STATEMENTS OF POLICY

Title 28—HEALTH AND SAFETY

DEPARTMENT OF HEALTH

[28 PA. CODE CH. 9]

Managed Care Organizations; Quality Health Care Accountability and Protection

The Department of Health (Department) adopts the statement of policy in Chapter 9, Subchapter E (relating to quality health care accountability and protection for managed care plans) as set forth in Annex A.

Background

This statement of policy reflects laws governing managed care plans as defined in Article XXI of the Insurance Company Law of 1929 (40 P. S. §§ 991.2101—911.2193) (act). The Department shares responsibility with the Insurance Department to ensure that the act is implemented in an effective and cost-efficient manner on the effective date of January 1, 1999. The Department and the Insurance Department (Departments) have recognized the significant lead time necessary by the managed care industry to revise existing processing systems, amend subscriber contracts, enrollee literature and other materials, train internal staff regarding these new systems, and, when necessary or appropriate, to submit evidence of compliance for review or approval, or both. In addition, it is important that managed care plans operate their enrollee complaint and grievance systems in a similar manner, since consumers often have the right to transfer among managed care plans during open enrollment periods. The only feasible way to provide the guidance necessary in the short period of time is to adopt appropriate statements of policy. Major stakeholders who depend upon the guidance of the Department have supported the preliminary issuance of statements of policy to meet the tight deadlines imposed by the act.

It is the intent of the Department, in cooperation with the Insurance Department, to develop and publish regulations for comment in 1999, and to base those regulations, in part, upon the experience gained in implementing the act's provisions under the guidance of the statements of policy.

In providing guidance to managed care plans regarding the act compliance, the Department has concentrated on those areas most important to consumer enrollees of health care plans: (1) the new consumer complaint system; (2) the new consumer and provider grievance system; (3) the certification of utilization review entities to create a list to which consumer and provider grievance appeals may be assigned on a rotational basis for review, analysis and decision. Areas of compliance not addressed in this statement of policy will be addressed in the proposed regulations.

It is the intent of the Departments to publish their respective statements of policy regarding the act implementation in the same *Pennsylvania Bulletin* issue (*Editor's Note*: See 28 Pa.B. 5019 (October 3, 1998).), and to possibly follow publication with a jointly sponsored training session in Harrisburg for stakeholders to review the guidance provided in the statements and to receive and consider questions regarding implementation.

The Department notes that during the period July 1997 to December 1997 it convened seven managed care policy work groups with significant representation from major managed care stakeholders, including managed care plans, providers, purchasers and consumers. These work groups contributed greatly to the Department's understanding of the respective views of stakeholder groups regarding both broad policy and technical issues in managed care and managed care consumer protection. Further, the work groups provided significant input to the Department regarding public policy and regulatory issues in managed care and useful recommendations, many of which were incorporated into the act and this statement of policy.

Persons and Entities Affected

The managed care plan provisions of the act, effective January 1, 1999, affect a significant portion of the 5 million Pennsylvanians enrolled in managed care plans in the Commonwealth and managed care plans themselves by requiring adoption and implementation of new procedures for addressing consumer complaints and consumer and provider grievances. The act will affect the thousands of providers who participate in managed care plans by providing them with an opportunity to file grievances, with the consent of the patient enrollee, and to have explicit standards applied to the utilization review of covered health care services. Finally, the act will affect managed care plans and licensed insurers which will have to bring their existing utilization review systems into compliance with the operational standards for utilization review programs, and independent utilization review entities required to obtain or electing certification under the act. This statement of policy, by providing guidance on uniform implementation of the act will affect these same parties, but only to the extent that the statement clarifies operational procedures for successful implementation of the act.

Form and Effect

This statement of policy provides guidance regarding the standards to be utilized by the Department in determining managed care plan compliance with of the act, and for certifying utilization review entities. This statement of policy does not constitute a rule or regulation entitled to the force and effect of law.

Companion Statement of Policy

This statement of policy is issued in conjunction with a companion statement of policy issued by the Insurance Department. Managed care plans covered by the act are subject to regulation by both the Department and the Insurance Department. Accordingly, both statements of policy must be consulted to gain a clear understanding of the implementation requirements for managed care plans under the act.

Fiscal Impact And Paperwork Requirements

The Department does not anticipate that there will be significant fiscal impact and paperwork requirements after adoption of this statement of policy, since it provides only interim guidance to promote the successful implementation of the act requirements until regulations can be adopted. There will be both a fiscal impact (an increase in operational expenses) and a change in paperwork requirements for the Commonwealth in connection with review of initial filings and submissions from man-

aged care plans. The fiscal impact and changes in paperwork requirements result from the requirements of the act itself.

The Department will establish an initial utilization review certification fee, as well as a renewal fee for utilization review certifications, in subsequent regulations.

Contact Person

Persons desiring more information regarding this statement of policy should contact, Thomas J. Chepel, CLU, CPCU, Director, Division of Certification, Bureau of Managed Care, Room 1030 Health & Welfare Building, P. O. Box 90, Harrisburg, Pa 17108-0090, (717) 787-5193. Any written comments received will be considered by the Department in the preparation of its regulations. Persons with disabilities may submit information requests regarding the statement of policy in alternative formats, such as by audio tape, braille or by using TDD: (717) 783-6514. Persons with a disability requesting alternative forms (that is, large print, audio tape, braille) may contact Mr. Chepel so that he may make the necessary arrangements.

Effective Date

This statement of policy is effective January 1, 1999. Upon promulgation of regulations, this statement of policy will be rescinded.

DANIEL F. HOFFMANN,
Secretary

(*Editor's Note*: The regulations of the Department, 28 Pa. Code Chapter 9, are amended by adding a statement of policy in §§ 9.501—9.519 (relating to quality health care accountability and protection) to read as set forth in Annex A.)

Fiscal Note: 10-153. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 28. HEALTH AND SAFETY

CHAPTER 9. MANAGED CARE ORGANIZATIONS

Subchapter E. QUALITY HEALTH CARE ACCOUNTABILITY AND PROTECTION—STATEMENT OF POLICY

Sec.

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§ 9.501. Applicability and purpose.

(a) This subchapter establishes the guidelines which the Department will utilize to determine managed care plan and utilization review entity compliance with the act. It sets forth the Department's expectations regarding act implementation until formal regulations are adopted. This subchapter applies to each health plan meeting the definition of "managed care plan" contained in the act.

(b) This subchapter is effective January 1, 1999, and applies and provides compliance guidance to assist managed care plans, licensed insurers and utilization review entities subject to the act.

(c) The terms and conditions of group and individual contract renewals and new business written by managed care plans on or after January 1, 1999, shall conform to the act.

§ 9.502. Definitions.

The following words and terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise:

Act—Article XXI of The Insurance Company Law of 1921 (40 P. S. §§ 991.2101—991.2193) as added by Act No. 68 of 1998 regarding quality health care accountability and protection.

Department—The Department of Health of the Commonwealth.

Gatekeeper—A primary care provider selected by an enrollee at the time of enrollment or appointed by a health plan from whom an enrollee shall obtain covered health care services or a referral or approval for covered, nonemergency health services as a condition for the payment of the highest level of benefits/services available under the plan.

