

# Regulatory Analysis Form

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DEPARTMENT OF REVENUE  
HARRISBURG, PENNSYLVANIA

(1) Agency

Insurance Department

Bush

(2) I.D. Number (Governor's Office Use)

11-195

IRRC Number: #2046

(3) Short Title

Quality Health Care Accountability and Protection

(4) PA Code Cite

31 Pa. Code, Chapter 154, §§154.1-154.11

(5) Agency Contacts & Telephone Numbers

Primary Contact: Peter J. Salvatore, Regulatory Coordinator,  
1326 Strawberry Square, Harrisburg, PA 17120, (717) 787-4429  
Secondary Contact:

(6) Type of Rulemaking (check one)

- Proposed Rulemaking  
 Final Order Adopting Regulation  
 Final Order, Proposed Rulemaking Omitted

(7) Is a 120-Day Emergency Certification Attached?

- No  
 Yes: By the Attorney General  
 Yes: By the Governor

(8) Briefly explain the regulation in clear and non-technical language.

The proposed regulations are necessary to carry out the provisions of act 68 of 1998 (P.L. 464, No. 68)(40 P.S. §§ 991.2101 – 991.2193). This regulation establishes a framework of requirements to be followed by managed care plans and licensed insurers for implementation of, and on-going operations under, the provisions of the act. Managed care plans covered by the act are subject to regulation by both the Insurance Department and the Department of Health. Department of Health regulations are scheduled to be promulgated separately from the Insurance Department's regulations.

(9) State the statutory authority for the regulation and any relevant state or federal court decisions.

The Department proposes the amendments to Title 31 under the authority of section 2181 of the Insurance Company Law of 1921 (40 P.S. § 991.2181), added by the act of June 17, 1998 (P.L. 464, No. 68) and sections 206, 506, 1501 and 1502 of the Administrative Code of 1929 (71 P.S. §§ 66, 186, 411, and 412).

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(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.

Yes. Act 68 of 1998 (P.L. 464, No. 68)(40 P.S. §§ 991.2101 – 991.2193). Act 68 of 1998 (the “act”) was signed into law by the Governor on June 17, 1998. Article XXI, the Quality Health Care Accountability and Protection provisions, became effective January 1, 1999.

(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

The Insurance Department seeks to adopt Chapter 154, §§154.1-154.11 to be consistent with the authorizing statute. Moreover, it is in the public interest to establish regulatory requirements concerning the quality health care provided and the accountability of the same.

(12) State the public health, safety, environmental or general welfare risks associated with nonregulation.

There are no public health, safety, environment or general welfare risks associated with this rulemaking.

(13) Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)

Insurers, providers and the public will benefit from the regulation to the extent that it will be consistent with the statute. The adoption of Chapter 154 will set guidelines for insurers, providers and the public, as to the procedures that need to be followed in order to account for the provisions of act 68.

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**(14) Describe who will be adversely affected by the regulation. (Quantify the adverse effects as completely as possible and approximate the number of people who will be adversely affected.)**

There will be no adverse effects on any party as a result of the adoption of this regulation.

**(15) List the persons, groups or entities that will be required to comply with the regulation. (Approximate the number of people who will be required to comply.)**

This regulation applies to all managed care plans and licensed insurers issuing or underwriting health insurance contracts and policies in the Commonwealth.

**(16) Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who were involved, if applicable.**

Comments regarding the adoption of this regulation were solicited from the various trade associations representing the insurance industry, health care providers, consumer groups, the Department of Health, the Department of Aging and the Department of Public Welfare. Comments were received and are available upon request. Comments were taken into consideration in developing this regulation.

**(17) Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures which may be required.**

Adoption of this regulation, consistent with the mandates of act 68, may result in additional costs for the Commonwealth, managed care plans and licensed insurers. However, this regulation is necessary for the Department to effectively implement, and for managed care plans and licensed insurers to comply with act 68 of 1998. Costs to the Commonwealth are not expected to be significant.

### **Regulatory Analysis Form**

(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures which may be required.

There are no cost savings associated with this regulation as they pertain to local government.

(19) Provide a specific estimate of the costs and/or savings to state government associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required.

Adoption of this regulation, consistent with the mandates of act 68, may result in additional costs for the Commonwealth, managed care plans and licensed insurers. However, this regulation is necessary for the Department to effectively implement, and for managed care plans and licensed insurers to comply with act 68 of 1998. Costs to the Commonwealth are not expected to be significant.

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(20) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years. N/A

	Current FY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
<b>SAVINGS:</b>	\$	\$	\$	\$	\$	\$
Regulated Community						
Local Government						
State Government						
<b>Total Savings</b>						
<b>COSTS:</b>						
Regulated Community						
Local Government						
State Government						
<b>Total Costs</b>						
<b>REVENUE LOSSES:</b>						
Regulated Community						
Local Government						
State Government						
<b>Total Revenue Losses</b>						

(20a) Explain how the cost estimates listed above were derived.

N/A.

## Regulatory Analysis Form

(20b) Provide the past three year expenditure history for programs affected by the regulation.  
N/A.

Program	FY -3	FY -2	FY -1	Current FY

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs.

No costs or adverse effects are anticipated as a result of this regulation.

(22) Describe the nonregulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal.

