health services.

(a) An HMO may require supplemental health services payments, in addition to the basic health services payments, for the provision of each health service included in the supplemental health services set forth in § 110.103 for which subscribers have contracted, or it may include supplemental health services in the basic health services provided its members for a basic health services payment.

(b) Supplemental health services payments may be made in any agreed upon manner, such as prepayment or fee-for-service. Supplemental health services payments which are fixed on a prepayment basis, however, 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 at an accredited institution of higher education. In the case of an HMO which provided comprehensive health services on a prepaid basis before it became a qualifed HMO, the community rating requirement shall not apply to that HMO during the forty-eight month period beginning with the month following the month in which it became a qualifed HMO.

(c) When the HMO provides supplemental health services on a prepayment basis for which the member is entitled to benefits under a workers' compensation law or an insurance policy, the HMO may take the actions described in § 110.105(d)(1) or (2) (respecting charges for basic health services which are benefits under a workers' compensation law or insurance policy) as appropriate.

§ 110.107 Availability, accessibility, and continuity of basic and supplemental health services.

Within the HMO's service area, basic health services and those supplemental health services for which members have contracted shall be:

(a) Provided or arranged for by the HMO;

(b) Available and accessible to each of the HMO's members promptly as appropriate with respect to:

(1) Geographic location, hours of operation, and provisions for after-hours services (medically necessary emergency services must be available and accessible 24 hours a day, 7 days a week); and

(2) Staffing patterns within generally accepted norms for meeting the projected membership needs; and

(c) Provided in a manner which assures continuity, including but not limited to:

(1) Provision of a health professional who is primarily responsible for coordinating the member's overall health care; and

(2) Development of a health (including medical) recordkeeping system through which pertinent information relating to the health care of the patient is accumulated and is readily available to appropriate professionals.

§ 110.108 Organization and operation.

(a) *Fiscally sound operation and administrative and managerial arrangements.* (1) Each HMO shall have a fiscally sound operation as demonstrated by:

(i) Total assets being greater than total unsubordinated liabilities. In this evaluation, loan funds awarded or guaranteed under section 1305 of the Act are not included as liabilities, and if the funds have not been disbursed to the HMO by the Secretary or by an escrow agent, they are not included as assets;

(ii) Sufficient cash flow and adequate liquidity to meet obligations as they become due;

(iii) A net operating surplus. If the HMO has not earned a cumulative net operating surplus during the three most recent fiscal years, did not earn a net operating surplus during the most recent fiscal year, does not a have positive net worth, or is seeking a Federal loan or loan guarantee under sections 1305 or 1305A of the Act, the HMO shall submit a financial plan satisfactory to the Secretary to achieve net operating surplus within available fiscal resources. This plan shall include:

(A) A detailed marketing plan;

(B) Statements of revenue and expense on an accrual basis;

(C) Sources and uses of funds' statements; and

(D) Balance sheets;

(iv) A plan for handling insolvency which allows for continuation of benefits for the duration of the contract period for which payment has been made, continuation of benefits to members who are confined on the date of insolvency in an inpatient facility until their discharge, and payments to unaffiliated providers for services rendered;

(v) A fidelity bond or bonds, procured and maintained by the HMO, in an amount fixed by its policymaking body but not less than $100,000 per individual, covering each officer and employee entrusted with the handling of its funds. The bond may have reasonable deductibles, based upon the financial strength of the HMO;

(vi) Insurance policies or other arrangements, secured and maintained by the HMO and approved by the Secretary to insure the HMO against losses arising from professional liability claims, fire, theft, fraud, embezzlement, and other casualty risks; and

(vii) A plan to maximize its enrollment in a manner consistent with sound management.

(2) Each HMO shall have administrative and mangerial arrangements satisfactory to the Secretary, as demonstrated by at least the following:

(i) A policymaking body which exercises oversight and control over the HMO's policies and personnel to assure that management actions are in the best interest of the HMO and its membership; and

(ii) Personnel and systems sufficient for the HMO to organize, plan, control and evaluate the financial, marketing, health services, quality assurance program, administrative and management aspects of the HMO. At a minimum, the HMO shall be managed by an executive whose appointment and removal are under the control of the HMO's policymaking body.