Managed care plan—

(i) A health care plan that:

(A) Uses a gatekeeper to manage the utilization of health care services.

(B) Integrates the financing and delivery of health care services to enrollees by arrangements with health care providers selected to participate in the plan on the basis of specific standards.

(C) Provides financial incentives for enrollees to use the participating health care providers in accordance with procedures established by the plan.

(ii) A managed care plan includes health care arranged through an entity operating under any of the following:

(A) Section 630 of the Insurance Company Law of 1921 (40 P. S. § 764a).

(B) The Health Maintenance Organization Act (40 P. S. §§ 1551—1568).

(C) The Fraternal Benefit Societies Code (40 P. S. §§ 1141-101—1141-905).

(D) 40 Pa.C.S. Chapter 61 (relating to hospital plan corporations).

(E) 40 Pa.C.S. Chapter 63 (relating to professional health services plan corporations).

(iii) The term includes an entity, including a municipality, whether licensed or unlicensed, that contracts with or functions as a managed care plan to provide health care services to enrollees.

(iv) The term does not include an indemnity arrangement which is primarily fee for service or an ancillary health care plan, including those which provide coverage exclusively for dental or vision services, or benefits supplementing benefits payable under the Federal Medicare or Civilian Health And Medical Program of the Uniformed Services (CHAMPUS).

(v) The term does not include "passive gatekeeper" preferred provider organizations (PPOs). A passive gatekeeper includes plans in which enrollees are not required to preselect a particular primary care physician, but require, as a condition for receipt of a higher level of benefits or reimbursement level, or both, that an enrollee receive care from or a referral from a participating preferred primary care physician. See 31 Pa. Code § 152.102 (relating to definitions).

§ 9.503. Enrollee complaint system.

(a) The act gives the Department and the Insurance Department shared oversight over the enrollee complaint process.

(b) A complaint is a dispute or objection regarding a participating health care provider, coverage, including contract exclusions and noncovered benefits as well as the operations or management policies of a managed care plan. Examples of issues constituting complaints which will be handled by the Department, include:

(1) Quality of care or quality of service issues.

(2) Denial of payment for treatment by a nonparticipating provider for failure to obtain a necessary referral or to utilize a participating provider when the enrollee alleges that the reason for seeking the care was inadequate care by the managed care plan, primary care provider or participating providers.

(c) The following applies to filing of complaints.

(1) An enrollee may file a written or oral complaint with the plan's internal complaint system as well as written data or other information in support of the complaint.

(2) An enrollee should indicate the remedy or corrective action being sought.

(3) Second level review.

(i) It is recommended that the one-third membership of a plan's internal second level review committee who are not plan employes include actual enrollees, or representatives of plan enrollees, such as employe benefits administrators, collective bargaining agents, consumer advocates or similar individuals.

(ii) The deliberations of the plan's second level review committee, including the enrollee's comments and written submissions, should be transcribed or summarized and maintained as part of the complaint record.

(iii) Attendance at the second level review hearing should be limited to members of the review committee, the enrollee or enrollee's representative, the enrollee's provider or applicable witnesses, and appropriate plan representatives. All persons attending and their respective roles at the hearing should be identified for the enrollee.

(iv) The second level review should provide reasonable flexibility in terms of time and travel distance when scheduling a hearing to facilitate the enrollee's attendance. If an enrollee cannot appear in person at the informal hearing, the enrollee should be provided the opportunity to communicate with the review committee by telephone or other appropriate means.

(v) The notice of the second level review decision shall include the basis for the decision and the procedure for appealing the decision to the Department or the Insurance Department, including the address and phone numbers of the Departments. The decision of the second level review committee should be binding on the plan unless appealed by the enrollee.

(d) The following applies to Department review of a complaint:

(1) An enrollee appeal of a decision by a managed care plan's second level review committee may be directed to either the Department or the Insurance Department. Appeals directed to the Department should include, at a minimum, the enrollee's name, address and telephone number, identification of the managed care plan, the enrollee's plan ID number and a brief description of the issue being appealed, and should be sent to:

Bureau of Managed Care
Department of Health
Attention: Complaint Appeals
P. O. Box 90
Harrisburg, Pennsylvania 17108-0080

(2) Upon receipt of the appeal, the Department will verify that the appeal was submitted within 15 days from the enrollees' receipt of the notice of the decision by the managed care plan's second level review committee. The Department will review the complaint to ensure that it involves a matter appropriate for review by the Department. If the Department believes that the appeal more appropriately relates to issues and matters under the jurisdiction of the Insurance Department—for example, an issue involving interpretation of a coordination of benefits provision, the Department will notify the enrollee in writing of its finding and promptly transmit the appeal to the Insurance Department for consideration.

(3) Upon receipt of the appeal, the Department will request the complete complaint case file, including, but not limited to, records from the initial and second level review, including hearing transcript or summary, medical records, if appropriate, and other case materials be forwarded within 15 business days to the Department. The Department may request additional information from the managed care plan, enrollee or participating providers involved in the complaint. The enrollee, managed care plan or provider may submit additional materials relating to the appeal.

(4) The enrollee may be represented by an attorney or other individual before the Department. The Department will make the decision based on the written record.

(5) The Department may take any of the following actions:

(i) Request, for specified reasons, that the managed care plan's second level review reconsider the complaint.

(ii) Request an independent review by a consulting provider or certified utilization review entity, if the complaint involves the exercise of clinical judgement.

(iii) Issue a recommendation to the managed care plan and enrollee regarding the complaint.

(6) If the plan determines that additional information from the enrollee or the provider justifies reconsideration and resolution of a complaint, the resolution shall terminate a review by the Department.

(7) If the Department determines that the complaint reflects a violation of the act by the managed care plan, it may proceed with an enforcement action authorized by the act.

§ 9.504. Enrollee and provider grievance system.

(a) The act sets forth a procedure to deal with grievances by enrollees and health care providers.

(b) A grievance is a request by an enrollee or a health care provider, with the written consent of the enrollee, to have a managed care plan or utilization review entity review the denial of a health care service based on medical necessity and appropriateness. This includes cases in which the managed care plan: disapproves full or partial payment for a requested health service; approves the provision of a requested health care service for a lessor scope or duration than requested; or disapproves payment of the provision of a requested service but approves payment for the provision of an alternative health care service.

(1) If it is unclear to the enrollee or health care provider whether the issue in dispute is a complaint or a grievance, it is recommended that the plan classify the issue in dispute as a complaint or grievance.

(2) The primary test of determining whether a dispute is a complaint or a grievance is whether medical necessity is the primary issue in dispute. For a denial to be a grievance, the requested service or treatment shall clearly be covered under the contract and must be denied because of the managed care plan's determination that the service or treatment is not medically necessary in accordance with the definition of medical necessity found in the enrollee's contract. Examples of issues considered to be grievances, include:

(i) Denial of an emergency claim on the basis that the condition did not meet the definition of an emergency.

