Regulatory Analysis Form

This space for use by IRRC

(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, §§154.1-154.18

(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.

This regulation is 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 amends 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).

Regulatory Analysis Form

(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 is seeking to adopt Chapter 154, §§154.1-154.18 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.

Regulatory Analysis Form

(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.

The regulation underwent a 30-day public comment period. Comments were received from American Association of Retired Persons, American College of Emergency Physicians, American College of Obstetricians and Gynecologists and American College of Nurse Midwives, David Farrick of Blair Orthopedic Associates & Sports Medicine, BlueCross of Northeastern Pennsylvania, Capital Blue Cross, Commonwealth of Pennsylvania Department of Public Welfare, Community Medical Center, Delaware Valley Hospital Council of the Healthsystems Association of Pennsylvania, Eastern Paralyzed Veterans Association, Highmark, Inc., The Hospital and Healthsystem Association of Pennsylvania, Independence Blue Cross, Insurance Federation of Pennsylvania, Inc., Keystone Health Plan Central, Inc., League of Women Voters, Managed Care Association of Pennsylvania, Pennsylvania Academy of Family Physicians, Pennsylvania Catholic Health Association, Pennsylvania Community Providers Association, Pennsylvania Health Law Project, Pennsylvania Medical Society, Pennsylvania Psychological Association, Pennsylvania Psychiatric Society. During its regulatory review, the Independent Regulatory Review Commission (IRRC) submitted comments to the Department. A separate comment and response document has been prepared to address these comments and is available upon request.

(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.

Regulatory Analysis Form

(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
SAVINGS:	$	$	$	$	$	$
Regulated Community						
Local Government						
State Government						
Total Savings						
COSTS:						
Regulated Community						
Local Government						
State Government						
Total Costs						
REVENUE LOSSES:						
Regulated Community						
Local Government						
State Government						
Total Revenue Losses						

(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, §§154.1-154.18 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. Stakeholder meetings were held on March 5, 1999, March 11, 1999 and October 7, 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 effect upon approval of the final form regulation by the legislative standing committees, the Independent Regulatory Review Commission, and the Office of the Attorney General 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.

Copies of the final form regulation listed below were sent today to those named. (Commentators are noted by the date that the comment was received).

Reg #	*Regulation Title*
11-195	*Quality Health Care Accountability and Protection*

Ms. Roxanne Plaskow
Chester Co. Coalition for Manage Care
154 Daylesford Blvd.
Berwyn PA 19312-

Date Comment Was Received:

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Mr. Hugh O. Allen *Senior Legislative Liaison*
Eastern Paralyzed Veterans Association
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Date Comment Was Received: *8/5/1999*

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Blair Orthopedic Associates & Sports Medicine

Date Comment Was Received: *8/5/1999*

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Mr. Harry D. Madonna
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Date Comment Was Received: *8/17/1999*

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Ms. Kristi Wasson *Executive Director*
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Date Comment Was Received: *8/25/1999*

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Regulatory Affairs Director

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Mr. Samuel R. Marshall
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President

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Ms. Kimberly J. Kockler
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Executive Director

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Mr. Richard F. Levins
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Deputy Chief Counsel

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Mr. Robert Jones
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Date Comment Was Received: *8/30/1999*

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Ms. Suzanne Love — *Director*
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Date Comment Was Received: *8/30/1999*

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DPW, Bureau of Policy and Program Development
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Date Comment Was Received: *8/30/1999*

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Date Comment Was Received: *8/30/1999*

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Mr. John C. Hickey , Esq. — *Vice President, Legal and Government Programs*
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Date Comment Was Received: *8/30/1999*

Phone: (717) 703-3458 X00000 *EMail:* John.Hickey@khpc.com

Ms. Ann S. Torregrossa , Esq.
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Ms. C. Lu Conser , MPH — *Director of Government Relations*
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Date Comment Was Received: *8/30/1999*

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Mr. David Blunk — *Executive Director*
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Date Comment Was Received: *8/30/1999*

Phone: (717) 558-7750 X01468 ***EMail:*** dblunk@paacep.org

Ms. Deb Cohen — *Senior Director, POS Programs*
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Date Comment Was Received: *8/30/1999*

Phone: (717) 541-7412 X00000 ***EMail:*** debra.cohen@capbluecross.com

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Mr. John S. Jordan — *Executive Vice President*
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Date Comment Was Received: *8/30/1999*

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Ms. Nancy Bucher
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Date Comment Was Received:

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Date Comment Was Received: *8/30/1999*

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FACE SHEET
FOR FILING DOCUMENTS
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(Pursuant to Commonwealth Documents Law)

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INDEPENDENT REGULATORY
REVIEW COMMISSION

DO NOT WRITE IN THIS SPACE

Copy below is hereby approved as to form and legality. Attorney General	Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:	Copy below is hereby approved as to form and legality. Executive or Independent Agencies
By _____ (Deputy Attorney General)	Insurance Department (AGENCY)	BY _____
_____ Date of Approval	DOCUMENT/FISCAL NOTE NO. 11-195	1/21/00 DATE OF APPROVAL
→ Check if applicable. Copy not approved. Objections attached.	DATE OF ADOPTION: _____	(DEPUTY GENERAL COUNSEL) ~~(CHIEF COUNSEL, INDEPENDENT AGENCY)~~ (STRIKE INAPPLICABLE TITLE)
	BY: M. Diane Koken M. Diane Koken Insurance Commissioner	→ Check if applicable. No Attorney General approval or objection within 30 days after submission.
	TITLE: _____ (EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)	

NOTICE OF FINAL RULEMAKING

INSURANCE DEPARTMENT

31 Pa. Code, Chapter 154
§§ 154.1-154.18

Quality Health Care Accountability and Protection

PREAMBLE

The Insurance Department (Department) hereby amends Chapter154, §§154.1-154.18 of Title 31 of the Pennsylvania Code, Quality Health Care Accountability and Protection, as set forth in Annex A. The Department is publishing the amendment of the regulation as a final form rulemaking.

Statutory Authority

The final form regulation is adopted under the authority of sections 206, 506, 1501 and 1502 of the Administrative Code of 1929 (71 P.S. §§66, 186, 411 and 412); section 320 of the Insurance Department Act of 1921 (40 P.S. §443); and 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) ("Act").

Comments and Response

A Notice of Proposed Rulemaking for this Regulation was published at 29 Pa.B. 4064 (July 31, 1999) with a 30-day comment period ending August 30, 1999. During the 30-day comment period, comments were received from American Association of Retired Persons ("AARP"), American College of Emergency Physicians ("ACEP"), American College of Obstetricians and Gynecologists and American College of Nurse Midwives ("ACOP/ACNM"), David Farrick of Blair Orthopedic Associates & Sports Medicine ("BLAIR"), BlueCross of Northeastern Pennsylvania ("BCNE"), Capital Blue Cross ("CBC"), Commonwealth of Pennsylvania Department of Public Welfare ("DPW"), Community Medical Center ("CMC"), Delaware Valley Hospital Council of the Healthsystems Association of Pennsylvania ("DVHC"), Eastern Paralyzed Veterans Association ("EPVA"), Highmark, Inc. ("HIGHMARK"), The Hospital and Healthsystem Association of Pennsylvania ("HAP"), Independence Blue Cross ("IBC"), Insurance Federation of Pennsylvania, Inc. ("IFP"), Keystone Health Plan Central, Inc. ("KHPC"), League of Women Voters ("LWV"), Managed Care Association of Pennsylvania ("MCAP"), Pennsylvania Academy of Family Physicians ("PAFP"), Pennsylvania Catholic Health Association ("PCHA"), Pennsylvania Community Providers Association ("PCPA"), Pennsylvania Health Law Project ("PHLP"), Pennsylvania Medical Society ("PMS"), Pennsylvania Psychological Association ("PPA"), Pennsylvania Psychiatric Society ("PPS")

During its regulatory review, the Independent Regulatory Review Commission (IRRC) submitted comments to the Department. A separate comment and response document has been prepared to address these comments and is available upon request.

Affected Parties

The rulemaking applies to all insurers and Managed Care Plans licensed to do the business of health insurance in this Commonwealth.

Fiscal Impact

State Government

Adoption of this regulation, consistent with the mandates of act 68, may result in additional costs for the Commonwealth. 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.

General Public

There will be no fiscal impact to the public.

Political Subdivisions

The rulemaking will not impose additional costs on political subdivisions.

Private Sector

Adoption of this regulation, consistent with the mandates of act 68, may result in additional costs for 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.

Paperwork

The adoption of the rulemaking will not impose additional paperwork on the Department; however, new disclosure requirements will be required of the industry.

Effectiveness/Sunset Date

This rulemaking becomes effective upon publication in the Pennsylvania Bulletin. No sunset date has been assigned.

Contact person

Any questions regarding this regulation should be directed to Peter J. Salvatore, Regulatory Coordinator, Office of Special Projects, 1326 Strawberry Square, Harrisburg, PA 17120, phone (717) 787-4429. In addition, questions or comments may be e-mailed to psalvato@ins.state.pa.us or faxed to (717) 705-3873.