(b) *Financial risk.* Each HMO shall assume full financial risk on a prospective basis for the provision of basic health services, except that it may obtain insurance or make other arrangements: (1) For the cost of providing to any member basic health services the aggregate value of which exceeds $5,000 in any year;

(2) For the cost of basic health services provided to its members other than through the HMO because medical necessity required their provision before they could be secured through the HMO; and

(3) For not more than 90 percent of the amount by which its costs for any of its fiscal years exceed 115 percent of its income for that fiscal year.

(c) *Broadly representative enrollment.* After full and fair disclosure of its benefits, coverage, rates, grievance procedures, location, and hours of service, and a general description of its participating providers and financial condition, each HMO shall offer enrollment to persons who are broadly representative of the various age, social, and income groups within its device area. In the case of an HMO which has a medically underserved population located in its service area, not more than 75 percent of the HMO members may be enrolled from the medically underserved population unless the area in which that population resides is also a rural area.

(d) *Open enrollment.* If the HMO has either provided comprehensive health services on a prepaid basis for a period of at least 5 years or has an enrollment of at least 50,000 members, it shall have an open enrollment period at least once during the fiscal year next following each fiscal year in which it did not have a financial deficit. (For purposes of this paragraph, financial deficits must be reported and certified by an independent Certified Public Accountant.) The period of open enrollment shall be determined under paragraph (d)(1) of this section. During open enrollment, the HMO shall accept individuals for membership in the order in which they apply for enrollment and, except as provided in paragraph (d)(2) of this section, without regard to preexisting illness, medical condition, or degree of disability.

(1) An open enrollment period for an HMO 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 the open enrollment period is held. In determining the total net increase in enrollment in an HMO, the HMO need not include any individual who is (A) enrolled in the HMO through a group which had a contract or other arrangement for health care services with the HMO when the HMO was determined to be a qualified HMO, or (B) entitled to insurance benefits under Title XVIII of the Social Security Act or to medical assistance under a State plan approved under Title XIX of that Act and was enrolled in the HMO when the HMO was determined to be a qualified HMO.

(2) An HMO is not required to enroll individuals who are confined to an institution because of (i) chronic illness, (ii) permanent injury, or (iii) other infirmity which would cause economic impairment to the HMO, as demonstrated to the satisfaction of the Secretary, if these individuals were enrolled.

(3) And HMO may defer the effective date of benefits for individuals enrolled under this paragraph for up to 90 days after the date of enrollment.

(4) An HMO may require an individual applying for membership at periods other than the required annual open enrollment period to submit to and pay for a health status questionnaire or a health examination. An HMO may deny enrollment based on results of this questionnaire or health examination.

(5) The Secretary may, under paragraph (e) of this section, waive the requirements of this paragraph for an HMO which demonstrates that compliance with the provisions of this paragraph would jeopardize its economic viability.

(e) *Waiver of open enrollment.* In order to obtain a waiver under paragraph (d)(5) of this section, the HMO shall submit documentation that it has prospectively determined on an actuarial basis, using data available in the area or from similar organizations elsewhere, that the average utilization of services of potential individual members would so increase costs as to jeopardize the economic viability of the organization if it maintained an open enrollment period.

(f) *Health status and enrollment.* The HMO shall not expel or refuse to re-enroll any member nor refuse to enroll individual members of a group, on the basis of the health status, health care needs, or age of the member or individual. For purposes of this paragraph, a "group" is an entity which consists of members who enroll in the HMO through a contract or other arrangement which provides for the enrollment of two or more subscribers. Nothing in this subpart prohibits an HMO from requiring that, as a condition of continued eligibility for membership, dependents of a subscriber, upon reaching a specified age, convert to nongroup membership consistent with the terms of § 110.108(g).

(g) *Conversion of membership.* Each HMO shall offer membership on the same terms and conditions as are available to a nongroup subscriber to:

(1) Each subscriber (and his enrolled dependents) leaving a group; and

(2) Each member who would otherwise cease to be eligible for HMO membership because of his or her age or the death or divorce of a subscriber.