Adopting Chapter 154, §§154.1-154.11 is the most efficient method to achieve consistency with the authorizing statute. No other alternatives were considered.

(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

No other regulatory schemes were considered. The adoption of the regulation is the most efficient method of updating the regulatory requirements.

## **Regulatory Analysis Form**

(24) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulation.

No.

(25) How does this regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?

The rulemaking will not put Pennsylvania at a competitive disadvantage with other states. It merely provides for consistency with the statute.

(26) Will the regulation affect existing or proposed regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

No.

(27) Will any public hearings or informational meetings be scheduled? Please provide the dates, times, and locations, if available.

No public hearings or informational meetings are anticipated. Two stakeholder meetings were held on March 5, 1999 and March 11, 1999 in order for the Department to share the proposed rulemaking with the parties that would be affected.

## **Regulatory Analysis Form**

(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports which will be required as a result of implementation, if available.

Adoption of this regulation, consistent with the mandates of act 68, may result in additional paperwork for the Commonwealth, managed care plans and licensed insurers. However, these regulations are necessary for the Department to effectively implement, and for managed care plans and licensed insurers to comply with act 68 of 1998.

(29) Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

The rulemaking will have no effect on special needs of affected parties.

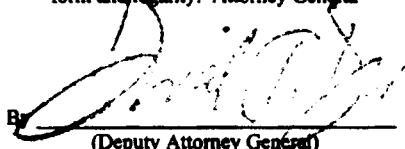
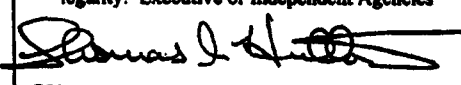
(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

The rulemaking will undergo a 30-day public comment period and will take effect upon approval of the final form regulation by the legislative standing committees, the Office of the Attorney General, and the Independent Regulatory Review Commission and upon final publication in the *Pennsylvania Bulletin*.

(31) Provide the schedule for continual review of the regulation.

The Department reviews each of its regulations for continued effectiveness on a triennial basis.



CDL-1  <b>FACE SHEET FOR FILING DOCUMENTS WITH THE LEGISLATIVE REFERENCE BUREAU</b>  (Pursuant to Commonwealth Documents Law)		93 JUL 20 PM 4:23  REVIEW DIVISION
# 2046		DO NOT WRITE IN THIS SPACE
Copy below is hereby approved as to form and legality. Attorney General   BY: _____ (Deputy Attorney General)  _____ Date of Approval  → Check if applicable. Copy not approved. Objections attached.	Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated  <b>Insurance Department</b> _____ (AGENCY)  DOCUMENT/FISCAL NOTE NO. <u>11-195</u>  DATE OF ADOPTION: _____ BY: <u>M. Diane Koken</u> <b>M. Diane Koken</b> <b>Insurance Commissioner</b> TITLE: _____ (EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)	Copy below is hereby approved as to form and legality. Executive or Independent Agencies   BY: _____  <u>6/15/99</u> DATE OF APPROVAL _____ (DEPUTY GENERAL COUNSEL) ( <del>CHIEF COUNSEL, INDEPENDENT AGENCY</del> ) (STRIKE INAPPLICABLE TITLE)  → Check if applicable. No Attorney General approval or objection within 30 days after submission.

**NOTICE OF PROPOSED RULEMAKING**

**INSURANCE DEPARTMENT**

**31 Pa. Code, Chapter 154**

**§§ 154.1-154.11**

**Quality Health Care Accountability and Protection**

## PREAMBLE

By this notice the Pennsylvania Insurance Department ("Department") hereby proposes to amend Title 31 of the Pennsylvania Code by adopting Chapter 154, Quality Health Care Accountability and Protection, to read as set forth in Annex A. The Department is publishing this regulation as a proposed rulemaking. The Department proposes the amendments to Title 31 under the authority of section 2181 of the Insurance Company Law of 1921 (40 P.S. § 991.2181), added by the act of June 17, 1998 (P.L. 464, No. 68) and sections 206, 506, 1501 and 1502 of the Administrative Code of 1929 (71 P.S. §§ 66, 186, 411, and 412).

### Purpose

Chapter 154 is being promulgated to implement the Quality Health Care Accountability and Protection provisions of Act 68 of 1998 (P.L. 464, No. 68)(40 P.S. §§ 991.2101 – 991.2193). Act 68 of 1998 (the "act") was signed into law by the Governor on June 17, 1998. Article XXI, the Quality Health Care Accountability and Protection provisions, became effective January 1, 1999. The Department originally issued a Statement of Policy to provide interim guidance to entities subject to the act, specifically managed care plans, as defined by the act, and licensed insurers. See 28 Pa.B. 5019 – 5023 (October 3, 1998). Upon adoption of these regulations, the Statement of Policy shall be rescinded.

The proposed regulations are necessary to carry out the provisions of the act. This regulation establishes a framework of requirements to be followed by managed care plans and licensed insurers for implementation of, and on-going operations under, the provisions of the act. Managed care plans and licensed insurers covered by the act are subject to regulation by both the Insurance Department and the Department of Health. Department of Health regulations are scheduled to be promulgated separately from the Insurance Department's regulations.

### Explanation of Regulatory Requirements

Section 154.1 (relating to applicability and purpose) sets forth the applicability of this chapter to entities under the Department's authority.