(ii) Denial of a request by an enrollee for a referral to a nonparticipating provider with special skills, knowledge, experience or reputation regarding the performance of a needed procedure or treatment, on the basis that the procedure or treatment can be rendered appropriately by a participating provider.

(iii) Denial of a request for an organ transplant on the basis that the existence of complicating medical factors and the patient's condition make a transplant inappropriate.

(iv) Denial of a prescription drug on the basis that the drug is not part of the managed care plan's approved formulary.

(v) Denial of a request for treatment at or by a nonparticipating provider on the basis that a participating provider is available to provide the treatment or service.

(vi) Discharge from a facility on the basis that the continued stay is no longer medically necessary.

(vii) Refusal to continue to pay for skilled nursing facility care on the basis that continued care is not medically necessary at the skilled nursing care level, but rather is custodial in nature.

(viii) Denial of a referral to a specialist.

(c) The following applies to second level review of grievances:

(1) The deliberations of the plan's second level grievance review committee, including the enrollee's or provider's comments and written submissions, should be transcribed or summarized and maintained as a part of grievance record.

(2) The second level review should provide reasonable flexibility in terms of time and travel distance when scheduling a hearing to facilitate the enrollee's or provider's attendance. If the enrollee or the provider cannot appear in person, the enrollee or provider should be given the opportunity to communicate with the review committee by telephone or other means.

(3) The written notice of a decision by the second level grievance review committee denying a health care service should include the basis and clinical rationale for the decision and the procedure for filing an external grievance.

(d) The following applies to external grievances:

(1) The managed care plan shall acknowledge receipt of an external grievance in writing to the enrollee or the health care provider, the utilization review entity that conducted the internal grievance review and the Department.

(2) In addition to the information required under section 2162 of the act (40 P. S. § 991.2162), the plan shall submit its contractual definition of "medical necessity" and any clinical criteria utilized by the plan in making its initial decision.

(3) To avoid duplication of grievances and related expenses, the provider filing a grievance with the written consent of the enrollee should be the primary provider (that is, the provider who manages the treatment and orders care) of the disputed services to the enrollee. If the external grievance is ultimately decided in favor of the enrollee or provider, all related disputed claims arising from that incident or service should be paid by the managed care plan. For example, if the enrollee grants written consent to a hospital to appeal a denial of services on the basis that a true emergency did not exist, separate grievance appeals need not be filed by related providers of emergency care which are covered services and which are medically necessary and appropriate, such as the ambulance company who transported the enrollee, the independent physician group which employs the ER physician, the independent radiology and laboratory medicine physicians providing the professional component of interpreting test results, and the like.

(e) The following applies to the processing of a grievance appeal by the Department:

(1) Requests for assignment of a certified utilization review entity to conduct an external grievance should be addressed to:

Bureau of Managed Care
Department of Health
Attention: Grievance Appeals
P. O. Box 90
Harrisburg, Pennsylvania 17108-0080

(2) The request should include the following basic information:

(i) An identification of the managed care plan, the enrollee/patient and the health care provider.

(ii) Whether the external grievance is being filed by the enrollee or a health care provider with written consent of the enrollee.

(iii) The plan ID (including group number and enrollee ID number).

(iv) The date of receipt of the external grievance by the managed care plan from the enrollee or health care provider.

(v) A brief (few line) description of the medical necessity/claim denial being appealed.

(vi) The filing fee, if any, the enrollee has been charged by the managed care plan.

(3) Upon receipt of an external grievance, the Department will assign on a rotational basis a utilization review entity to conduct the review within 2 business days of receiving the request. The Department may notify the managed care plan of the selection of the utilization review entity selected by means of telephone or facsimile machine, with written follow-up notification. Upon receipt of notification from the Department, the managed care plan should notify the enrollee or health care provider and utilization review entity which conducted the internal grievance review. The Department may assign the external grievance a uniform tracking number, which should be utilized by the plan, external utilization review entity, enrollee and provider to communicate with or report to the Department.

(4) If the Department fails to select a utilization review entity within 2 business days of receipt of the external grievance, the managed care plan may designate a certified utilization review entity to conduct the review. No certified utilization review entity affiliated, directly or indirectly, with the plan may be selected to review the external grievance.

(5) Upon notification of the utilization review entity selected to conduct the external grievance, the managed care plan, utilization review entity, provider or enrollee should have 2 business days to object to the assignment of the utilization review entity on the basis that the entity has a conflict of interest, for example, that the review entity is a subsidiary or affiliate of the managed care plan. The Department will review the objection within 5 business days and either uphold the assignment of the utilization review entity, or assign the review to the next utilization review entity on the rotational schedule.

(6) A managed care plan should provide to the Department the name, title and phone number of a primary and alternative external grievance coordinator with whom the Department can communicate regarding the assignment of utilization review entities to undertake grievance reviews.

(7) If additional information provided by the enrollee or provider during the external grievance results in a reconsideration of the plan's denial on the basis of medical necessity, and the plan grants coverage, the external grievance shall be terminated upon notification to the utilization review entity.

(f) The following applies to the utilization review entity processing of a grievance review:

(1) The utilization review entity shall certify that the external grievance decision was made by one or more physicians or approved licensed psychologists, as specified in the act, and shall indicate whether the health care service denied by the internal grievance process is medically necessary and appropriate under the terms of the plan.

(2) In reviewing a grievance relating to emergency services, the utilization review entity should utilize the emergency services standards of the act and the definitions of medical necessity and emergency in the enrollee's current certificate of coverage.

§ 9.505. Reporting provisions for complaint and grievance systems.

(a) A managed care plan should maintain records of first and second level complaint and grievance decisions, including expedited reviews. A managed care plan should include in its quarterly and annual reports to the Department data regarding complaints and grievances during that reporting period. A managed care plan should periodically analyze, and make available to the Department, issues involved in complaints and grievances to identify potential areas for improvement or increased disclosure. Data which plans should submit to the Department in routine reports include:

(1) The total number of formal complaints filed, decided and pending, in the reporting period.

(2) The total number of complaints at the first internal committee review:

(i) Settled in favor of the plan.

(ii) Settled in favor of the enrollee.

(3) The total number of complaints at the second level internal review:

(i) Settled in favor of the plan.

(ii) Settled in favor of the enrollee.

(4) The total number of complaints appealed to the Commonwealth: (if known, to the Department; if known, to the Insurance Department).

(5) The total number of formal grievances filed, decided and pending, in the reporting period.

(6) The total number of grievances at the first internal review level:

(i) Settled in favor of the plan.

(ii) Settled in favor of the enrollee.

(iii) Settled in favor of the provider.

(7) The total number of grievances at the second level internal review:

(i) Settled in favor of the plan.

(ii) Settled in favor of the enrollee.

(iii) Settled in favor of the provider.

(8) The total number of internal expedited reviews conducted:

(i) Settled in favor of the plan.

(ii) Settled in favor of the enrollee.

(iii) Settled in favor of the provider.

(b) Reports should be filed with the Department as follows:

(1) *Quarterly reports*. 45 days after the last day of the quarter (such as, the report for the lst quarter covering January, February and March should be filed no later than May 15th).

