

Version as of April 21, 2003

NOTICE OF FINAL ADOPTION

AGENCY FOR HEALTH CARE ADMINISTRATION

DIVISION OF MANAGED CARE AND HEALTH QUALITY

BUREAU OF MANAGED HEALTH CARE

PROGRAM: HEALTH FACILITY AND AGENCY LICENSING

RULE TITLE:	RULE NUMBER:
Definitions	59A-12.002
Administration, Forms, Fees	59A-12.003
Governing Body	59A-12.004
Quality of Care	59A-12.006
Quality of Assurance	59A-12.007
Accreditation	59A-12.0071
Accreditation Organizations	59A-12.0072
Subscriber Grievance Procedures	59A-12.010

STATEMENT OF FACTS AND CIRCUMSTANCES JUSTIFYING THE RULES:

The purpose of the proposed amendments is to establish and clarify the procedures for Health Maintenance Organizations health care services. The Agency for Health Care Administration is proposing to amend rule 59A-12.002, 59A-12.003, 59A-12.004, 59A-12.006, 59A-12.007, 59A-12.0071, 59A-12.0072, and 59A-12.010, Florida Administrative Code, to implement section 641.56 Florida Statutes. As required in section 641.56, Florida Statutes, the proposed rules for Healthcare Maintenance Organizations (HMOs) and Prepaid

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Health Clinics (PHCs) provide amended requirements and procedures for, administration of provider certificates, the form for regulatory assessment and fees, the governing body responsibility for risk management programs, quality of care documentation and information given to subscribers and grievance improvement actions, quality assurance utilization review responsibility, accreditation, accreditation organizations reporting, and definitions clarification.

They specify requirements for the organization of physicians in an HMO or PHC to maintain acceptable standards of care in the betterment and delivery of health care services. They change the availability for inspections of the Grievance files from the Division of Financial Services (DOI) to the agency; and exclude peer review from the information in the quality assurance process.

RULE SUMMARY: As required in section 641.56, Florida Statutes, the proposed rules for Healthcare Maintenance Organizations (HMOs) and Prepaid Health Clinics (PHCs) provide amended requirements and procedures for, administration of provider certificates, the form for regulatory assessment and fees, the governing body responsibility for risk management programs, quality of care documentation and information given to subscribers and grievance improvement actions, quality assurance utilization

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review responsibility, accreditation, accreditation organizations reporting, and definitions clarification.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COST: No statement of estimated regulatory cost has been prepared. Any person who wishes to provide information regarding the statement of estimated regulatory costs or to provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

THE FULL TEXT OF THE PROPOSED RULE IS:

CHAPTER 59A-12 HEALTH MAINTENANCE ORGANIZATIONS AND PREPAID HEALTH CLINICS

59A-12.002 Definitions.

(1) Through (3) no change.

(4) PCP. Primary Care Provider shall be abbreviated as PCP in these rules.

(5)~~(4)~~ Renumbered. No change.

(6)~~(5)~~ Medical Staff of the HMO or PHC. A formal organization of ~~employed~~ physicians in an HMO or PHC with responsibility ~~the delegated responsibility~~ to maintain acceptable standards concerning ~~in~~ the delivery of health care and to plan for continued betterment of that care.

(7)~~(6)~~ Minimum Services. Minimum services include the following:

(a) Emergency Care. Emergency inpatient, outpatient and physician services shall be available on a 24-hour, 7-day a week basis, either by the HMO or PHC through its own facilities or through arrangements with providers. Emergency resuscitation supplies shall be available. In addition, emergency services, as defined in these rules, shall be covered by the HMO or PHC;:-

(b) Inpatient Hospital Services. Inpatient hospital services shall be available on a 24-hour, 7-day a week basis either through the HMO's own facility or through arrangements with hospitals. Inpatient hospital services shall include, for example: 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, radiation therapy, inhalation therapy, and administration of whole blood and blood plasma;:-

(c) Physician Care. Physician care, provided or supervised by physicians licensed under Chapter 458, 459, 460 or 461, F.S., to include PCPs and specialists of sufficient type and number to adequately provide for the contracted services. Physician care shall include consultant and referral services by a physician;:-

(d) Ambulatory Diagnostic Treatment. Outpatient diagnostic treatment services with an emphasis directed toward primary care. Ambulatory diagnostic treatment shall include diagnostic laboratory and diagnostic radiological services;~~;~~ and

(e) Preventive Health Care Services. A program of health evaluation, education and immunizations which is designed to prevent illness and disease and to improve the general health of HMO or PHC subscribers. This program shall include at least the following:

1. Well-child care from birth;
2. Periodic health evaluations for adults;
3. Eye and ear screenings by a physician for children through age 21 ~~17~~ to determine the need for vision or hearing correction; and
4. Pediatric and adult immunizations, in accord with accepted medical practice.