Regulatory review

Under section 5(a) of the Regulatory Review Act, (71 P.S. §745.5(a)), the agency submitted a copy of this regulation on July 20, 1999 to the Independent Regulatory Review Commission and to the Chairmen of the Senate Banking and Insurance Committee and the House Insurance Committee. In addition to the submitted regulation, 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, "Regulatory Review and Promulgation." A copy of that material is available to the public upon request.

In preparing this final form regulation, the Department considered all comments received from IRRC, the Committees and the public. This final form regulation was (deemed) approved by the Senate and House Committees _____. In accordance with section 5a(d) of the Regulatory Review Act (71 P.S. §745.5a(d)), IRRC met on _____ and approved the regulation in accordance with section 5a(e) of the Regulatory Review Act (71 P.S. §745.5a(e)).

Findings

The Commissioner finds that:

(1) Public notice of intention to adopt this rulemaking as amended by this order has been given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No240) (45 P.S. §§1201 and 1202) and the regulations thereunder, 1 Pa. Code §§7.1 and 7.2.

(2) The adoption of this rulemaking in the manner provided in this order is necessary and appropriate for the administration and enforcement of the authorizing statutes.

Order

The Commissioner, acting under the authorizing statutes, orders that:

(1) The regulations of the Department, 31 Pa. Code, are amended by adopting §§ 154.1-154.18, to read as set forth in Annex A.

(2) The Commissioner shall submit this order and Annex A to the Office of General Counsel and Office of Attorney General for approval as to form and legality as required by law.

(3) The Commissioner shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.

(4) The order shall take effect upon final publication in the *Pennsylvania Bulletin.*

M. Diane Koken
Insurance Commissioner

Comments and Response

A Notice of Proposed Rulemaking for this Regulation was published at 29 Pa.B. 4064 (July 31, 1999) with a 30-day comment period ending August 30, 1999. During the 30-day comment period, comments were received from American Association of Retired Persons ("AARP"), American College of Emergency Physicians ("ACEP"), American College of Obstetricians and Gynecologists and American College of Nurse Midwives ("ACOP/ACNM"), David Farrick of Blair Orthopedic Associates and Sports Medicine ("BLAIR"), BlueCross of Northeastern Pennsylvania ("BCNE"), Capital Blue Cross ("CBC"), Community Medical Center ("CMC"), Commonwealth of Pennsylvania Department of Public Welfare ("DPW"), Delaware Valley Hospital Council of the Healthsystems Association of Pennsylvania ("DVHC"), Eastern Paralyzed Veterans Association ("EPVA"), Highmark, Inc. ("HIGHMARK"), The Hospital and Healthsystem Association of Pennsylvania ("HAP"), Independence Blue Cross ("IBC"), Insurance Federation of Pennsylvania, Inc. ("IFP"), Keystone Health Plan Central, Inc. ("KHPC"), League of Women Voters ("LWV"), Managed Care Association of Pennsylvania ("MCAP"), Pennsylvania Academy of Family Physicians ("PAFP"), Pennsylvania Catholic Health Association ("PCHA"), Pennsylvania Community Providers Association ("PCPA"), Pennsylvania Health Law Project ("PHLP"), Pennsylvania Medical Society ("PMS"), Pennsylvania Psychological Association ("PPA"), Pennsylvania Psychiatric Society ("PPS")

During its regulatory review, the Independent Regulatory Review Commission (IRRC) submitted comments to the Department. A separate comment and response document has been prepared to address these comments and is available upon request.

The following is a detailed analysis of the comments received during the 30-day public comment period.

Section 154.1. Applicability and purpose.

AARP, ACEP, CBC, DPW, IBC, IFP, PMS and the IRRC commented on the applicability and purpose section.

AARP wanted this section to apply to PPOs and networks that contract directly with employers.

ACEP wants identification of all entities that would be required to follow the provisions set forth in the act.

CBC wanted a clarification of the meaning of and an example on "which issues subscriber contracts covering enrollees." in subsection (c).

DPW stated that the term entity was too broad and that it was difficult to determine the "subcontracting entity." in subsection (c).

IBC wanted additional language in subsection (a) and clarification to subsection (c).

IFP wanted clarification to the term "cost plus products."

PMS wanted the Department to add a subsection to clarify when the Plan will apply to subcontracts from an otherwise exempt entity and wanted the phrase "which issues subscriber contracts covering enrollees." clarified.

PPA wanted "cost plus products" defined.

The IRRC suggested clarification to: 1) the term "entity", 2) the phrase "which issues subscriber contracts covering enrollees" and 3) whether the regulation is applicable to subcontracted services that are subcontracted for an exempt entity if the subcontract is with a Plan that were mentioned in subsection (c). The IRRC also suggested that the Department define or clarify the term "cost plus products" in subsection (d).

The Department agrees that the term "cost plus products" is confusing and has eliminated the reference to "cost plus products" and replaced it with the term "policies" which is more applicable. The Department is also clarifying subsection (a) to exclude health care services and claims processed under automobile and workers' compensation policies and to clarify that the Department and the Department of Health share regulatory authority under the act and subsection (c) to include integrated delivery systems and by deleting "which issues subscriber contracts covering enrollees." The regulations would not apply in IRRC's comment #3 because the act's applicability is based on the entity issuing the enrollee contract. The Department believes it is both unnecessary and impossible to produce a list of all insured and self-insured plans that are not covered by the act. The act clearly defines those entities that are managed care plans.

<u>Section 154.2. Definitions.</u>

AARP, CBC, CMC, DPW, DVHC, EPVA, HIGHMARK, HAP, IBC, MCAP, PAFP, PHLP, PMS, PPA, PPS and the IRRC commented on the definition section.

AARP wanted clarification on whether disputes about benefits are included as part of "coverage issues" in the term *complaint* and wanted to specifically know if quality of care could be considered a *complaint*. AARP wanted to know if the three provisions address a reduction or termination in an existing service under the definition and wanted *grievance* to ensure a grievance can be filed about any aspect of the provision. AARP also felt that the definition *utilization review* severely limits the functions of a plan's utilization review program.

CBC wanted to tighten the definition *gatekeeper* so that PPOs and indemnity plans are not included.

CMC wanted "pre-certification" added to the term *utilization review*. CMC also wanted "pre-certification" included in the term *grievance*.

DPW wanted the term *gatekeeper* deleted as they do not pertain to Behavioral Health MCOs and *gatekeepers* in HealthChoices do not understand the term "agent." DPW also recommended that

ongoing course of treatment be included in § 154.15, relating to continuity of care and recommended that "including a chronic condition" be deleted from the term *emergency service.*

DVHC suggested that "defect or impropriety" be further defined in the term *clean claim.* DVHC suggested that the term *gatekeeper* include "any persons or entities appointed by the managed care plan from whom an enrollee must obtain a referral or approval." DVHC also suggested that "clean portion" of a claim be further defined. DVHC also recommended that PPO be removed from definition of *licensed insurer* and move to *managed care plan.*

EPVA wanted *gatekeeper and managed care plan* to reflect "passive gatekeepers." EPVA also wanted *enrollee* to include a parent, designee or legal representative.

HAP recommended clarification of the term *clean claim.*

HIGHMARK suggest that *ongoing course of treatment* be more specific and recommended that "treatment has been rendered within 3 most recent months..." HIGHMARK felt that the definition *licensed insurer* could be construed to exempt nonprofit hospital and professional health plan corporations. HIGHMARK also suggested clarification that the term *emergency services* include "...including a sudden and unexpected medical event involving..." otherwise it may allow for the use of emergency room services for chronic conditions that are not emergency situations.

IBC suggested merging clause (i)(C) and subparagraph (ii) in the definition of *emergency service.* IBC wanted a third level of appeal to be added to *grievance.* IBC also wanted clarification that ambulance services and chronic conditions are considered only when conditions or symptoms are present that are considered an emergency situation. IBC also wanted to expand the definition of *ongoing course of treatment.*

IFP asked for further clarification of the term "chronic conditions" in the definition of *emergency service.* They also sought clarification that the term *managed care plans* includes "passive gatekeeper products" but not plans that do not require enrollees to obtain a referral for specialty services from a primary care provider.

MCAP suggested that *prospective enrollee* contain "those persons eligible, but not yet enrolled." MCAP suggested that *health care service* specifically exclude prescription drugs. MCAP suggested that *ongoing course of treatment* be clarified by including "authorized by the previous insurer or managed care plan." MCAP also suggested that *grievance* "not include a provider appeal for clarification of claims payment." MCAP suggested that term "provider" be changed to "practitioner" in the definition *health care service.* MCAP also suggested removing "including chronic condition" from *emergency services.*

PAFP recommended that *primary care provider* not include advanced practice nurses or physician assistants. PAFP also suggested that the Department add the definition of "primary care" to the proposed rulemaking.