Section 154.2 (relating to definitions) sets forth the definitions necessary to clearly understand this chapter. Most of the definitions in this section have been adopted from the act to provide greater clarity and understanding to this chapter. The terms "Act", "commissioner", "department", "gatekeeper", "licensed insurer", "ongoing course of treatment" and "prospective enrollee," and their corresponding definitions have been added to provide greater clarity and understanding to this chapter.

Section 154.3 (relating to changes, modifications and disclosures in subscriber and other contracts and in other materials) sets forth how managed care plans shall

implement changes to identified contracts and other materials to meet the requirements of the act.

Section 154.4 (relating to managed care plan requirements) sets forth the requirements under which managed care plans will allow enrollees with life threatening, degenerative or disabling diseases or conditions, to request and receive an evaluation and, if the plan's established standards are met, a standing referral to a specialist, or the designation of a specialist as a primary care provider. This section also establishes standards which plans may impose in meeting this requirement.

Section 154.5 (relating to direct enrollee access to obstetrical and gynecological services) sets forth the requirements under which managed care plans will allow enrollees direct access to obstetrical and gynecological services without prior approval from a primary care provider. This section clarifies that a plan may require the obstetrical or gynecological provider to obtain prior authorization for selected services such as diagnostic testing or subspecialty care. This section also establishes the timeframe by which participating providers who provide direct obstetrical or gynecological services to enrollees must inform the enrollee's primary care provider of the services rendered. This section further sets forth coverage responsibilities for managed care plans with self-referral options.

Section 154.6 (relating to managed care plan reporting of complaints and grievances) sets forth the requirements for managed care plans to follow to report enrollee complaints and grievances to the Department.

Section 154.7 (relating to emergency services) sets forth the requirements applicable to coverage of emergency services by managed care plans. This section amplifies and clarifies the emergency services requirements of the act. This section also clarifies the requirements for emergency health care providers to notify managed care plans of the provision of emergency services to an enrollee.

Section 154.8 (relating to continuity of care) sets forth the requirements under which managed care plans must provide the continuity of care option to an enrollee who is currently in an ongoing course of treatment with a provider that is terminated by the plan, or to a new enrollee, joining the plan, who is in an ongoing course of treatment with a non-participating provider. This section clarifies that the continuity of care provision is at the option of the enrollee. Providers under this section must agree to the managed care plan's terms and conditions for providing health care services.

Section 154.9 (relating to information for enrollees) sets forth the information that managed care plans must provide to enrollees and, on written request, to prospective enrollees and health care providers. The information disclosed shall be in writing and shall be easily understandable to the layperson. This section also establishes the time periods for the disclosure of information to enrollees, prospective enrollees and health care providers.

Section 154.10 (relating to complaints) sets forth the requirements which managed care plans must follow in accordance with the complaint processes established under the act. Managed care plans must establish an internal complaint process with two levels of review. Examples of complaints, which could then be appealed by an enrollee to the Department, are listed in this section. This section also includes the information that an enrollee needs to provide to the Department, when appealing a managed care plan's second level complaint decision.

Section 154.11 (relating to prompt payment) applies to managed care plans and licensed insurers ("insurers"). This section sets forth the requirements that insurers and managed care plans must comply with to meet the prompt payment provisions of the act. The prompt payment provisions of the act and this chapter are not intended to supercede the unfair claims settlement practices provisions of the Department's regulations under the Unfair Insurance Practices Act (31 Pa. Code §§146.1-146.10) for the direct payment of claims to an insured or claimant. This section also sets forth the information health care providers need to provide to the Department to file a complaint.

#### Fiscal Impact

Adoption of this regulation, consistent with the mandates of act 68, may result in additional costs for the Commonwealth, managed care plans and licensed insurers. However, this regulation is necessary for the Department to effectively implement, and for managed care plans and licensed insurers to comply with act 68 of 1998. Costs to the Commonwealth are not expected to be significant.

#### Paperwork

Adoption of this regulation, consistent with the mandates of act 68, may result in additional paperwork for the Commonwealth, managed care plans and licensed insurers. However, these regulations are necessary for the Department to effectively implement, and for managed care plans and licensed insurers to comply with act 68 of 1998.

#### Persons Regulated

This regulation applies to all managed care plans and licensed insurers issuing or underwriting health insurance contracts and policies in the Commonwealth.

#### Contact Person

Questions or comments regarding the proposed rulemaking may be addressed in writing to Peter J. Salvatore, Regulatory Coordinator, 1326 Strawberry Square, Harrisburg, Pennsylvania 17120 within 30 days following the publication of this notice in the Pennsylvania Bulletin.

Questions or comments may also be e-mailed to [psalvato@ins.state.pa.us](mailto:psalvato@ins.state.pa.us) or faxed to (717) 705-3873.

### Regulatory Review

Under Section 5(a) of the Regulatory Review Act, Act 24 of 1997 (71 P.S. § 745(a)), the agency submitted a copy of the regulations with the proposed amendments on July 20, 1999 to the Independent Regulatory Review Commission (the Commission) and to the Chairpersons of the House Committee on Insurance and the Senate Committee on Banking and Insurance. In addition to submitting these proposed amendments, the agency has provided the Commission and the Committees with a copy of a detailed Regulatory Analysis Form prepared by the agency in compliance with Executive Order 1996-1. A copy of this material is available to the public upon request.