(h) *Policymaking body.* (1) In the case of a private HMO, no later than one year after becoming operational as a qualified HMO, at least one-third of the membership of its policymaking body must be members of the HMO who reside in or in proximity to the service area of the HMO. An HMO with regional components and one overall policymaking body must assure that the individuals satisfying the one-third member requirement reside in, or in proximity to, the service area of at least one of the HMO's regional components. HMOs with policymaking bodies consisting of the same individuals must assure that the individuals satisfying the one-third member requirement reside in, or in proximity to, the service area of at least one of the HMOs.

(i) No member having ownership of or financial interest in, or employed by, or gaining financial reward from direct dealings with, the HMO or a plan-

affiliated institution or organization, and no members of the immediate family of such member shall be included in the minimum one-third member representation on the policymaking body. However, none of the foregoing prohibits the payments of directors' fees or other similar fees, or interest and dividends derived from membership in an HMO cooperative, to persons serving on the policymaking body.

(ii) There shall be equitable representation on the member portion of the policymaking body of members from the medically underserved populations served by the HMO in proportion to their enrollment relative to the entire enrollment; except that if the membership from these medically underserved populations is at least 5 percent of the total enrollment, then those populations shall not be without representation.

(2) In the case of public HMO, have an advisory board to its policymaking body operating the HMO which board meets the requirements of subparagraph (1) of this paragraph, and to which may be delegated policymaking authority for the HMO.

(i) *Grievance procedures.* Each HMO shall have and use meaningful procedures for hearing and resolving grievances between the HMO (including the staff of the HMO, the medical group, and the IPA) and the members of the HMO. These procedures must assure that: (1) Grievances and complaints will be transmitted in a timely manner to appropriate decisionmaking levels within the HMO which have authority to take corrective action; and (2) appropriate action will be taken promptly, including a full investigation if necessary and notification of concerned parties as to the results of the HMO's investigation.

(j) *Quality assurance program.* Each HMO shall have an ongoing quality assurance program for is health services which:

(1) Stresses health outcomes to the extent consistent with the state of the art;

(2) Provides review by physicians and other health professionals of the process followed in the provision of health services;

(3) Uses systematic data collection of performance and patient results, provides interpretation of these data to its practitioners, and institutes needed change; and

(4) Includes written procedures for taking appropriate remedial action whenever, as determined under the quality assurance program, inappropriate or substandard services have been provided or services which should have been furnished have not been provided;

(k) *Certification of institutional providers.* Each HMO shall assure that institutional providers through which it provides basic and supplemental health services (1) are certified either under Title XVIII of the Social Security Act (Medicare) in accordance with 42 CFR Part 405 or under Title XIX of the Social Security Act (Medicaid) in accordance with the regulations governing participation of providers in the Medical Assistance Program; or (2) in the case of hospitals, are either accredited by the Joint Commission on Accreditation of Hospitals or certified by Medicare; or (3) in the case of clinical laboratories (except for laboratories exempted from section 353 of the Public Health Service Act by paragraphs (d)(2), (i), or (1) of that section), certified by Medicare or Medicaid or licensed under section 353.

(l) *Continuing education of health professionals.* Each HMO shall provide, or make arrangements for, continuing education for its health professional staff;

(m) *Health education.* In support of the provision of health services, each HMO shall actively provide its members:

(1) Health education services including instruction in personal health care measures;

(2) Information about its services, including education on generally accepted medical standards for use and frequency of its services; and

(3) Nutritional education and counseling;

(n) *Medical social services.* In support of the provision of health services, each HMO shall offer its members medical social services, which shall include appropriate assistance in dealing with the physical, emotional and economic impact of illness and disability. These services may include pre- and post-hospitalization planning, referral to services provided through community health and social welfare agencies, and related family counseling;

(o) *Reporting and disclosure requirements.* (1) While safeguarding the confidentiality of the doctor-patient relationship, each HMO shall provide an effective procedure to develop, compile, evaluate, and report to the Secretary, to its members, and to the general public, at the times and in the manner the Secretary requires, statistics and other information relating to:

(i) The cost of its operations;

(ii) The patterns of utilization of its services;

(iii) The availability, accessibility, and acceptability of its services;

(iv) To the extent practical, developments in the health status of its members;

(v) Information demonstrating that the HMO has a fiscally sound operation;

(vi) Other matters as the Secretary may require;

(2) Each HMO shall report to the Secretary annually, within 180 days of the end of its fiscal year (unless for good cause shown, the Secretary authorizes an extension of time):

(i) The information required to be reported by disclosing entities under regulations implementing section 1124 and section 1902(a)(38) of the Social Security Act (see 42 CFR 420.206 and 42 CFR 455.104), respectively.