PHLP suggested that *enrollee* include "parents of minor enrollees as well as designees or legal representatives who are entitled or authorized to act on behalf of an enrollee." PHLP suggested revising the definition of *ongoing course of treatment.* PHLP also suggested that the definition of *grievance* be deleted in its entirety. PHLP suggested that the Department delete "the highest level of and available" from the definition of *gatekeeper.* PHLP wanted "or a plan authorized non-participating provider" added after "health care provider" in the definition of *complaint.*

PMS suggested that services listed on the HCFA 1500 be considered a claim in the definition of *clean claim.* PMS also suggested that the consent to treatment by the patient should serve as authorization to pursue the claim with the client's insurer and that this consent should be considered under the definition of *grievance.*

PPA suggested that the definition of *emergency service* be clarified with regards to "chronic condition." PPA suggested that *managed care plan* be clarified so that a plan that does not require the enrollee to obtain a referral from any PCP in its network as a condition to receiving specialty care shall not be considered a managed care plan. PPA suggested that *licensed insurer* should be clarified so that this applies only to health policies, while claims submitted under auto and worker's compensation policies are subject to their own rules under those acts.

PPS raised concerns about the definition of *primary care provider* as it relates to the definition of gatekeeper.

The IRRC objected to the reiteration of statutory definitions. IRRC recommended that the Department should reference the statutory definition in *emergency services.* IRRC recommended that the Department add a provision to § 154.14 that clarifies a severe and sudden onset of a chronic condition that meet the prudent layperson standard can be classified as emergency services. IRRC recommended that the Department clarify whether *gatekeeper* includes plans using a passive or multiple-choice gatekeeper structure. IRRC recommended that the Department clarify whether the enrollee must select a primary care provider from a list provided by the Plan in the definition of *gatekeeper.* IRRC also wanted to know the propose of the phrase "or the plan or an agent of the plan serving as the primary care provider?" that is in the definition of *gatekeeper.* IRRC suggested that *plan* should be used consistently in place of managed care plan. IRRC recommended that the Department clarify the application of the "single diagnosis" phrase to § 154.15 because it is unclear and may place needless limits on the applicability of this section under the definition of *ongoing course of treatment.* IRRC recommended that the Department include references to the definitions of ancillary service plans and referrals in section 2102 of the act. IRRC recommended that the Department explain how and when others may represent other enrollees under the act in the definition of *enrollee.*

The Department agrees that repetition of the definitions is not necessary and has made changes to reflect referral to section 2102 of the act. The Department has also eliminated the phrase "including a chronic condition" from the definition *emergency services* and moved it to § 154.14(c). This definition now reflects language found in the act. The Department also expanded the definition of *enrollee* to include "For purposes of the complaint and grievance process, the term shall include parents of minor enrollees as well as designees or legal representatives who are entitled or authorized to act on behalf of the

enrollee." The phrase "or the plan or an agent of the plan" in the definition of *gatekeeper* is intended to recognize the dynamic, changing nature of managed care where some plans allow enrollees to obtain referrals for health care services from the plan or their agent rather than their primary care provider. The Department believes that the selection process for primary care providers is an operational issue for the plan to determine. Regarding the issue of "passive" or "multiple choice" gatekeeper structures, the Department clarified the use of gatekeepers by plans that allow enrollees to access any primary care provider to obtain referrals in the definition of *managed care plan*. Regarding the use of the terms "managed care plan" and "plan", the Department used both terms throughout the chapter because we believe it makes the chapter more readily understood and readable. In addition, the Department revised the definition of *ongoing course of treatment* to more accurately reflect the suggestions from IRRC. The phrase "single diagnosis" has been removed and the definition rephrased to reflect that treatment will continue after the plan's termination for reasons other than cause or new coverage. The Department also referenced *ancillary service plan* and *referral* as suggested by the IRRC in the definition section. In addition, the Department has added the needed definition for *Integrated Delivery Systems (IDS)* and modified the definition of *prospective enrollee* by adding "but not yet enrolled".

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

MCAP suggested that the term "but not limited to" be included in this section.

The Department has been advised by the Legislative Reference Bureau that use of the term "including but not limited to" could be construed as more inclusive than mere use of "including." The Department was further advised that in performing its function, the Legislative Reference Bureau routinely edits, where appropriate, the term by substituting the term "including" for "including but not limited to"; therefore, this change was not implemented.

Section 154.11. Managed care plan requirements.

AARP, DPW, EPVA, MCAP, PHLP, PPS and the IRRC commented on managed care plan requirements section.

The Department modified subsection (a) by adding "approval for" before "either" to clarify that these are the results if the plan's established standards are met.
AARP suggested that the continuity of care provision also require the non-network physician, to meet the plans quality standards, to accept the same payment required of network physicians, and to communicate relevant patient care information to the PCP, as appropriate, to keep them informed.

The Department believes that the quality standards, for network or non-network physicians, to be a Department of Health issue; therefore, no change was made.

DPW suggested clarification so that the time limit is more than an across the board limitation. DPW recommended the following language be inserted in 154.11: "Time limits on the approved treatment plans of such standing referrals or designations of specialists shall be based on best medical practice and the individual enrollee's situation."

The Department believes the quality standards to be a Department of Health issue; therefore, no change was made.

EPVA recommended that the Department disclose those procedures and any limitations as they pertain to access to specialty care.

The Department cannot expand its statutory authority. The authority to implement this recommendation is within the Department of Health's purview and not that of the Insurance Department.

MCAP suggested "If the specialist agrees to act as the enrollee's primary care provider, the specialist shall agree to the plan's terms and conditions."

The Department did not expand this area as it is taken directly from the statute.

PPS recommends the regulation should be amended to include a reasonableness standard consistent with the standard of practice of the medical community. PHLP recommends revising the language as follows: "Reasonable time restrictions on approved treatment plans, which include standing referrals or specialist designations, based on a determination of the estimated time when a standing referral may no longer be needed. The enrollee, PCP and as appropriate, the specialist, shall approve the treatment plan."

The Department believes the quality standards to be a Department of Health issue; therefore, no change was made.

MCAP suggested that the phrase "within a reasonable time" be added at the end of the sentence that requires the specialist to notify the primary care provider of all care provided. PHLP recommended revising the language as follows: "Requirements that the specialist notify the enrollee's primary care provider of all care provided at reasonable intervals." And the IRRC recommended establishing a maximum time period within which the specialist must notify the primary care provider.

The Department agrees with IRRC and revised paragraph (b)(3) to require this notification "within 30 days".

PHLP had several comments concerning this section. PHLP recommended adding language to be found at subsection (c) as follows: "Managed care plans shall approve a request for a standing referral for a specialist or for a specialist to coordinate care if the enrollee has life-threatening, degenerative or disabling condition and this condition needs ongoing involvement by a specialist to best manage that condition." PHLP recommended adding language to be found at subsection (d) as follows: "Managed care plans shall approve or disapprove a request pursuant to this

section within 5 business days, or sooner, as required if the enrollee's health could be jeopardized by a delay in receiving the requested specialist referral. Any disapproval by the managed care plan shall be made in writing and shall include the information considered, the reason and basis for the decision and how the enrollee may appeal the decision." PHLP also recommended adding language to be found at subsection (e) as follows: "Managed care plans shall submit for approval to the Department of Health within 30 days of the effective date of this regulation, the procedures, notices, treatment plan formats, criteria, etc. that it will use to implement this regulation."

Most of the suggestions from PHLP are areas (procedural) that will be better addressed by the Department of Health in their regulation rather than this rulemaking.

The IRRC suggested that the phrase "approved treatment plans" is unclear. IRRC recommends referencing section 2111(6) of the act in paragraph (b)(2).

The Department agrees with the IRRC on referencing the act and has made the necessary changes in paragraph (b)(1) to include the statutory citation.

Section 154.12. Direct enrollee access to obstetrical and gynecological services.

ACOP/ACNM, BCNE, CBC, IBC, KHPC, MCAP, PAFP, PHLP, PMS and the IRRC commented on this section.

ACOP/ACNM recommended that the Department consider language that states subspecialty services such as reproductive endocrinology, gynecologic-oncology and maternal and fetal medicine are the only restrictions for enrollee direct access to OB/GYN care. PMS supported this position.

The Department modified subsection (b) to clarify that the provider of services, not the enrollee, must obtain prior authorization for selected obstetrical and gynecological services.

CBC had concerns that the regulation prohibits a managed care plan from requiring prior authorization for maternity and other services listed in subsection (a). Maintains this goes beyond the scope of the act and interprets the act as only requiring the elimination of the gatekeeper for OB/GYN services. Argues that their on-time global authorization improves overall member health by identifying high-risk pregnancies and enrolling those individuals in a maternity care program. Suggests amending the act to include routine pregnancy. Also suggests if the phrase "prior authorization" is too strong to use state "A managed care plan may require an obstetrical or gynecological provider to notify the plan of a covered member's seeking pregnancy care, so that the plan can inform the pregnant member of additional maternal and child services available from the plan."

The Department believes that notification to the Primary Care Physician (PCP) is essential for enrollees to receive proper care. This will allow the PCP to track the treatment provided. In addition, the Department has addressed this issue with language that has been added to subsection (c). Subsection (c) now reads "For routine obstetrical services,

an initial notification and final notification, subsequent to the postpartum visit shall meet the notification requirements."

KHPC wanted the Department to delete the word "and" after "referrals " so that the wording is identical to that in section 2117(7) in the act. The current wording of the regulation is broader than the act in that it could permit the OB/GYN provider to refer the enrollee on to a subspecialist without going through the PCP.