If the commission has any objections to any portion of the proposed amendments, it will notify the agency within 30 days after the close of the public comment period. The notification shall specify the regulatory review criteria that have not been met by that portion. The Act specifies detailed procedures for review of objections raised, prior to final publication of the regulations by the agency, the General Assembly and the governor.

M. Diane Koken  
Insurance Commissioner

CONTINUATION SHEET FOR FILING DOCUMENTS  
WITH THE LEGISLATIVE REFERENCE BUREAU  
(Pursuant to commonwealth Documents Law)

**ANNEX A**

Title 31. Insurance. Chapter 154. Quality Health Care Accountability and Protection

**General Provisions**

Sec.

- 154.1. Applicability and purpose.
- 154.2. Definitions.
- 154.3. Changes, modifications and disclosures in subscriber and other contracts and other materials

**Required Provisions and Enrollee Disclosures**

- 154.4. Managed care plan requirements.
- 154.5. Direct enrollee access to obstetrical and gynecological services
- 154.6. Managed care plan reporting of complaints and grievances.
- 154.7. Emergency services.
- 154.8. Continuity of care.
- 154.9. Information for enrollees.
- 154.10. Complaints.
- 154.11. Prompt payment.

**General Provisions**

**§ 154.1. Applicability and purpose.**

(a) This chapter governs quality health care accountability and protection and applies to “managed care plans” and “licensed insurers” subject to the provisions of 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, must conform to the provisions of the act.

(c) Any entity subcontracting with a managed care plan to provide services to enrollees which issues subscriber contracts covering enrollees must meet the requirements of the act and this chapter for services provided to those enrollees.

(d) Cost plus products, or their equivalent, which partially insure an entity’s risk, must meet the requirements of the act if they are issued by a managed care plan.

**§ 154.2. Definitions.**

The following words and terms, when used in this chapter, shall 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), added by the act of June 17, 1998 (P.L. 464, No. 68).

*Clean claim* -- A claim for payment for a health care service which has no defect or impropriety. A defect or impropriety shall include lack of required substantiating documentation or a particular circumstance requiring special treatment which prevents timely payment from being made on the claim. The term shall not include a claim from a health care provider who is under investigation for fraud or abuse regarding that claim.

*Commissioner* – The Insurance Commissioner of the Commonwealth.

*Complaint* -- A dispute or objection regarding a participating health care provider or the coverage, operations or management policies of a managed care plan, which has not been resolved by the managed care plan and has been filed with the plan or with the Department of Health or the Insurance Department of the Commonwealth. The term does not include a grievance.

*Department* -- The Insurance Department of the Commonwealth.

*Emergency service* -- Any health care service provided to an enrollee after the sudden onset of a medical condition, including a chronic condition, that manifests itself by acute symptoms of sufficient severity or severe pain, such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in:

- (1) Placing the health of the enrollee, or, with respect to a pregnant woman, the health of the woman or her unborn child, in serious jeopardy;
- (2) Serious impairment to bodily functions; or
- (3) Serious dysfunction of any bodily organ or part.

Emergency transportation and related emergency service provided by a licensed ambulance service shall constitute an emergency service.

*Enrollee* -- Any policyholder, subscriber, covered person or other individual who is entitled to receive health care services under a managed care plan.

*Gatekeeper* – A primary care provider selected by an enrollee or appointed by a managed care plan, or the plan or an agent of the plan serving as the primary care provider, from whom an enrollee shall obtain covered health care services, a referral, or approval for covered, nonemergency health services as a pre-condition to receiving the highest level of coverage available under the managed care plan.

*Grievance* -- As provided in section 2161 of the act (40 P.S. § 991.2161), 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 reconsider a decision solely concerning the medical necessity and appropriateness of a health care service. If the managed care plan is unable to resolve the matter, a grievance may be filed regarding the decision that:

- (1) Disapproves full or partial payment for a requested health care service.
- (2) Approves the provision of a requested health care service for a lesser scope or duration than requested; or
- (3) Disapproves payment for the provision of a requested health care service but approves payment for the provision of an alternative health care service.

The term does not include a complaint.

*Health care provider* -- A licensed hospital or health care facility, medical equipment supplier or person who is licensed, certified or otherwise regulated to provide health care services under the laws of this Commonwealth, including a physician, podiatrist, optometrist, psychologist, physical therapist, certified nurse practitioner, registered nurse, nurse midwife, physician's assistant, chiropractor, dentist, pharmacist or an individual accredited or certified to provide behavioral health services.

*Health care service* -- Any covered treatment, admission, procedure, medical supplies and equipment, or other services, including behavioral health, prescribed or otherwise provided or proposed to be provided by a health care provider to an enrollee under a managed care plan contract.

*Licensed insurer* -- Any individual, corporation, association, partnership, reciprocal exchange, inter-insurer, Lloyds insurer and any other legal entity engaged in the business of insurance, and fraternal benefit societies as defined in the act of December 14, 1992 (P.L. 835, No. 134), known as the "Fraternal Benefits Societies Code," and preferred provider organizations as defined in section 630 of the act of May 17, 1921 (P.L. 682, No. 284), known as "The Insurance company Law of 1921," and 31 Pa. Code § 152.2 (relating to definitions).