(2) *Annual reports*. No later than April 1st of the calendar year following the calendar year being reported.

§ 9.506. Alternative dispute resolution systems for external grievance.

(a) A managed care plan may submit for Department review and approval a system for dispute resolution as an alternative to the external grievance to be included in contracts between the plan and its participating providers. The alternative may apply only to grievances filed by providers and may include a provision that a decision from the alternative dispute resolution system shall be final and binding on both the managed care plan and provider.

(b) A proposed alternative dispute resolution system shall be impartial and include specific time limitations to initiate appeals, receive written information, conduct hearings and render decisions.

§ 9.507. Department review of complaint and grievance systems.

A managed care plan should file with the Department and maintain an updated detailed written description of its enrollee complaint and enrollee and provider grievance systems.

§ 9.508. Transition between former grievance system and new complaint and grievance systems.

(a) Prior to January 1, 1999, health maintenance organizations and gatekeeper preferred provider organizations (including "point-of-service" plans) were required to establish, operate and maintain a consumer grievance system complying with Department requirements in § 9.73 (relating to subscriber grievance systems), and various technical advisories and guidelines. To assure an orderly transition to the new systems, group and individual contract renewals and new business written by managed care plans on or after January 1, 1999, shall conform to the act, and the following:

(1) Any enrollee complaint or grievance filed prior to the first renewal date of the enrollee's managed care plan contract on or after January 1, 1999, should be processed under the enrollee grievance system contained in the enrollee's contract.

(2) Any complaint or grievance filed by an enrollee, or a provider with the written consent of the enrollee, on or after the first renewal date of the enrollee's managed care plan contract in 1999 should be processed in accordance with the complaint and grievance systems established under the act.

(b) A managed care plan may voluntarily comply with the complaint and grievance procedures under the act for all complaints and grievances filed on or after January 1, 1999, if authorized by the enrollee contract.

§ 9.509. Application of enrollee complaint and enrollee and provider grievance systems to self-funded plans and nonmanaged care plans.

(a) The Department encourages managed care plans that administer, through their provider network and gatekeepers, the managed care programs of self-funded insurers under the Federal Employee Retirement Income Security Act (ERISA) to voluntarily extend the new complaint and grievance systems to self-funded enrollees.

(i) The self-funded group may elect to treat any grievance appeal decision rendered by a utilization review entity as: binding, unless appealed to a court of competent jurisdiction; or as advisory.

(ii) An appeal from the plan's second level complaint review or second level grievance review may be to the self-funded group itself.

(b) Some health care plans/insurers, particularly those associated or affiliated with health maintenance organizations and gatekeeper PPOs, voluntarily extended the Department's consumer grievance system to enrollees in health benefits plans without gatekeepers. Effective January 1, 1999, these grievance systems shall be amended to remove right of appeal to the Department, insofar as the appeal is inconsistent with the act.

(c) It is the Department's expectation that a managed care plan will apply its Department approved quality improvement system to all enrollees, including those enrolled in a self-funded employe benefit plan administered by the managed care plan, to protect enrollees from the risk of inadequate or poor quality care arising out the use of gatekeepers, financial incentives and limited provider networks.

§ 9.510. Fees for initial certification and renewal of utilization review entities.

Fees will be established in regulation for certification and renewal of utilization review entities.

§ 9.511. Content of an application for certification as a utilization review entity.

(a) A utilization review entity seeking certification, including an integrated delivery system as defined in § 9.402 (relating to definitions) performing utilization review under a delegation agreement from a managed care plan, shall submit two copies of an application to the Department at the following address:

Bureau of Managed Care
Pennsylvania Department of Health
Attention: Utilization Review Certification
P. O. Box 90
Harrisburg, Pennsylvania 17108-0090

(b) A utilization review entity operating in this Commonwealth on or before January 1, 1999, shall comply with the act effective January 1, 1999, but need not file an application for certification until January 1, 2000. To avoid backlogs and time delays which might arise if all entities waited until January 1, 2000, to file, entities are encouraged to apply for certification as early in 1999 as possible. A utilization review entity will not be placed on the Department's list of certified utilization review entities for external grievances unless the entity is certified. Entities desiring to be placed on the rotational list to hear external grievances should file their applications as soon as possible after adoption of this subchapter. A new utilization review entity not operating in this Commonwealth on or before January 1, 1999, may not operate until it receives a certification from the Department.

(c) The application shall contain the following:

(1) The name, address and telephone number of the entity as it should appear on the Department's official list of certified utilization review entities.

(2) The name, title, address and telephone number of a primary and at least one backup designee with whom the Department will communicate regarding assignment of external grievances and other issues.

(3) The name, title, address and telephone number of a primary contact responsible for answering any Department questions regarding the application.

(4) Information relating to its organization, structure and function, including:

(i) The location of the principal office handling utilization review in this Commonwealth.

(ii) The articles of incorporation and bylaws, or similar documents, regulating the internal affairs of the applicant.

(iii) If the applicant is publicly held, the name of each owner of more than 5% of the shares of the corporation.

(iv) A chart showing the internal organization of the applicant's management and administrative staff (which the applicant may designate as "confidential and proprietary" and not subject to public disclosure).

(v) The name and type of business of each corporation, affiliate or other organization that the applicant controls, the nature and extent of the affiliation or control and a

chart or list clearly identifying the relationships between the applicant and affiliates (which applicant may designate as "confidential and proprietary" and not subject to public disclosure).

(vi) Biographical information about officers, directors and executives (which the applicant may designate as "confidential and proprietary" and not subject to public disclosure).

(5) A listing of each managed care plan in this Commonwealth for which the entity currently conducts utilization review.

(6) A disclosure of any potential conflict of interest which would preclude its review of an external grievance—for example, ownership or affiliation with a competing managed care plan or health insurance company.

(7) A description of the:

(i) Provision of toll-free telephone access.

(ii) Maintenance of a telephone answering service or recording system during nonbusiness hours.

(iii) Ability to respond to each telephone call received as required by the act.

(8) A description of procedures for protecting the confidentiality of medical records and certification that it will comply with the confidentiality provisions of the act and all other applicable State and Federal laws.

(9) A description of its procedures to ensure that a health care provider is able to verify that an individual requesting information on behalf of the managed care plan is a legitimate representative of the utilization review entity/plan.

(10) A description of its ability, including staffing and resources, to meet the time frames for decisions specified in the act.

(11) A certification that utilization review decisions resulting in a denial shall be made by a licensed physician or approved licensed psychologist, and that any utilization conducted not resulting in a denial shall be made by personnel having current licenses in good standing or other credentials, without restrictions, from the appropriate agency.

(12) A description of its ability to notify the health care provider of additional facts or documents required to complete the utilization review within 48 hours of receipt of the request for review.

(13) A description of its ability to maintain a written record of utilization review decisions adverse to enrollees for at least 3 years, including a detailed justification and all required notifications to the health care provider and enrollee.

(14) A certification that compensation from a managed care plan to a utilization review entity, employe, consultant or other person performing utilization review on its behalf does not contain incentives, direct or indirect, to approve or deny payment for the delivery of any health care service.