The Department agrees with the suggested language for subsection (a). The Department has deleted the "and" that appears after the "referral."

MCAP suggested adding language that would allow the health plan to determine services the OB/GYN provider must obtain prior authorization. Recommends inserting the phrase, "to be determined by the health plan."

The Department believes the requested language is too broad and has not made the requested change.

PAFP suggested that the regulation states that a MCP cannot penalize a family physician based upon an enrollee's direct access to OB/GYN services. PAFP recommended amending the regulations to allow enrollees to obtain direct access to OB/GYN services; to provide reimbursement coverage for such services; to allow self-referral to a family physician other than the PCP for such services without prior approval from the enrollee's PCP; and to credential family physicians for the provision of OB/GYN services where they have obtained the requisite training and experience. PAFP also recommended requiring plans include family physicians with training and experience in OB/GYN on the list of OB/GYN providers. PHLP stated that the proposed regulations place limitations on Direct Enrollee Access to Obstetrical and Gynecological Services that are not permitted by the act.

The Department believes that it is clearly stated in the statute that enrollees are to be provided with direct access to OB/GYN services and therefore no changes have been made to the regulation.

PHLP suggested that limitations placed on services must be disclosed to enrollees. The proposed regulations do not ensure or require this limitation to be disclosed in writing and this notification should be incorporated into the regulations at subsection (h). Any materials describing this direct access must inform enrollees of this limitation.

The Department believes that this issue is clearly addressed in § 154.16 and therefore should not be duplicated in this section.

PHLP recommended adding the following language: "Any written materials describing this direct access in accordance with subsection (h) must also inform enrollees that direct access may only be to participating providers. Such information shall be made available in writing in English and in languages other than English and reasonable accommodations shall be made to provide this information to enrollees with disabilities."

The Department does not believe that it has statutory authority to implement this change.

PHLP recommended deleting "selected services such as diagnostic testing or subspecialty care for example, reproductive endocrinology, oncology gynecology and maternal and fetal medicine." Recommends adding the following language: "for services that are outside the scope of practice for that provider. Where disputes arise over whether services are outside the scope of practice for an obstetrical or gynecological provider, such disputes are to be resolved through the grievance process as governed by the Department of Health regulations."

The Department believes that the provision described above is sufficiently addressed in the regulation. Therefore, no change has been made.

ACOP/ACNM strongly encouraged the Department to define obstetrical care as the duration of the pregnancy since pregnancy related visits are frequent and ongoing for close to one year. Reporting each obstetrical visit within 30 days would be cumbersome and burdensome for the obstetrical and primary care providers. Also would be consistent with current billing practices that are done subsequent to the postpartum visit, not on a visit-by-visit basis.

BCNE found the regulation excessive in allowing 30 days for the specialist health care provider to communicate the health services provided to the primary care provider. They recommended the notification be provided within 14 days of the services being provided rather than the 30 days established in the proposed regulations (§ 154.12(c)).

MCAP recommended revising the last sentence as follows: "The health care provider shall communicate the information to the primary care provider within 30 days of the service being provided." PHLP recommended adding the following language: "Where an enrollee has been receiving ongoing treatment or services, a provider shall communicate with the plan at least every 60 days to provide information of all health care services provided to the enrollee within the prior 60 days. A provider may not charge an enrollee for services for which the plan denies payment because of the provider's failure to timely notify the plan of such services." PMS recommended requiring that the obstetrician/gynecologist provide a report to the primary care provider, which covers the duration of the enrollees' pregnancy following the postpartum visit. Other conditions not related to the pregnancy could be reported within 30 days.

The Department agreed with ACOP/ACNM and has changed the regulation to reflect this position.

IRRC questioned whether subsection (d) meant that self-referrals would be paid at the same rate as referred services. IBC requested clarification of the Department's intent of this subsection. It appears as if the intent is for the purposes of direct access to obstetrical and gynecological services only, self-referred services, is that it be paid at the higher referred rate. PHLP recommended adding the following language: " If an enrollee utilizes a non-participating provider for these services, the services may be covered at the lower self-referred benefit level."

The intent of subsection (d) is to require that plans pay for self referred services at the same rate as referred services. The Department has revised the language in this subsection in order to clarify the intent of the section as it applies to self-referral options.

The IRRC recommended that the Department clarify whether a time limit exists on the services provided for in subsection (a). The IRRC also stated that for clarity, the Department should state that these services are provided for enrollees, regardless of whether they are pregnant. IRRC also wanted to know if enrollees have direct access as long as services are needed and if so, the Department should clarify that there are no time restrictions that apply to direct access to these services.

The Department agrees with the IRRC on subsection (a) and has made the change by adding the following to subsection (a): "No time restrictions shall apply to the direct accessing of these by enrollees." The act and regulations specifically apply to direct access for both obstetrical and gynecological services. No further clarification is necessary that this section applies to more than pregnancy.

Section 154.13. Managed care plan reporting of complaints and grievances.

AARP, ACEP, CBC, PHLP, PPA and the IRRC commented on the managed care plan reporting of complaints and grievances section.

AARP Strongly supports accurate and standardized reporting of complaint and grievance information. Also would like consumers to have access to standardized comparative grievance information.

ACEP wanted the regulations to address the frequency as to which plans are required to report complaints and grievances. Suggests that managed care plan issue timely reports to the Department of Health and Insurance Department at least quarterly. These reports should contain a status report on all complaints and grievances, whether or not they have a disposition.

CBC believed it would be in everyone's best interests to have uniform reporting of complaint and grievance data under the act.

IFP recommended amending this provision to state "report this information to the Departments," not just the Department. This would clarify the information need only be reported in one format.

PPA suggested that the Departments of Health and Insurance work together to ensure the formats required by each agency match as to avoid undue administrative burden on managed care plans.

PHLP stated that the utilization of the old reporting format does not comply with the act's requirements and recommended deleting "based on the format utilized to report information prior to the effective date of the act" and adding "per the format designated by the Department detailing for each complaint, the reason the enrollee is contesting the managed care plan's action, the disposition of the complaint at each level and the product line in which the enrollee is

enrolled. The Department should also report the number of expedited complaints and the disposition of each complaint."

The IRRC suggested that the Department coordinate reporting requirements with the Department of Health.

The Department agrees and will work to ensure that there is coordination between the Insurance and Health Departments. The agencies will use one format to obtain all necessary information and will insure that the report will meet both Department of Health's and the Insurance Department's needs.

The IRRC suggested that when this final regulation is submitted, the Department should explain the nature of the reports, the expected cost of preparation, the reasonableness of and need for the format requirements in § 154.13. The IRRC also wanted clarification on whether "type" of services included services such as obstetrical and gynecological services, emergency services and continuity of care was included in subsection (a) in the "number, type and disposition" of complaints and grievances. The IRRC felt that the language in subsection (a) was too vague. The IRRC suggested that the Department provide guidance in the regulation regarding what information it will require. The IRRC also suggested that the last sentence of subsection (a) (which is a format requirement) should be moved to subsection (b) along with the possible amendments or changes to format requirements.

The Department agrees with the moving of the sentence and has clarified the language and moved the sentence to subsection (b). The Department has also changed old subsection (b) to (c) in order for this section to have better continuity. The term "type" in subsection (a) refers to whether the complaint or grievance being reported was at the first or second level or if it was appealed to either Department. The Department intends to use the current Department of Health reporting format to gather the information required by the act and this section.

Section 154.14. Emergency services.

AARP, ACEP, BCNE, CBC, DPW, DVHC, HAP, MCAP, PHLP, PPA and the IRRC commented on the emergency services section.

AARP suggested replacing the phrase "during the period of the emergency," with language used by the NAIC which states "screening and stabilization" of an emergency episode in subsection (b).

PPA also recommended clarifying this section to refer to the evaluation and if necessary the stabilization of the condition of the enrollee."

The Department agrees with the concept and has revised subsection (b) to read "...including but not limited to evaluation, test, and if necessary, the stabilization of..."

ACEP suggested including, "the definition establishes the concept of a prudent layperson, who possesses an average knowledge of health and medicine when determining whether a medical emergency exists" in subsection (a). ACEP suggested inserting "or medical record," after "as document by the claim." and suggested that the regulations follow a 1998 HCFA directive which states, "Coverage of emergency service by a MCO will be determined under the prudent layperson standard. MCOs may not retroactively deny a claim for an emergency screening examination because the condition, which appeared to be an emergency medical condition under the prudent layperson standard turned out to be non-emergency in nature...In these cases, the MCO must review the presenting symptoms of a beneficiary and must pay for all services involved in the screening examination where the presenting symptoms were of sufficient severity to have warranted emergency attention under the prudent layperson standard" in subsection (c). ACEP also suggested requiring insurance companies work together to establish a standardized claim form in subsection (c).

MCAP suggested revising the language in subsection (c) to state: "Plans are required to consider the presenting symptoms as documented along with the claim, and the services provided, when processing claims for emergency services." Typically emergency room claims do not include information about presenting symptoms. Presenting symptom information is usually included as an attachment to the claim.