(8) ~~(7)~~ Renumbered. No change.

(9) ~~(8)~~ Renumbered. No change.

(10) ~~(9)~~ Renumbered. No change.

(11) ~~(10)~~ Renumbered. No change.

(12) ~~(11)~~ Second medical opinion. A consultation by a physician other than the member's primary care physician, whose specialty ~~speciality~~ is appropriate to the need, and whose services are obtained when the member disputes the

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appropriateness or necessity of a surgical procedure, is subject to a serious injury or illness, including failure to respond to the current treatment plan.

(13) ~~(12)~~ Renumbered. No change.

Specific Authority 641.56 FS. Law Implemented ~~641.36~~ 641.51 FS. History-New 1-28-88, Amended 3-11-92, Formerly 10D-100.002, Amended 4/10/03.

59A-12.003 Administration, Forms, Fees.

(1) Application. "Application for Health Care Provider Certificate", AHCA Form 3002, Feb.1998, ~~HRS Form 1710, Nov. 87~~ obtained from the Agency for Health Care Administration, 2727 Mahan Drive, Mail Stop 26, Tallahassee, Florida 32308, which forms are incorporated herein by reference, must be completed in the manner specified within the application in order for each individual item to be considered complete for the purpose of determining that a properly completed application has been filed. The application shall be accompanied by a filing fee of \$1,000.00 payable to ~~the~~ AHCA and shall be completed by each entity desiring to obtain a Health Care Provider Certificate as an HMO or PHC. The application shall specify the contact person or persons for the HMO or PHC. During the review ~~investigation~~ of the entity only contact persons specified within the application shall be allowed access to the application materials submitted.

(2) Application Review Process for Health Care Provider Certificate. Upon receipt of the Application for Health Care Provider Certificate from a proposed HMO or PHC, ~~the~~ AHCA shall review the application within 30 days of receipt. ~~The~~ AHCA shall provide notification to the proposed HMO or PHC of deficiencies in the application within this 30-day period. The applicant has 90 days from the date of the filing of the application to file any additional information requested by ~~the~~ AHCA. By the end of the 90-day period if the additional information has not been received the application will be denied in accordance with Chapter 120, F.S. Within 90 days after the application has been completed ~~the~~ AHCA shall approve or deny the application.

(3) Certificate of Authority. The application for a Health Care Provider Certificate must include a copy of the letter from the Department of Insurance accepting the receipt of an application for a Certificate of Authority submitted by the organization.

(4)~~(3)~~ Geographic Area Expansions. The HMO or PHC may not change its geographic area unless it follows the applicable requirements set forth in Section 641.495(2), F.S. Each HMO or PHC shall submit the required notarized "Affidavit by HMO for Expansion of Service Area", AHCA Form 3160-1005, April 2002 ~~HRS Form 1693, Feb. 87~~, which is hereby adopted and incorporated by reference. Copies may be

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obtained by writing ~~the~~ AHCA, 2727 Mahan Drive, Mail Stop 26, Tallahassee, Florida 32308.

(5)~~(4)~~ Annual Assessment. The Agency for Health Care Administration shall determine the regulatory assessment percentage necessary to be imposed for each calendar year. AHCA Form "Regulatory Assessment Worksheet for Health Maintenance Organizations, Prepaid Health Clinics, and Exclusive Provider Organizations", AHCA Form 3160-1004, July 1995, which is hereby adopted and incorporated by reference, will be provided to the organization for calculating the annual regulatory assessment percentage and premium volume. Copies may be obtained by writing the Agency for Health Care Administration, 2727 Mahan Drive, Mail Stop 26, Tallahassee, Florida 32308. The annual regulatory assessment shall not exceed the statutory limitations and must be paid by the date specified in the Administrative Assessment Order.