(15) An indication that it is willing and able to participate on a rotational basis in an external grievance.

(16) A certification that all external grievances will be reviewed in accordance with the act.

(17) If the utilization review entity proposes to utilize licensed psychologists to perform utilization reviews for behavioral health care services within the psychologists' scope of practice, a request for approval to do so. The request shall include a description of the credentialing criteria and process the entity shall utilize to ensure that behavioral health service reviewed by the psychologist falls within the psychologist's scope of practice; the psychologist's clinical experience is sufficient to review specific behavioral health services; and any other standards the entity has adopted for approval of a licensed psychologist. The request shall also certify that licensed psychologists will not review the denial of payment for a health care service involving inpatient care or a prescription drug.

(18) Evidence of any approval, certification or accreditation received by a Nationally recognized accrediting body in the area of utilization review.

(19) A description of its ability to maintain records regarding grievances that result in a decision adverse to the enrollee for at least 3 years and to provide records and other data to the Department upon request.

(20) Its agreement to provide information to the Department upon request regarding fees charged to perform utilization reviews to allow the Department to respond to a complaint by a managed care plan, enrollee or provider that the fees of a particular certified utilization review are excessive. This information shall be proprietary and confidential.

(21) If the plan is currently operating in this Commonwealth, a disclosure of how long it has been operating, and a list of three clients for which it has conducted utilization review in this Commonwealth, including the name, address, position and telephone number of contact persons for each client. The Department may contact these references for an assessment of the applicant's past performance, particularly its ability to meet the review times for prospective, concurrent and retrospective utilization review under the act.

(22) If the entity desires to be placed on the rotational list to receive and decide external grievances a description of its ability to:

(i) Receive and decide any and all external grievances.

(ii) Receive and decide only behavioral health grievances (mental health and drug and alcohol related medical necessity issues).

(23) If the entity desires to be placed on the rotational list to decide external grievances, a description of its ability and agreement to maintain the information obtained in the review of the grievances, including outcomes, in a manner that is confidential and unavailable to affiliated entities or persons who may be direct or indirect competitors to the managed care plan being reviewed.

§ 9.512. Department review and approval of a certification request.

(a) The Department will review the application for certification as a utilization review entity. If the Department finds that the application meets the requirements of the act, it will approve it. If the Department finds deficiencies, it will notify the applicant identifying the changes required to bring the application into compliance. If the Department takes no action within 45 days of receiving the certification application, or a requested revision, the application shall be deemed to have been approved.

(b) Upon certification, the Department will add the name of the utilization review entity to its rotational list of entities to conduct external grievances, if requested by the entity.

(c) The Department may utilize site visits or a Nationally recognized accrediting body acceptable to the Department to determine an applicant's ability to comply with the act.

(d) The Department may utilize the following to verify a certified utilization review entity's continuing compliance with the act:

(1) Periodic onsite reviews by the Department.

(2) Accreditation by a Nationally recognized accrediting body acceptable to the Department.

(3) If the entity is not accredited by a Nationally recognized accrediting body acceptable to the Department, an onsite inspection by an accreditation body acceptable to the Department, reimbursed directly by the entity.

(e) The initial certification is valid for 3 years, unless certification is rescinded or restricted prior to that date for cause by the Department. Verification of compliance with the act is required to receive certification renewal.

§ 9.513. Nationally recognized accrediting bodies.

(a) The Department will identify and maintain a list of Nationally recognized accrediting bodies whose standards meet or exceed the requirements of the act regarding utilization review. The list will be public information.

(b) A utilization review entity or managed care plan seeking to demonstrate compliance with the act may submit documentation of its accreditation by a Nationally recognized accrediting body for consideration by the Department as evidence of compliance with the act.

(c) The Department may recognize the standards of a Nationally recognized accrediting body whose standards partially meet the requirements of the act to certify a utilization review entity. The Department will require the utilization review entity or managed care plan to submit evidence of compliance with the act not met by the standards of the accrediting body. The Department may permit an accrediting body qualified under subsection (d) to verify compliance with the act not met by the standards of an accrediting body at the expense of the entity seeking certification. An accrediting body performing a verification of compliance under this subsection shall submit a report certifying compliance with the act.

(d) The Department may qualify an accrediting body that has standards that meet or exceed the act to assist the Department to enforce the act with regard to entities performing utilization review for managed care plans, to include compliance monitoring and certification renewal, at the entity's expense.

(e) A utilization review entity that is not accredited by a Nationally recognized accrediting body shall verify compliance with the act through an audit performed by a qualified accrediting body at the entity's expense or through an onsite verification by the Department. For a utilization review entity that maintains its records and other information at a location outside of this Commonwealth, a qualified accrediting body shall be utilized for certification and renewal verifications.

§ 9.514. Managed care plan and licensed insurer compliance with utilization review requirements.

(a) Managed care plan compliance with the utilization review requirements of the act will be verified by the Department during the course of its routine compliance monitoring of plans, including, but not limited to, external quality reviews required 1 year after licensure and every 3 years thereafter.

(b) Licensed insurers performing utilization review services for or on behalf of managed care plans within this Commonwealth shall file with the Department evidence of compliance with the standards and procedures in section 2152 of the act (40 P. S. § 991.2152), at the same time as the annual statement filing with the Insurance Department, beginning with the annual statement for Fiscal Year 1999.

§ 9.515. Continuity of care and expanded care provisions.

(a) A managed care plan shall adopt and maintain procedures by which an enrollee with a life-threatening, degenerative or disabling disease or condition shall be permitted to receive either a standing referral to a specialist with clinical expertise in treating the disease or condition, or designation of a specialist to assume responsibility to provide and coordinate the enrollee's primary and specialty care, subject to the plan's utilization management requirements and plan criteria. The managed care plan should make a decision regarding the referral within 30 days of the receipt of the enrollee's request. An enrollee may appeal the decision through the enrollee complaint process.

(b) Whenever the plan is required to pay for care provided to enrollees by a nonparticipating provider under section 2117 of the act (40 P. S. § 991.2117), the plan may require a nonparticipating health care provider to:

(1) Accept the plan's payment as payment in full for covered services, less any permitted deductibles or copayments.

(2) Require that all referrals for specialty care, diagnostic testing and related services be made to participating providers.

(3) Require that all nonemergency inpatient care be provided at a participating hospital or facility.

(4) Require that the provider provide copies of the patient's medical records to the plan or the enrollee's participating primary care physician, or both.

(5) Require that plan procedures requiring precertification or prior approval of specified nonemergency services or procedures be met.

(c) The plan should provide affected enrollees and affected nonparticipating providers with written disclosure of the requirements which shall be met for the plan to be responsible for payment for services rendered by the provider.

§ 9.516. Confidentiality.

A managed care plan and a certified utilization review entity should adopt and maintain procedures to ensure that all identifiable information regarding enrollee health, diagnosis and treatment is adequately protected and remains confidential in compliance with the act and other applicable Federal and State laws and professional ethical standards. A copy of the procedures shall be filed with the Department within 30 days of adoption.

§ 9.517. Provider credentialing.