The Department incorporated the concept of a prudent layperson in subsection (b). The Department does not have statutory authority to require insurance companies to work together in developing a standardized claim form. The Department also realizes that emergency room claims do not always have the information about presenting symptom, has changed the language in old subsection (c), now renumbered subsection (d) to reflect that "claim file" be more appropriate. Therefore, the Department modified subsection (c) to include a "claim file" as a "medical record."

BCNE suggested that the *Plan* needs to be notified within 48 hours of the provision of emergency services whether the patient was admitted or not. Recommends deleting paragraph (2) and inserting the following language to paragraph (1): "...regardless if the enrollee has been admitted to the hospital."

The Department believes that the paragraphs are appropriate and has not modified or deleted the renumbered paragraph (e)(2).

CBC wanted plans to be allowed to request that enrollees contact their PCP after the receipt of emergency services to enhance coordination of care.

The Department does not have statutory authority in this matter. Therefore this suggestion was not done.

DPW and the IRRC noted that the citation in subsection (a) was incorrect.

The Department has corrected the citation in the final form rulemaking.

DVHC recommend that managed care plans be prohibited not only from requiring a prior authorization, but also from requiring a referral from a gatekeeper or any managed care plan in subsection (a). DVHC recommended adding an amendment to clarify the provisions regarding the scope of emergency services. DVHC suggested the following language: "Plans are required to pay all reasonably necessary costs associated with the provision of emergency services to a patient meeting the prudent layperson definition for emergency services, including, without limitation, the following: (i) emergency transportation and related services; (ii) all services reasonably necessary to screen the patient (including, without limitation, triage, examination, medical tests or any screening of diagnostic service) whether or not the patient is ultimately determined to be in need of emergency treatment; and (iii) all services reasonably necessary to diagnose, stabilize and treat the patient. Plans are prohibited from requiring an enrollee to utilize any particular emergency transportation services organization for emergency care or a participating emergency transportation services organization for emergency care." Several commentators had similar suggestions to (iii) from the previous sentence. DVHC also recommended modifying the provision by excluding cases in which to condition of the patient or information provided by the patient precludes the hospital from accurately determining the identity of the enrollee's insurer. DVHC recommended adding the following language: "...except in cases where the condition of, or information provided by the patient preclude the hospital or health care provider from accurately determining the identity of the enrollee's insurer or managed care plan."

HAP offered a similar suggestion. HAP recommended adding the following language: "An exception to this requirement will be made where the medical condition of the patient precludes the provider form accurately determining the identity of the enrollee's insurer or managed care plan within 48 hours of admission. The IRRC raised a similar concern in their comments

The Department agrees with the language in (iii) and has added this to subsection (b). Old paragraph (d)(1) now paragraph (e)(1) has the language suggested by HAP and requested by the IRRC added in order to clarify this section.

HAP recommended that the following language be added to clarify the definition of reasonably necessary costs: "Plans are required to pay all reasonably necessary costs for patients meeting the prudent layperson definition for emergency services, to include: emergency transportation, services reasonably necessary to screen the patient, services reasonably necessary to diagnose, stabilize and treat the patient."

IFP recommended that the reference to "all reasonably necessary costs associated with the emergency services provided during the period of the emergency" be clarified to refer to the evaluation and, if necessary, the stabilization of the condition of the enrollee.

PHLP recommended adding "Plans are required to pay cost for all services reasonably necessary at the time of the presenting symptoms which were..." and deleting "reasonably necessary costs."

The Department believes that the evaluation, testing and, if necessary, the stabilization of the patient is of paramount importance and that costs associated with these services during the period of the emergency are necessary and therefore should be paid.

HAP recommended requiring insurers and managed care plans to incorporate the "prudent layperson definition" in all plan policies, consumer literature, marketing materials and provider contracts.

The Department believes that this is addressed in paragraph (b)(2) and therefore no change was made to section as it pertains to "prudent lay person."

DPW stated that the time frames in old paragraph (d)(1), now paragraph (e)(1) was ambiguous. DPW recommends notification within 48 hours and deleting the next business day whichever is later.

The Department believes that there are certain holidays during the year that would prevent the 48-hour requirement from being fulfilled and therefore has not made any change here.

PHLP recommended adding the following provision:" A provider may not charge an enrollee for emergency services for which the plan denies payment because of the provider's failure to timely notify the plan of such services" to subsection (d).

The Department does not have statutory authority to make such a change; therefore no change was made.

ACEP suggested current language implies that only current enrollees will be automatically supplied with information concerning the provision of emergency services. ACEP suggested including original (pre-purposed) draft language.

The Department believes that the regulation meets the statutory intent and therefore no change was made.

DVHC recommended amending subsection (e), now subsection (f) to require the prudent layperson definition of emergency services and specific claims payment policies be incorporated in all subscriber, master group, contracts and all other documents including marketing materials. DVHC suggested the following language: "Plans shall incorporate the prudent layperson definition of emergency services set forth in the act and this chapter, and specific plan policies concerning the provision of and payment for emergency services in the claims processing and payment, enrollee complaint, and enrollee and provider grievance systems in all of their subscriber, master group contracts and provider contracts, and in all other appropriate documents including marketing materials."

PHLP recommended modifying subsection (e), now subsection (f) as follows: "Managed care plans shall supply each enrollee, and upon written request, each prospective enrollee or health care provider, with the written information concerning emergency services along with the

information provided to enrollees under § 154.16 in subsection (h) (relating to information for enrollees). Such information shall be made available in writing in English and in languages other than English and reasonable accommodations shall be made to provide this information to enrollees with disabilities."

The Department believes that the language found at subsection (f) sufficiently addresses the situation, therefore no change was made.

ACEP suggested adding a subsection (f), which addresses the provision of emergency services in an out-of network situation. Wants plan enrollees to have the protection of coverage regardless of where they seek coverage, whether it is in or out of the network. ACEP also suggested adding a new section to clarify the last sentence of subsection (c) Medical Services, section 2116 of the act. Suggests including a definition of stabilization that is consistent with The Emergency Medical Treatment and Active Labor Act. ACEP also wanted the regulation to state that the physician must decide when the patient is stabilized and the decision is binding on the health plan as provided in the HCFA regulations on Medicare+Choice programs.

The Department disagrees. Plan enrollees should be aware of out-of-network situations. The HCFA regulations on Medicare+Choice do not pertain to this regulation or to state authority in this area, therefore, no changes were made.

The IRRC suggested that the Department clarify when the period of emergency ends and recommends clarifying the criteria that will be used to determine "reasonably necessary costs."

The Department believes that the period of emergency ends when the patient is stabilized and has changed subsection (b) to reflect that change. The Department believes that costs associated with the stabilization of the patient are permitted. Because there are many ways to treat patients and each situation could present a different scenario, the Department did not add the criteria that will be used to determine "reasonably necessary costs."

Section 154.15. Continuity of care.

AARP, ACOP/ACNM, BCNE, CBC, DPW, HAP, IBC, MCAP, PAFP, PHLP, PMS, PPA, PPS and the IRRC commented on the continuity of care section.

DPW stated that section 2111(6)(ii) requires the designation of a specialist to be based on a treatment plan that is approved by the MCO in consultation with the PCP, the enrollee and the specialist. DPW recommended that this requirement be added to the regulation.

PAFP wanted the Department to change the regulation so that it should make clear physicians have rights as well as obligations under the continuity of care options. For example, a physician should have standing to initiate a utilization review challenge.

The Department believes these issues to be the Department of Health's regulatory authority; therefore, it was not addressed in this regulation.

DPW recommended including reference to sections 2117(b), (c) and (f) in the various subsections of the regulation. The IRRC recommended referencing section 2117(b) of the act in subsection (a) and subsection (b).

The Department agrees to the section 2117(b) reference and has made the change accordingly. In addition, the Department has clarified paragraph (a)(2) so that the coverage is the responsibility of the plan unless these services are contractually covered by the terminated coverage.

PHLP stated that the regulations failed to ensure that plans act promptly to permit service to enrollees by non-participating providers and that the providers giving continuity of care services must agree to the same managed care plan terms that apply to participating provider.

The Department believes that this is addressed by the act; therefore, no change was made.

PHLP also stated that the regulation fail to provide sufficient guidance to assure the continuity of care protections are known and clearly understood and on terminations "for cause". Because the Department's intention in making these rules is to provide clarity and understanding, the term must be defined so that consumers and providers understand and are given clear guidance on what is and is not "cause". Otherwise plans can use varying standards and the protections of the act will be thwarted. PHLP also stated that the regulation failed to require any notice to enrollees of a need to change providers. This is a critical consumer protection provision contained in the act and it must be included in the Department's rules. PHLP stated that the regulation fail to require plans to assist consumers in a course of treatment in arranging alternative care.

The Department disagrees. The act defines reasons that can be considered cause in section 2117(b) and no further definition is necessary in the regulations. Regarding notice of need to change providers, the Department believes this is addressed by the act and therefore no change was made.

MCAP suggested revising the provision found in paragraph (a)(1) to read as follows: " A managed care plan terminates a contract with a participating provider for reasons other than for cause and the enrollee is currently in an ongoing course of treatment with that provider." While PHLP recommended the following revision: "A managed care plan terminates a contract with a participating provider for reasons other than for cause, as defined in § 154.2, and the enrollee is then in an ongoing course of treatment with that provider."