~~Assessments. The AHCA shall determine on or before December 1 of each year the regulatory assessment percentage necessary to be imposed for that calendar year which will be payable on or before the following April 1. HRS Form 1711, Nov. 87, "Health Maintenance Organizations or Prepaid Health Clinics Regulatory Assessment Work Sheet", which is hereby adopted and incorporated by reference, will be provided to the organization for calculating the annual regulatory assessment based on assessment percentage and premium~~

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~~volume. The annual regulatory assessment shall not exceed the statutory limitations.~~

Specific Authority 641.36, 641.41, 641.56, 641.58 FS. Law Implemented 120.60(2), 641.21, 641.22, 641.47, 641.495 FS. History-New 1-28-88, Formerly 10D-100.003, Amended 4-10-03.

59A-12.004 Governing Body.

(1) Each HMO or PHC shall have a governing body that sets policy and has overall responsibility for the organization including the following:

(a) Adopting organizational bylaws, rules and regulations or similar form of document which provides a clear concise statement of the mission, goals, and objectives of the organization;

(b) Adopting a quality assurance program that monitors the key areas of health care delivery to identify problems and insure the early recognition of opportunities to improve the delivery of quality health care services; and

(c) Maintaining ultimate responsibility for ongoing quality assurance, risk management programs and credentialing programs.

(2) No change.

Specific Authority 641.56 FS. Law Implemented 641.22, 641.49, 641.49(3), FS. History-New 1-28-88, Formerly 10D-100.004, Amended 4-10-03.

59A-12.006 Quality of Care.

Each HMO or PHC shall:

(1) Make available to each member an appropriate health assessment in accordance with preventive health guidelines and professional standards in the community.

(2) Provide for or arrange the following services as a minimum:

(a) Coordination of all necessary care contracted for with the subscriber;

(b) Acute episodic care, with appropriate ancillary services necessary for proper evaluation and treatment, for example:

1. Laboratory studies;
2. Diagnostic radiology;
3. Treatment plan; and
4. Specialty consultation referrals.

(c) Chronic disease screening, and follow-up treatment for prevention of complications, for example:

1. Periodic update of history and physical examination;
2. Hypertension follow-up; and
3. Diabetes follow-up.

(d) Health risk appraisal and prevention measures, for example:

1. Dietary counseling ~~counselling~~;

2. Smoking cessation education;
 3. Stress reduction counseling; ~~counseling~~ and
 4. Substance abuse education;
- (e) Family planning services.

(3) Ensure that the health care services it provides or arranges for are accessible to the subscriber with reasonable promptness.

Such services shall include, at a minimum:

- (a) Establishment of an appointment system;
- (b) A method to distinguish among emergency, urgent, and routine cases.

1. Emergencies will be seen immediately;
2. Urgent cases will be seen within 24 hours;
3. Routine symptomatic cases will be seen within two weeks; and

4. Routine non-symptomatic cases will be seen as soon as possible. ~~†~~

(c) A provision that patients with appointments should have a professional evaluation within one hour of scheduled appointment time. If a delay is unavoidable, patient shall be informed and provided an alternative;

(d) Average travel time from the HMO geographic services area boundary to the nearest primary care delivery site and to the nearest general hospital under arrangement with the HMO to provide health care services of no longer

than 30 minutes under normal circumstances. Average travel time from the HMO geographic services area boundary to the nearest provider of specialty physician services, ancillary services, specialty inpatient hospital services and all other health services of no longer than 60 minutes under normal circumstances. ~~The~~ AHCA shall waive this requirement if the HMO provides sufficient justification as to why the average travel time requirement is not feasible or necessary in a particular geographic service area;

(e) Provision of accessible hours of operation and after hours emergency services;

(f) Maintenance of staffing patterns within generally accepted HMO or PHC industry norms for meeting projected subscriber needs and for expeditiously satisfying the requirements of the benefit package as offered by the HMO or PHC; and

(g) Maintenance of a professional staff or arrangements with providers, duly licensed as required to practice in Florida.

(4) Make grievance files available during normal business hours for inspection by the agency. ~~Department together with~~ The files shall contain a written summary of the actions taken by the HMO or PHC, including actions taken through the review by the quality improvement process, with the exception of protected peer review information.

(5) Through (7) no change.

(8) Inform subscribers of their rights and responsibilities set forth in Section 381.026 F.S., as well as the rights and responsibilities of the managed care organization incorporated in the member's handbook. ~~Assure that physicians and hospitals treat all HMO and PHC patients with equal dignity and consideration as their non HMO and non PHC patients. If the department determines that a physician or hospital is not treating HMO and PHC patients with equal dignity and consideration, the AHCA shall notify the HMO or PHC immediately.~~

Specific Authority 641.56 FS. Law Implemented 641.49, 641.54, 641.495(3), 641.515 FS. History-New 1-28-88, Amended 3-11-92, Formerly 10D-100.006, Amended 4-10-03.