(a) A managed care plan should file a copy of its written credentialing process in the form of a separate and distinct document (even though it may be incorporated into a larger quality improvement plan) with the Department for approval. The process should include written criteria and procedures including:

(1) Qualifications which a provider shall meet to be accepted as a participating provider.

(2) Information which a provider shall provide as a part of the application process to demonstrate compliance with required qualifications.

(3) Requirements that a provider shall meet to be credentialed such as staff privileges at a participating hospital, board certification, or onsite review of office or medical records by the plan.

(4) Restrictions which a plan may place on the provider's status as a participating provider.

(5) Periodic recredentialing requirements.

(6) Termination procedures including any internal appeal procedures available to participating providers.

(7) Credentialing decisions to be made by a committee composed of practicing providers.

(b) A managed care plan may submit evidence of accreditation by the National Committee for Quality Assurance (NCQA) or other Nationally recognized accrediting body acceptable to the Department as evidence of compliance with this act.

(c) A managed care plan may refuse to accept applications for participation and credentialing if the plan believes it has sufficient providers of a given specialty in a given geographic area, provided that the refusal is done in a nondiscriminatory manner.

§ 9.518. Accessibility and availability.

The Department has, as a matter of practice, reviewed each applicant managed care plan's initial service area, and any expansions thereof, to ensure that the plan has adequate numbers of providers, distributed by specialty and geography, to provide covered health care services to enrollees in an accessible and available manner. The Department has utilized the informal standard for accessibility/availability that hospitalization services and primary care and frequently utilized specialty services be available within 20 miles/20 minutes in urban areas, and 30 miles/30 minutes in rural areas. The Department intends to continue to review initial and service area expansions, and to formalize the process and standards through adoption of regulations.

§ 9.519. Access for special needs populations.

A plan shall file with the Department its policies, plans and procedures for meeting the act's requirement to ensure that there are participating health care providers that are physically accessible to people with disabilities and can communicate with individuals with sensory disabilities in accordance with Title III of the Americans with Disabilities Act of 1990 (42 U.S.C.A. §§ 12181—12189), and a description of how the plan addresses the needs of non-English-speaking enrollees.

[Pa.B. Doc. No. 98-1641. Filed for public inspection October 2, 1998, 9:00 a.m.]

Title 31—INSURANCE

INSURANCE DEPARTMENT

[31 PA. CODE CH. 301]

Health Maintenance Organizations; Quality Health Care Accountability and Protection

This statement of policy is adopted under the authority of the Health Maintenance Organization Act (HMO Act) (40 P. S. §§ 1551—1568), section 630 of the Insurance Company Law of 1921, the Accident and Health Filing Reform Act (AHFRA) (40 P. S. §§ 3801—3815) and Article XXI of the Insurance Company Law of 1929 (40 P. S. §§ 991.2101—991.2193) (Act 68). Specifically, the Insurance Commissioner's (Commissioner) authority to review HMO contracts is set forth in section 8 of the HMO Act (40 P. S. § 1558); the Commissioner's authority to review subscriber contracts and other marketing materials for HMOs and Gatekeeper PPOs is set forth in section 3 of AHFRA (40 P. S. § 3803).

Introduction

The Insurance Department (Department) has adopted amendments to Chapter 301 (relating to health maintenance organizations) as set forth in Annex A, regarding the implementation of the quality health care accountability and protection provisions of Act 68. This statement of policy sets forth guidelines for compliance with the provisions of Act 68 with respect to "managed care plans," as that term is defined under Act 68. These guidelines apply to those provisions of Act 68 which vest regulatory authority with the Department.

Applicability

This statement of policy applies to managed care plans and licensed insurers and addresses the entities' compliance with Act 68 from the Department's regulatory perspective.

Background

Act 68 was signed into law by the Governor on June 17, 1998. Article XXI, the quality health care accountability and protection provisions, is effective January 1, 1999. This statement of policy is being issued to provide guidance to managed care plans and licensed insurers, on an interim basis, to effectively implement Act 68. The Department intends to promulgate regulations in 1999. However, with the short time available prior to the effective date of the statutory provisions, a statement of policy will provide guidance to affected entities while regulations are reviewed in accordance with the Regulatory Review Act (71 P. S. §§ 745.1—745.15).

Purpose and Effect

This statement of policy outlines the guidelines the Department will use when reviewing policy form filings, including subscriber contracts and marketing material, to ensure compliance with Act 68. This statement of policy also offers guidance to managed care plans and licensed insurers on issues related to the implementation of Act 68.

This statement of policy provides guidance only, and does not constitute a rule or regulation entitled to the force and effect of law.

Companion Statement of Policy

This statement of policy is issued in conjunction with a companion statement of policy issued by the Department of Health. (*Editor's Note*: See 28 Pa.B. 5011 (October 3, 1998).) Managed care plans covered by Act 68 are subject to regulation by both the Department of Health and the Department. Accordingly, both statements of policy must be consulted to gain a clear understanding of the implementation requirements for managed care plans under Act 68.

Fiscal Impact and Paperwork Requirements

Adoption of this statement of policy, consistent with the mandates of Act 68, may result in additional costs and paperwork for the Commonwealth, managed care plans and licensed insurers. However, these guidelines are

necessary for the Department to effectively implement, and for managed care plans and licensed insurers to comply with, Act 68. Costs to the Commonwealth are not expected to be significant.

Contact Person

Questions relating to this statement of policy may be directed to Geoffrey Dunaway, Director, Accident and Health Bureau, Insurance Department, 1311 Strawberry Square, Harrisburg, PA 17120, (717) 787-4192.

Effective Date/Sunset Date

This statement of policy is effective January 1, 1999. Upon promulgation of regulations as described in the Preamble, this statement of policy will be rescinded.

M. DIANE KOKEN,
Insurance Commissioner

(*Editor's Note*: The regulations of the Department, 31 Pa. Code Chapter 301, are amended by adding a statement of policy in §§ 301.401—301.403 and 301.411—301.416 (relating to quality health care accountability and protection) to read as set forth in Annex A.)

Fiscal Note: 11-191. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 31. INSURANCE

PART X. HEALTH MAINTENANCE ORGANIZATIONS

CHAPTER 301. HEALTH MAINTENANCE ORGANIZATIONS

Subchapter J. QUALITY HEALTH CARE ACCOUNTABILITY AND PROTECTION—STATEMENT OF POLICY

GENERAL PROVISIONS

Sec.
301.401. Definitions.
301.402. Applicability and purpose.
301.403. Changes, modifications and disclosures.

REQUIRED PROVISIONS AND ENROLLEE DISCLOSURES

301.411. Managed care plan requirements.
301.412. Emergency services.
301.413. Continuity of care.
301.414. Information for enrollees.
301.415. Complaints and grievances.
301.416. Prompt payment.

GENERAL PROVISIONS

§ 301.401. Definitions.

(a) For the purpose of this subchapter, the definitions in section 2102 of the Insurance Company Law of 1921 (40 P. S. § 991.2102), as added by the act are incorporated herein by reference as if set forth in their entirety.