The Department does not believe that either of these changes will enhance the regulation. Therefore, no changes were made.

PHLP recommended adding the following provisions to paragraph (a)(2) and paragraph (a)(3): To paragraph (a)(2) " If the plan is terminating the contract of any primary care provider, it must notify every enrollee served by that provider of the plan's termination of its contract and shall request the enrollee to choose another primary care provider. " To paragraph (a)(3) " A new enrollee enters a managed care plan and is then in an ongoing course of treatment with a non-participating provider."

The Department believes this is addressed by the act and therefore no change was made.

AARP wanted the definition of *ongoing course of treatment* repeated here and the IRRC wanted the Department to clarify the term.

The Department has altered the definition in § 154.2 in order to provide a better understanding of the term *ongoing course of treatment.*

BCNE recommended revising language found in subsection (b) and subsection (c) as follows: "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 to 6 weeks postpartum care related to the delivery. 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."

The Department believes that it does not have the statutory authority to set a time limit in this area.

IBC wanted to add "by mail or telephone" at the end of § 154.15.

The Department does not believe this is necessary; therefore, no changes were made.

MCAP recommended adding the phrase "terminated by the managed care plan" in order to clarify that the continuity of care option is only available to providers who have been terminated by the managed care plan and not to those who self-terminate.

The Department agrees and has changed the language found at subsection (b) to reflect the clarification.

PHLP recommended revising subsection (b) by using the following language: "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, as defined in § 154.2, for a transitional period of up to sixty days from the date, etc."

The Department does not believe this is necessary; therefore, no changes were made.

PMS requested clarification of subsection (e) to permit the enrollee to receive care appropriate to the needs of the patient even if that care must be provided by a non-network provider or at a non-participating facility.

MCAP recommended revising the language in paragraph (e)(1) as follows: "Nonparticipating providers and providers terminated by the managed care plan shall 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, all of the providers involved shall

agree to the managed care plan's terms and conditions and agree to utilize participating providers for the provision of all other health care services to enrollees."

The IRRC recommended changing "shall" to "may" in subsection (e) and paragraph (e)(1) in order to provide the flexibility intended by the act and to remain consistent with the act. IRRC recommended that the regulation should be revised to reflect that a *Plan* may impose the requirement contained in paragraph (e)(2).

The Department agrees with the IRRC and has made the change.

MCAP expressed that the continuity of care option for enrollees is not available to nonparticipating providers who do not agree to the managed care plan's terms and conditions.

PMS recommended adding the following language after enrollees: "consistent with the health care needs of the enrollee, as determined by the provider."

The Department believes that the issue raised by MCAP is already addressed by subsection (f). The Department does not have the statutory authority to add the language requested by PMS.

PHLP recommended adding to subsection (f) the following language: "Managed care plans shall take immediate action to enable providers to abide by the plan's applicable terms and conditions including promptly processing any paperwork necessary for a non-participating provider to be recognized by the plan. Plans should take whatever actions are necessary within 5 business days of notice to the plan that the enrollee is requesting continuity of care benefits to enable the non-participating provider to serve the enrollee."

The Department believes that this is addressed in subsection (i) and therefore no change was made.

DPW wanted the Department to revise "terminating provider" to read "providers in the process of termination."

The Department exercised its editorial license and did not make the change that was requested.

MCAP suggested adding the phrase "terms that include, but are not limited to" in subsection (g).

The Department considered this comment; however, the suggested changes were not made due to the previously cited court case (*McClelland v. HMO of PA*).

PHLP recommended adding the following provision to paragraph (g)(1) and re-numbering the section accordingly: "Complying with the plan's third party liability (TPL) policies."

The Department does not believe the requested change is necessary.

HAP argued that this provision found at paragraph (g)(4) defeats the purpose of the continuity of care. HAP uses the example that a patient visiting their nonparticipating physician in another state may not be able to receive diagnostic tests on the same day at the same geographic location of the visit. Recommends adding the following language: "to the extent possible and consistent with the delivery of appropriate care to the patient."

The Department agrees and has deleted the subsection section because it was contradictory to paragraph (e)(2).

ACOP/ACNM suggested removing paragraph (g)(5) because there are several scenarios where the patient's provider will not have admitting privileges at the managed care plan's participating hospital and the patient's continuity of care will be interrupted as soon as hospitalization is required.

HAP argued that this provision defeats the purpose of the continuity of care.

PMS recommended deleting this provision (g)(5) from the regulations because there may be situations where the physician providing care doesn't have privileges at a network facility approved by the enrollee's new plan.

PPA stated that this section is in direct violation of section 2113 of the act, which states that managed care plans may not prohibit a health care provider from discussing" medically necessary and appropriate care with or on behalf of an enrollee" and which prohibits managed care plans from terminating health care providers for advocating for medically necessary and appropriate health care...".

The Department agrees with the commentators on the continuity of care interpretation and is deleting paragraph (g)(5). The Department disagrees that this subsection is in violation of the anti-gag rule that was referred to by PPA; however, upon review the Department determined that paragraph (g)(5) was contrary to the provisions found at 154.15(e)(2).

PPS recommended amending paragraph (g)(6) to include the patient's consent and adherence to all applicable laws, regulations and professional ethical standards as required by the act. Also recommend the requirement be restricted to the PCP or the specialist who will be providing services to the enrollee, not the plan itself.

The Department believes that the statute is clear in this area and has not made any changes to this section.

BCNE believed that the provision found at subsection (h) of the regulation would conflict with NCQA requirements that providers, who will be taking care of members for a period of time, undergo credentialing.

MCAP urged the Department to remove this provision since NCQA accreditation standards require managed care plans to include only credential providers in provider networks.

The Department believes that NCQA recognizes the need for plans to comply with individual state statutory requirements; therefore, no change was made.

CBC did not believe that 10 days is sufficient time to provide the notice as stated in subsection (i). CBC suggested making this 10 business days or 15 calendar days. CBC suggested adding a similar time frame for the provider to respond whether or not he/she elects not to continue care under the term and conditions under the managed care plan's applicable provider contract.

MCAP recommended changing this subsection to reflect 10 business days.

The Department believes that 10 calendar days is sufficient time to provide the information; however, it is the Department's understanding that both the Legislative Reference Bureau and West Publishing interpret days to mean calendar days and not business days. Business days are specified as such where appropriate. Therefore, this suggestion was not implemented. (See 1 Pa.C.S. 1908, relating to computation of time).

PHLP recommended including in subsection (i) the following language: "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 including the managed care plan's marketing materials and member handbooks."

The IRRC wanted clarification as to what "all other appropriate" documents constituted.

The Department has changed the term "all other appropriate documents" to "enrollee handbook". The Department believes that this handbook when given to the enrollee would need to have the written disclosure included. This handbook is the enrollees' guide source to benefits and the most appropriate vehicle in which the disclosure should be included.

Section 154.16. Information for enrollees

AARP, ACEP, BCNE, DPW, HIGHMARK, IBC, KHPC, MCAP, PAFP, PCHA, PHLP, PMS, PPA, and the IRRC all commented on the information for enrollees section.

PHLP finds § 154.16 to be "deficient" in several areas. First PHLP suggested the regulations include the 15 categories of "information that a managed care plan shall supply each enrollee" outlined in section 2136(a) of the act as well as language clarifying the 15 categories. Also the act states information "be easily understandable by the layperson." Therefore, § 154.16 should define a reading level for disclosed information. Finally, PHLP recommended requiring plans to provide alternative forms of information to individuals who are visually impaired and to "non-English speaking enrollees." The IRRC also raised concerns with "the completeness and clarity" of § 154.16. The IRRC recommended the regulation include greater detail regarding the content of the information disclosed as well as other requirements in section 2136 of the act.

The Department believes the section 2136(a) of the act is straightforward in its requirements and thus to include these suggested requirements in the regulation would go beyond the scope of the act. Most insurers do have some type of literature for those

individuals who are visually impaired and to those who are non-English speaking; therefore, this request was not added to the regulation.

The Department received several comments pertaining to subsection (a) and subsection (b) of the act. DPW and PHLP requested subsection (a) specify the information that is to be released upon written request.

AARP, PHLP and the IRRC also suggested subsection (a) include a requirement on the format to disclose enrollee information.

AARP, PPA, PHLP and the IRRC also suggested subsection (b) explicitly state the Department will monitor these disclosure documents to ensure the information meet the standards set forth in the act.

The IRRC recommended subsection (a) include "basic standards for the format and content of the disclosure documents." The IRRC also recommended revising "should" to "shall" since "should" indicates the provision is optional and thus unenforceable.

The Department does not possess the statutory authority to require plans to disclose information in a specific format. However, under the Department's statutory authority in Act 159 of 1996 (40 P.S. section 3801 - 3813), documents distributed to enrollees are subject to the filing requirements of Act 159. Paragraph (a)(2) has been added to clarify the Department's authority in this area. The Department agrees with IRRC's recommendation that "should" be changed to "shall" and has revised the language in paragraph (a)(1) accordingly.

ACEP recommended the regulations require plans to automatically provide current and prospective enrollees with information regarding the provision of emergency services.