*Managed care plan* -- A health care plan that: uses a gatekeeper to manage the utilization of health care services; integrates the financing and delivery of health care services to enrollees by arrangements with health care providers selected to participate on the basis of specific standards; and provides financial incentives for enrollees to use the participating health care providers in accordance with procedures established by the plan. A managed care plan includes such health care arranged through an entity operating under any of the following:

- (1) Section 630 of the Insurance Company Law of 1921 (P.L. 246, No. 34)(40 P.S. § 764a).



(2) The Act of December 29, 1972 (P.L. 1701, No. 364), known as the "Health Maintenance Organization Act."

(3) The Act of December 14, 1992 (P.L. 835, No. 134), known as the "Fraternal Benefit Societies Code."

(4) 40 Pa.C.S. Ch. 61 (relating to hospital plan corporations).

(5) 40 Pa.C.S. Ch. 63 (relating to professional health services plan corporations).

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.

The term does not include ancillary service plans as defined by the act or an indemnity arrangement which is primarily fee for service.

*Ongoing course of treatment* – Continuous health care treatment which arises out of a single diagnosis provided to an enrollee by a health care provider.

*Plan* -- A managed care plan.

*Primary care provider* -- A health care provider who, within the scope of the provider's practice: supervises, coordinates, prescribes or otherwise provides or proposes to provide health care services to an enrollee; initiates enrollee referral for specialist care; and maintains continuity of enrollee care.

*Prospective enrollee* – For group contracts or policies, those persons eligible for coverage as either a subscriber or dependent of a subscriber. For individual contracts or policies, a person who meets the eligibility requirements of the managed care plan.

*Provider network* -- The health care providers designated by a managed care plan to provide health care services.

*Utilization review* -- A system of prospective, concurrent or retrospective utilization review, as defined by the act, performed by a utilization review entity of the medical necessity and appropriateness of health care services prescribed, provided or proposed to be provided to an enrollee. The term does not include any of the following:

(1) Requests for clarification of coverage, eligibility or health care service verification.

(2) A health care provider's internal quality assurance or utilization review process unless the review results in denial of payment for a health care service.

*Utilization review entity* -- Any entity certified pursuant to section 2151 of the act (40 P.S. § 991.2151) (relating to utilization review certification) that performs utilization review on behalf of a managed care plan.

**§ 154.3. Changes, modifications and disclosures in subscriber and other contracts and in other materials.**

Managed care plans shall implement changes, modifications and disclosures to subscriber and other contracts, marketing materials, member handbooks and other appropriate materials to meet the requirements of the act. Modifications can be implemented in several different ways including, but not limited to, contract endorsements, contract amendments and modification to the contract then in effect.

**Required Provisions and Enrollee Disclosures**

**§ 154.4. Managed care plan requirements.**

(a) Managed care plans shall adopt and maintain procedures by which an enrollee with a life-threatening, degenerative or disabling disease or condition shall, upon request, receive an evaluation, and, if the plan's established standards are met, be permitted to receive either:

- (1) A standing referral to a specialist with clinical expertise in treating the disease or condition; or
- (2) The designation of a specialist to provide and coordinate the enrollee's primary and specialty care.

(b) A managed care plan's established standards, as referenced in (a) may include, but are not limited to:

- (1) Time restrictions on approved treatment plans which include standing referrals or specialist designations.
- (2) Requirements that treatment plans be periodically reviewed and re-approved by the plan; and
- (3) Requirements that the specialist notify the enrollee's primary care provider of all care provided.

**§ 154.5. Direct enrollee access to obstetrical and gynecological services.**

(a) Managed care plans shall permit enrollees direct access to obstetrical and gynecological services for maternity and gynecological care, including medically necessary and appropriate follow-up care and referrals, and for diagnostic testing related

to maternity and gynecological care from participating health care providers without prior approval from a primary care provider.

(b) A managed care plan may require an obstetrical or gynecological provider to obtain prior authorization for selected services such as diagnostic testing or subspecialty care (for example: reproductive endocrinology, oncologic gynecology, and maternal and fetal medicine) .

(c) Any directly accessed participating health care provider providing services to an enrollee who has direct access to the provider in accordance with section 2111(7) of the act (40 P.S. §991.2111(7)) and this section, shall inform the enrollee's primary care provider, of all health care services provided to the enrollee. The health care provider shall communicate such information within 30 days of the services being provided pursuant to procedures established by the managed care plan.

(d) Managed care plans with enrollee self-referral options shall cover benefits provided by participating health care providers at the benefit level applicable to referred services.

#### **§ 154.6. Managed care plan reporting of complaints and grievances.**

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 Insurance Department with respect to the number, type and disposition of all complaints and grievances filed with the managed care plan. Managed care plans shall report this information to the Department based on the format utilized to report information prior to the effective date of the act. Notice of changes or amendments to the format required by the Department for reporting complaint and grievance information to the Department shall be published in the *Pennsylvania Bulletin*. The notice shall provide for a 30-day public comment period. Changes in format will become effective 30 days after publication of the revised format in a subsequent edition of the *Pennsylvania Bulletin*.

#### **§ 154.7. Emergency services.**

(a) Managed care plans are prohibited from requiring that enrollees or health care providers obtain prior authorization for emergency services as defined by the act (40 P.S. §991.2102).