(b) As used in this subchapter, the term "act" refers to Article XXI of the Insurance Company Law of 1921 (40 P. S. §§ 991.2101—991.2193), as added by the act of July 17, 1998 (P. L. 464, No. 68).

§ 301.402. Applicability and purpose.

(a) This subchapter is effective January 1, 1999, and applies and provides compliance guidance to assist managed care plans and licensed insurers subject to the act.

(b) The terms and conditions of group and individual contract renewals and new business written by managed care plans on or after January 1, 1999, shall conform to the act.

(c) This subchapter applies to products issued by a managed care plan which partially insure an entity's risk, including those products which are known as "cost plus" or their equivalent.

(d) This subchapter does not apply to managed care plans that do not meet the statutory definition of "managed care plan" specified in section 2102 of the act (40 P. S. § 991.2102). The Department and the Department of Health have determined that managed care plans utilizing a passive gatekeeper structure, whereby an enrollee needs a referral from a primary care provider in the network, rather than from a preselected primary care provider, before receiving specialty care, will not be considered managed care plans for purposes of implementation of the act.

§ 301.403. Changes, modifications and disclosures.

(a) Managed care plans and licensed insurers may implement changes, modifications and disclosures to subscriber and other contracts and marketing materials, as required under the act, in several different ways including, contract endorsements, contract amendments and modification to the contract then in effect.

(b) Managed care plans will be given reasonable discretion with respect to the precise manner in which the managed care plans modify their contracts and other documents to comply with the act. The Department will review all managed care plan documents within its regulatory authority intended to address the changes required by the act.

(c) Licensed insurers performing utilization review services for or on behalf of managed care plans within this Commonwealth shall file with the Department of Health evidence of compliance with the standards and procedures in section 2152 of the act (40 P. S. § 991.2152) at the same time as the annual statement filing to the Department, beginning with annual statements for Fiscal Year 1999.

REQUIRED PROVISIONS AND ENROLLEE DISCLOSURES

§ 301.411. Managed care plan requirements.

Section 2111(13) of the act (40 P. S. § 991.2111(13)) requires managed care plans to report specific information to the Department of Health and the Department with respect to the number, type and disposition of complaints and grievances filed with the managed care plan. Managed care plans currently report this type of information to the Department of Health with respect to grievances. The Departments will accept the information required by the act from managed care plans based on the current format utilized to report grievance information.

§ 301.412. Emergency services.

(a) For purposes of clarification, the sections of the act which apply to emergency services are:

(1) Section 2102 of the act (40 P. S. § 991.2102) which defines "emergency service."

(2) Section 2116 of the act (40 P. S. § 991.2116) which establishes the parameters for the appropriate provision of, and payment by managed care plans for, emergency services rendered to enrollees by emergency health care providers.

(3) Section 2136(a) of the act (40 P. S. § 991.2136(a)) which establishes the requirement that certain written

disclosures be provided to enrollees, and on written request, to prospective enrollees and health care providers.

(4) Section 2136(a)(9) of the act which sets forth the disclosure requirements with respect to managed care plans' procedures for providing emergency services.

(b) The definition of "emergency service," as provided in section 2102 of the act, and the written disclosures referenced in subsection (a), should be incorporated into subscriber and master group contracts and, beginning January 1, 1999, in all other appropriate documents, including marketing materials.

§ 301.413. Continuity of care.

(a) *Continuity of care.*

(1) Section 2117 of the act (40 P. S. § 991.2117) provides for continuity of care for enrollees when one of the following applies:

(i) A managed care plan terminates a contract with a participating provider.

(ii) A managed care plan terminates a contract with a participating provider for cause (in which case continuity of care is not required).

(iii) A new enrollee enters a managed care plan and is currently in an ongoing course of treatment with a nonparticipating provider.

(2) Continuity of care is at the option of the enrollee.

(b) *Continuation of ongoing treatment.* Section 2117(a) of the act allows an enrollee to continue an ongoing course of treatment with a provider whose contract has been terminated for reasons other than cause. Section 2117(d) allows new enrollees to continue an ongoing course of treatment with a nonparticipating provider when joining a new managed care plan. Health care services provided under these provisions shall, by statute, be "covered by the managed care plan under the same terms and conditions as applicable for participating health care providers." The Department interprets these requirements to require nonparticipating and terminated providers who agree to continue to provide care to an enrollee to accept the terms applicable to participating providers, including, prohibitions on balance billing and agreements to hold enrollees harmless for moneys which may be owed by the managed care plan to the provider.

(c) *Written disclosure.* Written disclosure of the continuity of care benefit requirements imposed under the act should be incorporated into the subscriber and master group contracts and all other appropriate documents, including marketing materials.

§ 301.414. Information for enrollees.

(a) Section 2136(a) of the act (40 P. S. § 991.2136(a)) sets forth an extensive list of written information required to be provided to enrollees and, on written request, to prospective enrollees and health care providers. Managed care plans may select the format for disclosure of required information. If the information is disclosed through these materials as subscriber contracts, schedules of benefits and enrollee handbooks, the information should be easily identified within the materials provided.

(b) For the purposes of section 2136 of the act, the Department has determined that the definition of "prospective enrollee" varies based on whether the coverage is offered on a group or individual basis. Accordingly:

(1) For group policies, prospective enrollees are those persons that are eligible for coverage under a specific group as either a subscriber or dependent. In the case of group policies, the distribution of information to prospective enrollees should be coordinated between the managed care plan and the group policyholder, with the group policyholder ordinarily handling the distribution of written materials supplied by the managed care plan. In those instances in which the group policyholder communicates to the managed care plan that it will not coordinate the distribution of information, the managed care plan should supply the information directly to prospective enrollees.

(2) For individual policies, a prospective enrollee is any person who meets the eligibility requirements of the managed care plan. In the case of potential individual coverage, the managed care plan is responsible for providing the required information to a prospective enrollee.

(c) The disclosure of information required by section 2136(a) of the act to enrollees, prospective enrollees and health care providers should be provided as follows:

(1) During open enrollment periods, including those which may occur prior to January 1, 1999, managed care plans may disclose summary information to enrollees and prospective enrollees. If the information does not include all the information required by section 2136(a) of the act, the managed care plan should simultaneously provide the enrollees and prospective enrollees (either directly or through the group policyholder) with a list of all other information which is required by this section but that has not been included with the open enrollment information. This information should also be available to enrollees and prospective enrollees upon request.

(2) Disclosure of information required by section 2136(a) of the act to enrollees following initial enrollment or upon renewal should be made within a reasonable period of time after the effective date, renewal date of coverage or the date of request for the information.

(3) Disclosure of information required by section 2136(a) of the act to health care providers should be made within a reasonable period of time from the date of request for the information.

(d) The act requires certain disclosures of information to enrollees, and, on written request, to prospective enrollees and health care providers, and that the disclosures are easily understandable by the layperson and include:

(1) The information specified in section 2136(a)(1)—(15) of the act.

(2) The information covered under section 2113(d)(2) of the act (40 P. S. § 991.2113(d)(2)), if applicable. If applicable, managed care plans shall disclose in their subscriber contracts, schedule of benefits and other appropriate material when the managed care plan does not provide, reimburse for or cover counseling, referral or other health care services due to a managed care plan's objections to the provision of the services on moral or religious grounds.