The disclosure requirements for this information is set out in the act and also referenced in paragraph (h)(2) and section 154.14(f). No change was made.

The IRRC recommended the Department delete portions of paragraphs (c)(1) and (2) that duplicate subsection (a).

The Department deleted duplicative sections, replacing them with a direct reference to subsection (a).

BCNE and Highmark suggested revising paragraph (c)(2) to allow companies to distribute regional directories to consumers rather than one voluminous document. IBC suggested paragraph (c)(2) be revised to allow plans to limit the list of health care providers to those whom the patient has direct access. The IRRC reiterates these concerns. Therefore the IRRC suggested the regulations set forth a directive of "what and who must be on the lists of participating providers."

After careful consideration and review, the Department agrees it is reasonable to allow plans to provide enrollees with lists limited to providers the enrollee will have direct access to and has modified the language accordingly. The Department also recognizes the cost associated with producing statewide directories of health care providers and thus has changed the language to allow plans to distribute regional or county directories.

PHLP recommended revising paragraph (c)(2) to require plans to designate providers who do not perform certain service on moral or religious grounds in their directory.

The Department does not believe this change is necessary, therefore no change was made.

DPW and the IRRC suggested the second sentence of paragraph (c)(3) does not belong in the section and recommended moving it to a new and separate section.

The Department agrees with this comment and has created paragraph (c)(4) and moved this language to it to address this issue.

MCAP and the IRRC requested the Department provide clarification of the definition of "marketing materials" referred to in subsection (d). The IRRC recommended using the definition used in 31 Pa. Code, Chapter 51, § 51.1 to define "marketing materials."

The Department agrees the term "marketing materials" warrants greater clarification and has included a direct reference to the definition of advertising materials in 31 PA Code 51.1, relating to advertising.

PAFP and PHLP suggested modifying subsection (e) to explicitly state the plan is responsible to disclose any information required section 2136(b) that the group holder might not have.

The Department believes the existing language in subsection (e) already implies the plan is responsible for information is provided and has not changed the language.

DPW suggested a complete list of required information be provided along with summary information in paragraph (g)(1). DPW suggested paragraph (g)(1) be identified as an exception. DPW and PHLP suggested including instructions on how to obtain the information not included with the summary information.

The Department does not believe these changes are necessary, therefore no changes were made.

Highmark and KHPC suggested deleting "or networks" in paragraph (g)(2) since plans already contact their members when there is a change in their PCP or specialist status.

MCAP also suggested removing the requirement that provider network directories be provided at initial enrollment or renewal since provider networks frequently change.

KHPC encourages the Department be flexible with paragraph (g)(2).

PHLP recommended revising paragraph (g)(2) to provide all disclosure information regardless if a change occurs. PHLP and the IRRC also recommended changing "should" to "shall" since this is a requirement and not an optional provision.

The Department interprets the act to require plans to notify enrollees if substantial changes occur in the network. Therefore the Department has added language that states if networks have "substantially" changed. The Department does not believe it was the intent of the act to notify enrollees of each time a change occurs within the network. The Department also agrees with PHLP and IRRC's suggestion of changing "should" to "shall" and has changed the language accordingly.

IBC requested clarification on when the time frames in paragraphs (g)(2), (3) and (4) begin. IBC suggested clarifying the time frames specified these sections begin on the date the plans receive the request. IBC also suggested revising paragraph (g)(2) to allow plans an extension beyond the 30-day time frame "if appropriate." MCAP suggested extending the 30-day time frame 45 days in paragraphs (g)(2) and (3). PHLP requested paragraph (g)(3) be revised to require plans to provide disclosure information to enrollees in less than the 30 day time frame if the open enrollment period does not fall within that time frame.

The Department believes the 30-day time frame is a reasonable requirement for both plans and enrollees. The Department has revised the language to clarify the time frames in paragraph (g)(2), (3) and (4) begin on the day the date of the "receipt of the" written request.

The IRRC would like clarification of what documents are covered by the term "all other appropriate documents" in subsection (h).

In order to avoid confusion, the Department has deleted the phrase" all other appropriate documents.

PHLP and the IRRC recommended including a requirement in subsection (h) that information be provided in formats or communication systems that are accessible to people with disabilities. PACHA recommended adding a requirement to subsection (h) that would require plans to provide the denial rate for requests which result in "medially not necessary/not meeting medical criteria" and a list of the rate of occurrence of reductions in the level of care provided to inpatients.

The Department believes that these requests are beyond the scope of the act and thus the Department does not have the statutory to implement such requirements; therefore, these changes were not done.

PPA recommended revising subsection (h) to require plans to include a statement that the "prudent layperson" standard is used to determine what constitutes an emergency.

The Department believes this is unnecessary since the paragraph (h)(2) specifically states the plan shall provide the enrollee with "a definition of emergency services as set forth in the act." The definition of emergency services in section 2102 of the act specifically refers to the "prudent layperson" standard.

PMS recommended § 154.16 require the plan to disclose their definition of "medical necessity" which has been approved by the Department of Health to both the enrollee and the provider.

There is no statutory authority in the act for the Department of Health to review or approve the definition of "medical necessity." The act requires disclosure in section 2136(9)(i) of the *plan's* (emphasis added) definition of medical necessity, which is required, by section 2111(3). Therefore it is not necessary to repeat this requirement in the regulation

In paragraph (h)(2), IRRC would like the phrase "consistent with" replaced with "as set forth in."

The Department agrees with this suggestion and has revised the language accordingly.

Section 154.17. Complaints

AARP, CBC, DPW, EPVA, HIGHMARK, HAP, IBC, IFP, KHPC, LWV, MCAP, PAFP, PCHA, PCPA, PHLP, PMS, PPA, PPS and the IRRC commented on the complaints section.

CBC asked why the Department removed the example, "Refusal of the plan to provide, arrange for or pay for a procedure, drug or treatment on the basis that such procedure, drug or treatment is experimental, investigation or a cosmetic service excluded under the contract's provision."

The Department deleted this example from its pre-Proposed regulation draft because this type of grievance falls under the Department of Health's jurisdiction.

IFP commented that the Insurance and Health Departments will have to work together to ensure an effective system of resolving complaints and grievances.

The Department has worked closely with the Department of Health to ensure that enrollee complaints and grievances are handled smoothly and by the proper agency. The Department intends to continue this close working relationship in the future. No language change was necessary or made.

EPVA requested § 154.17 clearly state the Department will monitor the complaint process closely to ensure the intent of the act.

The monitoring of consumer complaints is part of the Department 's overall operation, so it is unnecessary to include such a provision in the regulation.

The EPVA also requested that issues relating to denials that are related to clinical matters be categorized as grievances thereby allowing self-referrals to continue to be deemed as complaints.

Complaints and grievances are defined by the act. The Department's will review these issues as appropriate under the requirements of the act. This is part of the Department's overall operation, so it is unnecessary to include such a provision in the regulation.
Section 2111(3) of the act allows plans to adopt their own definition of medical necessity. PAFP believes it is within the intent of the act for the Department to set "parameters" of an acceptable definition of "medical necessity" in § 154.17. Specifically PAFP recommended the Department set the following parameters:

"Any therapeutic treatment, care or services reasonably expected by a prudent physician to improve, restore or prevent the worsening of any illness, injury, disease, disability, defect, condition or function of any body member.

"Objective clinical determinations which will be or are reasonable expected by a prudent physician to prevent the onset of an illness, condition or disability; reduce or ameliorate the physical or mental effects of an illness, condition, injury or disability; or alleviate the patient's pain or mitigate the severity of the patient's symptoms.

All relevant clinical data pertaining to the patient's condition as a whole must be taken into consideration.

The prevailing practice and standards of the medical profession and community the medical profession and community must be taken into consideration."

PAFP also recommended the Department set medical necessity definition parameters in § 154.17.

PAFP also recommended § 154.17 include a provision, which imposes a 30-day time limit on a plan to make the initial denial decision.

PAFP also requested the regulations include a provision that prohibits managed care plans from requiring family physicians to use hospitalist for their patients' inpatient care in § 154.17.

The Department does not have the statutory authority to prevent plans from requiring enrollees use hospitalists during their inpatient care or to include medical necessity parameters in the definition. The plan determinations are based on requirements in sections 2151 and 2152 of the act.

IFP recommended the Department prevent the suggestion by PMS that patients allow provider to file grievances on behalf of enrollees.

The Department does not possess the authority to address this issue. This issue is one that is more appropriately addressed by the Department of Health.

The IRRC recommended adding a subsection that will explain the enrollee's right to designate a representative as is required by section 2136(a)(8)(iii) of the act.

The Department agrees with the IRRC's suggestion and has added language in paragraph (i)(6) which clarifies that the enrollee has the right to designate a representative.

Sections 2141 and 2142 of the act delineate the plans' internal complaint process and the Department's responsibilities for appealing a complaint. The regulations combine these responsibilities into one section. The IRRC suggested combining these into one section compromises the clarity of the regulation. Therefore the IRRC recommended the plan's responsibilities and the Department's responsibilities be delineated in two separate sections.

The Department believes that the current section as written is clear and no changes have been made.