(b) Plans are required to pay all reasonably necessary costs associated with the emergency services provided during the period of the emergency.

(c) Plans are required to consider the presenting symptoms as documented by the claim, and the services provided, when processing claims for emergency services.

(d) The emergency health care provider shall notify the enrollee's managed care plan of the provision of emergency services and the condition of the enrollee.

(1) If the enrollee is admitted to a hospital or other health care facility, the emergency health care provider shall notify the enrollee's managed care plan of the emergency services delivered within 48 hours or on the next business day, whichever is later.

(2) If the enrollee is not admitted to a hospital or other health care facility, the claim for reimbursement for emergency services provided shall serve as notice to the enrollee's managed care plan of the emergency services provided by the emergency health care provider.

(e) Managed care plans shall supply each enrollee, and upon written request, each prospective enrollee or health care provider, with the information concerning emergency services which is listed in section 154.14(h).

#### **§ 154.8. Continuity of care.**

(a) Managed care plans are required to provide the option of continuity of care for enrollees in instances where:

(1) A managed care plan terminates a contract with a participating provider for reasons other than for cause and the enrollee is then in an ongoing course of treatment with that provider; or

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

(b) A current enrollee shall be allowed to continue an ongoing course of treatment with a provider whose contract has been terminated for reasons other than for cause for a transitional period of up to 60 days from the date the enrollee was notified by the plan of the termination or pending termination. The managed care plan, in consultation with the enrollee and the health care provider, may extend the transitional period if determined to be clinically appropriate. For an enrollee in the second or third trimester of pregnancy at the time of notice of the termination or pending termination, the transitional period shall be extended through postpartum care related to the delivery.

(c) A new enrollee shall be allowed to continue an ongoing course of treatment with a nonparticipating provider when joining a managed care plan for a transitional period of up to 60 days from the effective date of enrollment in the managed care plan. The managed care plan, in consultation with the enrollee and the health care provider, may extend the transitional period if determined to be clinically appropriate. For an enrollee in the second or third trimester of pregnancy on the effective date of enrollment, the transitional period shall be extended through postpartum care related to the delivery.

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

(e) Non-participating and terminated providers must agree to the same terms and conditions which are applicable to the managed care plan's participating providers. If multiple providers are involved in an ongoing course of treatment, either:

(1) All of the providers involved must agree to the plan's terms and conditions; or

(2) Those providers who accept the plan's terms and conditions must agree to utilize participating providers for the provision of all other health care services to enrollees.

(f) Health care services provided under the continuity of care requirements must be covered by the managed care plan under the same terms and conditions as applicable for participating health care providers. In order to be eligible for payment by plans, providers must agree to the terms and conditions of the managed care plan prior to providing service under the continuity of care provisions.

(g) Managed care plans may require non-participating or terminating providers to agree to terms that include, but are not limited to:

(1) Accepting the plan's payment as payment in full for covered services, without balance billing, except for permitted deductibles, copayments or coinsurance;

(2) Agreeing to hold the enrollee harmless for any moneys which may be owed by the managed care plan to the provider;

(3) Complying with the plan's utilization review and quality assurance requirements;

(4) Agreeing to make all referrals for specialty care, diagnostic testing and related services to the enrollee's current managed care plan's participating providers;

(5) Agreeing that all nonemergency inpatient care will be provided at one of the enrollee's current managed care plan's participating hospitals or facilities.

(6) Agreeing that the provider will provide copies of the enrollee's medical records to the plan or the enrollee's participating primary care provider, or both prior to the conclusion of the ongoing course of previously authorized treatment; and

(7) Agreeing to follow the plan's procedures for precertification or prior approval of specified nonemergency services or procedures.

(h) Managed care plans may not require non-participating providers to undergo the plan's credentialing process as part of the continuity of care provision.

(i) Written disclosure of the continuity of care benefit requirements imposed under the act and this chapter shall be incorporated into the subscriber and master group contracts and all other appropriate documents. This information and any other information necessary to provide continuity of care services shall also be provided in written form to

terminated or terminating and nonparticipating providers within 10 days of notice to the plan that an enrollee is requesting continuity of care benefits.

**§ 154.9. Information for enrollees.**

(a) Managed care plans shall provide the written information listed in section 2136(a) of the act (40 P.S. § 991.2136(a)) (relating to required disclosures) to enrollees and, on written request, to prospective enrollees and health care providers. Managed care plans may determine the format for disclosure of the required information. If the information is disclosed through materials such as subscriber contracts, schedules of benefits and enrollee handbooks, the information should be easily identifiable within the materials provided.

(b) The information disclosed to enrollees, prospective enrollees and health care providers shall be easily understandable to the layperson.

(c) The written disclosure of information shall include but not be limited to:

(1) All of the information specified in section 2136(a) of the act (40 P.S. 991.2136(a)).

(2) A list by specialty of the name, address and telephone number of all participating health care providers. The list may be a separate document and shall be updated at least annually. If a list of participating providers for only a specific type of provider or service is provided, it shall include all participating providers authorized to provide those services.

(3) The information covered under section 2113(d)(2)(ii) of the act (40 P.S. § 991.2113(d)(2)(ii)) (relating to medical “gag clause” prohibition). If applicable, managed care plans shall disclose in their subscriber contracts, schedule of benefits and other appropriate material, circumstances under which the managed care plan does not provide for, reimburse for or cover counseling, referral, or other health care services due to a managed care plan’s objections to the provision of such services on moral or religious grounds.