(3) The specified disclosure statement required by section 2136(a)(1) of the act. Subscriber and group master contracts and riders, amendments and endorsements, will not be considered to constitute marketing materials subject to the specified disclosure statement.

(e) For the purposes of section 2136 of the act, the information that shall be disclosed to enrollees will ordinarily be provided to the enrollee by the managed care plan. However, this information may also be provided to enrollees by the group policyholder or other designated entity.

(f) The act requires that managed care plans, on written request of enrollees or prospective enrollees, provide written information, which should be easily understandable by the layperson, as follows:

(1) The information specified in section 2136(b)(1)—(9) of the act.

(2) Other information, as required by the Department or the Department of Health, under section 2136(b)(10) of the act.

§ 301.415. Complaints and grievances.

(a) Section 2102 of act (40 P. S. § 991.2102) defines "complaints" and "grievances."

(b) The Department and the Department of Health have determined that the "complaint process" includes issues of contract exclusions and noncovered benefit disputes and the "grievance" process includes review of the medical necessity and appropriateness of services otherwise covered by the managed care plan. Examples of complaints to be filed with the Department include:

(1) Denial of payment by the plan based upon contractual limitation rather than on medical necessity, for example, denial of payment for a visit by an enrollee on the basis that the enrollee failed to meet the contractual requirement of obtaining a referral from a primary care provider.

(2) Failure of a plan to approve a standing referral to a specialist or to designate a specialist to serve as an enrollee's primary care provider for an enrollee with a life-threatening, degenerative or disabling disease or condition in accordance with the plan's established qualification standards for the referral or designation.

(3) Refusal of the plan to provide, arrange for or pay for a procedure, drug or treatment on the basis that the procedure, drug or treatment is experimental, investigational or a cosmetic service excluded under the contract's provisions.

(4) Upon a determination by the enrollee's primary care provider that a referral is medically necessary and appropriate, a restriction on the enrollee's ability to obtain a referral to a participating specialist or provider of the enrollee's choice, unless the restriction is clearly disclosed in the provider directory or other written materials provided to the enrollee.

(5) A dispute involving a noncovered benefit or contract exclusion—for example, a request for additional physical therapy services, even if medically necessary, beyond the number specified in the enrollee contract.

(6) Problems relating to:

(i) Coordination of benefits.

(ii) Subrogation.

(iii) Conversion coverage.

(iv) Alleged nonpayment of premium.

(v) Dependent coverage.

(vi) Involuntary disenrollment.

(c) Section 2141 of the act (40 P. S. § 991.2141) establishes an internal complaint process to be followed by managed care plans.

(d) Section 2141(c)(4) requires the managed care plan to notify the enrollee within 5 business days of the rendering of a decision by the second level complaint review committee, including the basis for the decision and the procedure for appealing the decision to the Department or the Department of Health.

(e) Section 2142 of the act (40 P. S. § 991.2142) establishes an external process for enrollees who wish to appeal the internal complaint decision of the managed care plan to either the Department or the Department of Health, dependent upon the subject matter of the complaint.

(f) Appeals of enrollee complaints to the Department should include information such as:

(1) The enrollee's name, address and daytime phone number.

(2) The enrollee's policy number, identification number and group number (if applicable).

(3) A copy of the complaint submitted to the managed care plan.

(4) The reasons for appealing the managed care plan's decision.

(5) Correspondence and decisions from the managed care plan regarding the complaint.

(g) If the Department believes that the appeal more appropriately relates to issues and matters under the jurisdiction of the Department of Health—for example, an issue involving quality of care, the Department will notify the enrollee in writing of its finding and promptly transmit the appeal to the Department of Health for consideration. The original submission date of the appeal will be utilized to determine compliance with the filing time frame provided for in section 2142(a) of the act (40 P. S. § 991.2142(a)).

(h) Section 2161 of the act (40 P. S. § 991.2161) establishes an internal grievance process to be followed by managed care plans.

(i) Section 2162 of the act (40 P. S. § 991.2162) establishes an external process for enrollees and, under certain circumstances, providers, who wish to appeal the internal grievance decision of the managed care plan. Regulatory oversight for the external grievance process lies with the Department of Health.

(j) The Department and the Department of Health intend to continue the joint regulation of complaints which is currently in place. The Department's focus is to review cases which concern the potential violation of insurance statutes, including, those that fall under the Unfair Insurance Practices Act (40 P. S. §§ 1171.1—1171.15). The Department of Health will focus on complaint issues primarily involving enrollee quality of care and quality of service.

(k) Complaint appeals can be filed with the Department at the following address:

Pennsylvania Insurance Department
Bureau of Consumer Services
1321 Strawberry Square
Harrisburg, Pennsylvania 17120

(l) Complaints and grievances that were filed with either the Department or Department of Health prior to January 1, 1999, will be reviewed and resolved under the system in place at the time the complaints and grievances were filed. Complaints and grievances filed on or after January 1, 1999, will be reviewed based on the contract provisions in effect on the date the complaint or grievance is filed.

§ 301.416. Prompt payment.

(a) Section 2166 of the act (40 P. S. § 991.2166) applies to licensed insurers and managed care plans. Although the Blue Cross and Blue Shield plans have not historically been defined as a "licensed insurer," the Blue Cross and Blue Shield plans will utilize the standards of section 2166 of the act regarding prompt payment.

(b) Section 2166 of the act requires that licensed insurers and managed care plans pay "clean claims," as defined in section 2102 of the act (40 P. S. § 991.2102), within 45 days of the licensed insurer's or managed care plan's receipt of the clean claim from the health care provider. The Department has determined that a claim is determined to have been "paid" on either the date:

(1) A check is issued by the licensed insurer or managed care plan to the provider.

(2) An electronic transfer of funds from the licensed insurer or managed care plan to the provider occurs.

(c) The act does not expressly require that licensed insurers or managed care plans notify health care providers if a claim is determined by the licensed insurer or managed care plan to be incomplete or to be other than a clean claim as defined by the statute. The Department strongly encourages licensed insurers and managed care plans to notify health care providers when claims are incomplete or determined by the licensed insurer or managed care plan to be other than a clean claim.

(d) Prior to filing a complaint with the Department, providers who believe that a licensed insurer or managed care plan has not paid a clean claim in accordance with the act should first contact the licensed insurer or managed care plan to determine the status of the claim, to ensure that sufficient documentation supporting the claim has been provided, and to determine whether the claim is considered by the licensed insurer or the managed care plan to be a clean claim.

(e) Complaints to the Department regarding the prompt payment of claims by a licensed insurer or managed care plan under the act should contain information such as:

(1) The provider's name, address and daytime phone number.

(2) The name of the licensed insurer or managed care plan.

(3) The dates of service and the dates the claims were filed with the licensed insurer or managed care plan.

(4) Relevant correspondence between the provider and the licensed insurer or managed care plan, including requests for additional information from the licensed insurer or managed care plan.

(5) Additional information which the provider believes would be of assistance in the Department's review.

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