(ii) A description of the following significant business transactions between the HMO and a party in interest, and a justification that the costs of these transactions do not exceed the costs which would be incurred if these transactions were to be with someone who is not a party in interest (or if they do, a justification that the higher costs are consistent with prudent management and fiscal soundness requirements):

(A) Sale, exchange, or leasing of property;

(B) Furnishing for consideration of goods, services (including management services, but excluding health services provided to members by staff, medical groups, IPAs, or any combination thereof and services provided by employees of the HMO in the normal course of their employment), or facilities; and

(C) Lending of money or other extension of credit.

(3)(i) Report to the Secretary annually, within 180 days of the end of its fiscal year (unless for good cause shown, the Secretary authorizes an extension of time), a combined financial statement for the organization and such entity if:

(A) Thirty-five percent or more of the costs of operation of the HMO go to a party in interest; or

(B) Thirty-five percent or more of the revenue of a party in interest is from the HMO.

The combined financial statements must display in separate columns the financial information for the HMO and each of these parties in interest. Inter-entity transactions must be eliminated in the consolidated column. These statements must have been examined by an independent auditor in accordance with generally accepted accounting principles, and must include appropriate opinions and notes.

(ii) The Secretary may, upon a written request from an HMO and for good

cause shown, waive the requirement that its combined financial statement include the financial information required in this paragraph with respect to a particular entity.

(p) *Human diginity.* Each HMO shall be organized and operated in a manner intended to preserve human dignity;

(q) *Confidentiality of health records.* Each HMO shall establish adequate procedures to insure confidentiality of its members' health (including medical) records; and

(r) *Referral information.* Each HMO shall make arrangements either directly or through its providers to assure that the HMO or the health professional coordinating the member's overall health care is kept informed about the services provided to its members by referral resources.

§ 110.109 Prohibited activities.

An HMO may not sell, market or promote, to an individual or group, directly or through arrangements with other entities, health insurance or a health service benefit plan for health benefits which the HMO includes in the prepaid health benefits package offered to that individual or group. In addition, the HMO may not permit its employees to do so in the normal course of their employment.

§ 110.110 Special requirements: Titles XVIII and XIX of the Social Security Act.

(a) As provided in section 1307(d) of the Act, an HMO which otherwise complies with section 1301(b) and section 1301(c) of the Act, and with the applicable regulations of this subpart, and which enrolls members who are entitled to insurance benefits under Title XVIII of the Social Security Act or to medical assistance under a State plan approved under Title XIX of that Act, may still be considered as an HMO, if with respect to its Title XVIII and Title XIX members it provides services and is operated as required by Title XVIII or XIX, as appropriate, and regulations thereunder.

(b) Notwithstanding any inconsistent requirements of this subpart, an HMO which enters into a contract with the Secretary under Title XVIII of the Social Security Act or with a State under Title XIX of that Act shall, with respect to its members entitled to insurance benefits or medical assistance under those titles, comply with the applicable Title XVIII or Title XIX requirements, including deductible and coinsurance requirements, enrollment mix and enrollment practice requirements, in accordance with the provisions of Title XVIII or the Title XIX State plan of the State with which it is contracting. Copayment options which are not in accordance with a Title XIX State plan may not be imposed on Title XIX enrollees.

(c) Any grievance procedures authorized under Title XVIII or Title XIX of the Social Security Act are not superseded by the provisions of § 110.108(i).

§ 110.111 Special requirements: Federal employee health benefits program.

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 an HMO for purposes of receiving assistance under this Part if with respect to its other members it (a) provides health services in accordance with section 1301(b) of the Act and the applicable regulations of this part and (b) is organized and operated in the manner prescribed by section 1301(c) of the Act and the applicable regulations of this part.

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