(d) The specified disclosure statement required by section 2136(a)(1)(40 P.S. § 991.2136). For the purposes of the specified disclosure statement, subscriber and group master contracts and riders, amendments, and endorsements, shall not constitute “marketing materials” subject to the specified disclosure statement.

(e) For group contracts and policies, the managed care plan must assure that the required disclosure information is provided to prospective enrollees upon written request. The managed care plan can either provide the information directly to prospective enrollees or allow the group policy holder or another entity to provide the information to prospective enrollees on behalf of the managed care plan.

(f) For individual contracts and policies, the managed care plan must provide the required disclosure information directly to prospective enrollees upon written request.

(g) The disclosure of information to enrollees, prospective enrollees and health care providers as required by section 2136 of the act (40 P.S. § 991.2136) shall be provided as follows:

(1) During open enrollment periods managed care plans may disclose summary information to enrollees and prospective enrollees. If the disclosure of information does not include all the information required by the act and this chapter, the managed care plan shall simultaneously provide enrollees and prospective enrollees with a list of all other information which has not been included with the open enrollment information. The listed information shall be made available to enrollees and prospective enrollees upon request.

(2) Following initial enrollment, or upon renewal, if benefits or networks have changed since the initial enrollment or last renewal, disclosure information should be provided to enrollees within 30 days of the effective date of the contract or policy, renewal date of coverage (if appropriate), or the date of request for such information.

(3) Disclosure information requested by prospective enrollees must be provided to prospective enrollees within 30 days of the date of the written request for such information.

(4) Disclosure information requested by health care providers must be provided to health care providers within 45 days of the date of the written request for such information.

(h) Managed care plans shall supply each enrollee, and upon written request, each prospective enrollee or health care provider, with the following information which shall be contained and incorporated into subscriber and master group contracts and all other appropriate documents:

(1) A description of the procedures for providing emergency services 24 hours a day.

(2) A definition of emergency services, consistent with the act.

(3) Notice that emergency services are not subject to prior approval.

(4) The enrollee's financial and other responsibilities regarding emergency services, including the receipt of these services outside the managed care plan's service area.

(i) Managed care plans, on written request of enrollees or prospective enrollees, shall provide written information as specified in section 2136(b) of the act (40 P.S. § 991.2136(b)). This information shall be easily understandable to the layperson.

#### **§ 154.10. Complaints.**

(a) Under the complaint process established by the act, the Insurance Department will consider complaints regarding issues of contract exclusions and non-covered benefit disputes. The “grievance” process, which is administered by the Department of Health, includes review of the medical necessity and appropriateness of services otherwise covered by the managed care plan. Examples of the types of complaints which may 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. However, a primary care provider’s refusal to make an enrollee referral to a specialist, on the basis that the referral is not medically necessary, would be considered a grievance);

(2) Disputes involving a non-covered 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);

(3) Problems relating to:

- (i) Coordination of benefits;
- (ii) Subrogation;
- (iii) Conversion coverage;
- (iv) Alleged non-payment of premium;
- (v) Dependent coverage; or
- (vi) Involuntary disenrollment.

(b) Managed care plans shall establish an internal complaint process with two levels of review to allow enrollees to file oral and written complaints regarding a participating health care provider or the coverage, operations or management policies of the plan.

(c) Inquiries regarding premium rate increases do not constitute “appeals” and can be filed with the Department without the necessity of following the plan’s internal complaint process.

(d) Managed care plans may establish time frames, not shorter than 30 days, for the filing of complaints and grievances with the plan.

(e) Managed care plans must complete the initial level of review of an enrollee complaint within 30 days of receipt of the complaint. The plan must notify the enrollee in writing of the plan’s decision following the initial review within 5 business days of the decision. The notification shall include the basis for the decision and the procedure to file a request for a second level review of the decision of the initial review committee.

(f) Managed care plans must complete the second level of review of an enrollee complaint within 45 days of receipt of the enrollee’s request for review. The plan must notify the enrollee in writing 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 Insurance Department or the Department of Health.

(g) Enrollees must follow and complete the plan's internal complaint process before filing an appeal of the complaint decision with the Insurance Department or the Department of Health.

(h) Appeals of complaints must be submitted to the Insurance Department within 15 days of receipt of notice of the second level review committee's decision.

(i) Appeals of complaints to the Insurance Department should include such information 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; and
- (5) All correspondence and decisions from the managed care plan regarding the complaint.

(j) If the Insurance 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 Insurance Department will notify the enrollee and the managed care plan in writing of this determination 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)) (relating to appeal of complaint).

(k) The Insurance Department and the Department of Health share the statutory responsibility to regulate the enrollee and managed care plan complaint process. The Insurance Department will focus on the review of cases which concern the potential violation of insurance statutes, including, but not limited to, 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.

(l) Complaint appeals under (i) can be filed with the Insurance Department at the following address:

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

**§ 154.11. Prompt payment.**

(a) Licensed insurers and managed care plans shall pay clean claims submitted by a health care provider for services provided on or after January 1, 1999 within 45 days of the licensed insurer's or managed care plan's receipt of the clean claim from the health care provider.