59A-12.007 Quality Assurance.

(1) Through (2) no change.

(3) The scope of the program shall include, at a minimum, the following:

- (a) Evaluation of clinical performance (peer review);
- (b) Review of medication usage;
- (c) Evaluation as to appropriate use of tests and studies, for example: lab, x-ray and EKG;
- (d) Evaluation of subscriber grievances;
- (e) A utilization review process;

(f)~~(e)~~ Evaluation of outcomes of care using criteria developed by physicians and other health professionals to evaluate patient care patterns and clinical performance for health services provided; and

(g)~~(f)~~ 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 provided were not.

(4) No change.

Specific Authority 641.56 FS. Law Implemented 641.49(3) (o), 641.495, 641.51 FS. History-New 1-28-88, Amended 3-11-92, Formerly 10D-100.007, Amended 4-10-03.

59A-12.0071 Accreditation.

As a condition of doing business in the state, each HMO or PHC shall apply for accreditation within 1 year and be accredited within 2 years of the organization's receipt of its Certificate of Authority. HMOs and PHCs with existing Certificates of Authority must apply for accreditation within 1 year and be accredited within 2 years of the effective date of this rule. All HMOs and PHCs must undergo reaccreditations not less than once every 3 years. Accreditation and reaccreditation must be awarded by an accreditation organization approved by the agency pursuant to Rule 59A-12.0072, F.A.C.

(1) The agency will provide technical assistance, upon request by an HMO or PHC, in order to assist new or existing organizations to develop and maintain quality assurance systems, ~~and for the purpose of complying with the accreditation requirement.~~

(2) Through (5) no change.

(3) No change.

(4) No change.

(5) No change.

(6) For those HMOs and PHCs failing an accreditation survey the agency shall assess the need to mitigate the penalties specified under subsection(5) based upon:

~~(a) The potential threat to subscribers' health, safety, and welfare as determined by assessing compliance with standards specified in Rule 59A-12, F.A.C. The agency shall also assess the findings of the accreditation survey;~~

(b) The financial viability of the organization as determined by the Department of Insurance pursuant to Sections 641.225 and 641.2261 F.S.; and

(c) The extent of the organization's efforts to initiate corrective action.

(7) No change.

(8) No change.

(9) No change.

(10) No change.

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~~(11) The Agency shall conduct annual validation surveys on accredited HMOs and PHCs to ensure ongoing compliance with accreditation standards. Selection of the organizations to be surveyed shall be based on the following information:~~

~~(a) Reports received from the accreditation organization, Department of Insurance, or other state or federal regulatory agency regarding the quality of care provided by the organization;~~

~~(b) Quality of care grievance reports received pursuant to s. 641.511, F.S.;~~

~~(c) Performance data submitted by the HMO pursuant to ss. 408.704(4), F.S.;~~

~~(d) Quality of care complaints received from subscribers or providers by the agency.~~

Specific Authority 641.56 FS. Law Implemented 641.495, 641.512, 641.515(1), 641.52(1)(e), 641.52(1)(g) FS. History- New 3-11-92, Formerly 10D-100.0071, Amended 11-21-94, Amended 4-10-03.

59A-12.0072 Accreditation Organizations.

The accreditation organization must have nationally recognized experience in HMO accreditation activities and in the appraisal of medical practice and quality assurance in an HMO setting. As a minimum requirement for approval of the accreditation organization, the following criteria must be met:

(1) The accreditation organization must allow representatives from the agency ~~department~~ to accompany the accreditation organization throughout the accreditation process, but the agency ~~department~~ representatives shall not participate in the final accreditation or assessment determination.

~~(2) Through (7) no change.~~

(8) The accreditation organization shall be required to submit its standards for HMO accreditation to the agency ~~department~~ every 3 years for approval.

(9) Through (12) no change.

Specific Authority 641.56 FS. Law Implemented 641.512 FS.

History-New 3-11-92, Formerly 10D-100.0072, Amended 4-10-03.

59A-12.010 Subscriber Grievance Procedure.

Each HMO or PHC shall establish a subscriber grievance procedure as specified under Section 641.511, F.S. ~~provided for by the Department of Insurance rule, Rule 4-31.078, F.A.C.~~

Specific Authority 641.56 FS. Law Implemented 641.511~~495(8)~~, 641.311 FS. History-New 1-28-88, Formerly 10D-100.010, Amended 4-10-03.