(b) For purposes of prompt payment, a claim shall be deemed to have been "paid" on either the date:

(1) A check is mailed by the licensed insurer or managed care plan to the health care provider; or

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

(c) Any interest due to a health care provider on a clean claim shall be calculated and paid by the licensed insurer or managed care plan to the health care provider and shall be added to the amount owed on the clean claim. The interest shall be paid at the time of payment of the claim. Any interest owed of less than \$2.00 on a single claim does not have to be paid by the licensed insurer or managed care plan. Interest can be paid on the same check as the claim payment or on a separate check. If the licensed insurer or managed care plan combines interest payments for more than one late clean claim, the check shall include information listing each claim covered by the check and the specific amount of interest being paid for each claim.

(d) Claims paid by a licensed insurer or managed care plan are considered clean claims and are subject to the interest provisions of the act. If a paid claim is re-adjudicated by the licensed insurer or managed care plan, the 45 day period for the prompt payment provision begins again at the time additional information prompting the re-adjudication is provided to the plan. Any additional monies which are owed or paid to the health care provider are subject to the prompt payment provisions of the act and this chapter. The prompt payment requirement of the act also applies to the uncontested portion of a contested claim. A contested claim is a claim for which all required substantiating documentation has been supplied to the licensed insurer or managed care plan, but where the licensed insurer or managed care plan has determined that it is not obligated to make payment.

(e) Prior to filing a complaint with the Insurance Department, health care providers who believe that a licensed insurer or managed care plan has not paid a clean claim in accordance with the act and this chapter 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. Licensed insurers and managed care plans shall respond to the health care provider's inquiries regarding the status of unpaid claims within a reasonable period of time.

(f) Health care providers may file a complaint with the Insurance Department prior to receipt of a determination from a licensed insurer or managed care plan as to whether a claim is considered a clean claim if either:

(1) The licensed insurer or managed care plan has not responded to a health care provider's inquiries regarding the status of an unpaid claim within a reasonable period of time; or

(2) The health care provider believes that the licensed insurer or managed care plan is otherwise not complying with the prompt payment provisions of the act.

(g) Complaints to the Insurance Department regarding the prompt payment of claims by a licensed insurer or managed care plan under the act and this chapter shall contain the following information:

(1) The provider's name, address and daytime telephone number; the claim number;

(2) The name and address of the licensed insurer or managed care plan;

(3) The name of the patient and employer;

(4) The date(s) of service and the date(s) the claims were submitted to the licensed insurer or managed care plan;

(5) Any 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; and

(6) Any additional information which the provider believes would be of assistance in the Department's review.



**COMMONWEALTH OF PENNSYLVANIA  
INSURANCE DEPARTMENT**

OFFICE OF SPECIAL PROJECTS  
1326 Strawberry Square  
Harrisburg, PA 17120

Phone: (717) 787-4429  
Fax: (717) 705-3873  
E-mail: [psalvato@ins.state.pa.us](mailto:psalvato@ins.state.pa.us)

July 20, 1999

Mr. Robert Nyce  
Executive Director  
Independent Regulatory Review Comm.  
333 Market Street  
Harrisburg, PA 17120

Re: Insurance Department  
Proposed Regulation No. 11-  
195, Quality Health Care  
Accountability and Protection

Dear Mr. Nyce:

Pursuant to Section 5(a) of the Regulatory Review Act, enclosed for your information and review is proposed regulation 31 Pa. Code, Chapter 154, Quality Health Care Accountability and Protection.

Chapter 154 is being promulgated to implement the Quality Health Care Accountability and Protection provisions of Act 68 of 1998 that became effective January 1, 1999. The proposed regulations are necessary to carry out the provisions of the act. This regulation establishes a framework of requirements to be followed by managed care plans and licensed insurers for implementation of, and on-going operations under, the provisions of the act. Managed care plans and licensed insurers covered by the act are subject to regulation by both the Insurance Department and the Department of Health. Department of Health regulations are scheduled to be promulgated separately from the Insurance Department's regulations.

If you have any questions regarding this matter, please contact me at (717) 787-4429.

Sincerely yours,

A handwritten signature in cursive script that reads "Peter J. Salvatore".

Peter J. Salvatore  
Regulatory Coordinator

**TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE  
REGULATORY REVIEW ACT**

I.D. NUMBER: 11-195  
SUBJECT: Quality Health Care Accountability & Protection  
AGENCY: DEPARTMENT OF INSURANCE

99 JUL 20 PM 4: 24

REGULATORY REVIEW  
COMMISSION

**TYPE OF REGULATION**

- X Proposed Regulation
- Final Regulation
- Final Regulation with Notice of Proposed Rulemaking Omitted
- 120-day Emergency Certification of the Attorney General
- 120-day Emergency Certification of the Governor
- Delivery of Tolled Regulation
- a. With Revisions                      b. Without Revisions

**FILING OF REGULATION**

DATE	SIGNATURE	DESIGNATION
7/20/99	<i>Shula Eshat</i>	HOUSE COMMITTEE ON INSURANCE
7/20/99	<i>Diana Bonell</i>	SENATE COMMITTEE ON BANKING & INSURANCE
7/20/99	<i>Ken C. ...</i>	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL
	<i>James ...</i>	LEGISLATIVE REFERENCE BUREAU

July 14, 1999