PHLP commented that the complaint provisions of the proposed rule do not ensure the "fairness of or uniformity" of the complaint process intended by the act. Specifically, PHLP finds the regulations "(1) fail to provide a clear picture of the appeal process at each stage of a complaint; (2) allow wide plan variations in how fairly consumer complaints are considered; and (3) result in major loss of current consumer protections." PHLP finds the regulation is lacking in that it fails to include details of how the complaint process will operate, it fails to include procedural safeguards from the Department of Health's Operational Standards and it fails to provide an "expedited" complaint process. Also PHLP commented the regulation does not clarify "whether an enrollees appeal from a managed care plan's refusal to designate a specialist as a PCP or to authorize a standing referral should be classified as a complaint or grievance." Also the regulations do not provide a mechanism to determine if an appeal should be classified as a complaint or grievance when the plan and the consumer disagree on the classification. PHLP recommended the regulation include a penalty for plans that do not issue a decision within a specific time frame. Finally, PHLP believes requiring consumers to submit all documentation received from the plan when submitting a complaint to the Department places an "unreasonable burden" on the consumer. In order to address these deficiencies, PHLP suggested additions and revisions to § 154.17.

The Department believes that these suggestions go beyond the scope of the act and the Department's statutory authority; therefore, the Department will not be revising the regulation as suggested.

PHLP also recommend renumbering subsection (e) to subsection (h) and including a list of the information that should be included in the plan's notification to the enrollee. PHLP also recommended requiring plans to notify the enrollee within 35 days or providing the "enrollee with the relief sought in his/her complaint." PHLP recommended adding subsection (i), which would require plans to render a decision within 48 hours in "medically necessary and pressing" cases. PHLP also recommended adding subsection (j) and subsection (k), which explains how the enrollee can request a second level review and the second level review process. In subsection (l), PHLP recommended requiring plans to not only complete a review within 45 days, but to also "render a decision" within that timeframe. PHLP also recommended requiring plans to notify the provider as well as the enrollee. Finally, PHLP recommended listing all the elements that should be included in the notice to the enrollee in subsection (l). PHLP suggested

renumbering subsection (h) to subsection (n) and requiring plans to notify the enrollee in writing of what the enrollee must provide the Department when he/she files a complaint. PHLP also recommended paragraph (n)(1) require the Department to verify the appeal was received within 15 days from the enrollees' receipt of the notice from the second level review committee. In paragraph (n)(2), PHLP recommended the Departments of Health and Insurance establish a single complaint tracking system. PHLP also recommended the Department establish the proper agency for review of the appeal within 10 days in paragraph (n)(3). PHLP recommended paragraph (n)(4) require the plan to provide the Department with all documents relating to the appeal. Finally PHLP recommended adding paragraph (n)(5) which allows the Department to hold a hearing at its discretion.

AARP raised concerns that the language in subsection (a) fails to cover all the issues on which consumers or providers may want to file a complaint or a grievance.

HAP recommended subsection (a) include a note that complaints can include problems relating to unduly burdensome claim submission requirements and/or an unreasonable definition of a clean claim.

The IRRC recommended the Department explain subsection (a) to provide further clarification of the issues that fall within the scope of complaints and to clarify the Department's responsibilities.

The Department agrees with the IRRC suggestions and has changed the language to state complaints include issues dealing with contract exclusions, noncovered benefit disputes and potential violations of the Unfair Insurance Practices Act. The Department also added a sentence clarifying the type of complaints the Department of Health will address.

The IRRC suggested citing the specific sections of the act, it references in subsection (a).

The Department agrees and has modified the language accordingly.

MCAP recommended incorporating language from subsection (g) into subsection (a) so the language clearly states the Department would only consider complaints after enrollees complete the plan's internal complaint process.

The Department believes that most consumers will follow the process set forth by the insurer. However, the Department realizes that sometimes processes are not completely followed. In those instances, the Department will assist the consumer in "getting back on track" in the process and may communicate with the appropriate parties to assist in the resolution of the complaint.

Highmark recommended using a different example in paragraph (a)(2) to illustrate what constitutes a "contract exclusion."

The Department believes this is a good example of what constitutes a "contract exclusion." Therefore no change was made.

The IRRC questioned the necessity of the phrase "do not constitute appeals" and MCAP recommended removing this phrase in subsection (c).

The Department agrees with these suggestions and has modified the language accordingly.

The IRRC asked the Department to clarify if "inquires" was the appropriate term in subsection (c).

The Department added language to subsection (c) to clarify the term "inquires" refers to both complaints and questions.

The IRRC and KHPC recommended subsection (d) specify when the 30-day time frame begins. KHPC would like subsection (d) to clarify the 30-day time frame applies to both levels of review. The IRRC also asked if the intent of the regulation was to give the enrollee a minimum of 30 days to file a complaint or grievance.

The Department has revised the language to state that if a plan establishes timeframes for the filing of a complaint or grievance, the plan must allow the enrollee at least 45 days from the date of the enrollees receipt of the notice of the plan's decision.

Highmark, MCAP and IBC recommended modifying subsection (e) to allow enrollees to grant plans an extension beyond the 30-day period of review.

IBC recommended revising subsection (f) to allow the enrollee to grant an extension beyond the 45-day time frame.

The Department does not have the statutory authority to allow such an extension to either subsection (e) or subsection (f).

The IRRC recommended requiring the plan to provide written notification to the enrollee of the right to appear before the second level review committee as is required by section 2141(c)(2) of the act.

The Department agrees with the IRRC's suggestion and has modified the language accordingly.

The IRRC questioned why subsection (f) referenced the Department of Health.

The Department agrees with IRRC and has deleted the phrase "or Department of Health."

PAFP recommended reducing the five-day notification in subsection (f) to two or three days.

The five-day notification period is required by section 2141(c)(4) of the act and thus cannot be modified by this regulation.

Highmark recommended including an additional provision in subsection (g) that would require the enrollee to exhaust the plan's internal mechanisms before filing a legal action. MCAP suggested the process of enrollees filing a complaint with the plan prior to filing a complaint with the Department be followed in all instances. The IRRC questions the need for subsection (g) since in some instances it would be appropriate for the enrollee to contact the Department prior to completion of the plan's review process and stated that if it was retained, it should reference the provisions of section 2143 of the act.

The purpose of subsection (g) is to note in most instances that the enrollee should complete the internal review process before contacting the Department. However, the Department recognizes in some cases it would be appropriate for enrollees to contact the Department prior to completion of the review process. Therefore the Department has changed "shall" to "should" and has included language to emphasize completing the plan's internal appeal process will expedite the appeal process. It was also changed to include a reference to section 2143 of the act.

PHLP recommended renumbering subsection (e) to subsection (h) and requiring the notification include:

1. A statement of the committee's understanding of the nature of the appeal and of all pertinent facts;
2. The committee's decision in clear terms and the basis or rational for the committee's decision
3. Reference to any evidence or documentation that supports the committee's conclusions
4. A timeframe in which a request for a second level of review of the decision must be made.

Additionally, PHLP recommended requiring plans to provide the enrollee with the relief sought in his/her complaint if the plan fails to notify the enrollee of its decision within 35 days of the receipt of the complaint.

The regulations are based on the act, which is clear on these requirements. The Department believes no revisions are necessary.

The IRRC raised several concerns with subsection (i). First, the IRRC expressed concern that the phrase "information such as" implies the information listed in paragraph (1) to (5) is optional rather than mandatory. Also the IRRC requested subsection (i) describe the manner in which records from the initial review and second level review be transmitted to the Department. The IRRC also questioned why the Department was requesting enrollees to provide the information in paragraph (i)(5). Finally the IRRC recommended adding paragraph (6) which requires the enrollee to notify the Department if an attorney or other individual is representing him.

The Department agrees that the phrase "information such as" may imply the information listed in paragraph (1) to (5) is optional, so the Department has deleted the phrase "such as" and replaced it with the "following information". Regarding enrollees providing the information in paragraph (i)(5), this is a standard request by the Department when reviewing any consumer complaints. The Department also agrees the enrollee should notify the Department if another individual is representing the enrollee and added paragraph (6) to subsection (i) to address this request. The Department added subsection (j) to describe the manner in which plans shall transmit records from the initial review and

second level review to the Department when an enrollee appeals a plan's complaint review determination.

DPW suggested disseminating the information in subsection (j) and subsection (l) through other means than the regulation since once this is in the regulation it can only be changed by an amendment.

DPW also suggested the information in subsection (k) would be more appropriate in the Preamble. The IRRC recommended deleting subsection (k) or combining it with subsection (a) since it contains no substantive information.

The Department agrees with the IRRC's comments and has combined the information previous found in subsection (k) into subsection (a).

Highmark recommended adding a provision to § 154.17 that requires the Department to notify both the enrollee and the plan of the final disposition of the complaint.

The Department agrees and has added language to subsection (j) and subsection (l), that requires the Department to notify plans when a complaint has been filed, and the final determination of a complaint. In addition, the Department has modified subsection (k) to clarify the appeal transfer process from the Department to the Department of Health.

Section 154.18 Prompt Payment

ACEP, BLAIR, DVHC, DVH, HAP, IBC, IFP, KHPC, MCAP, PAFP, PCHA, PCPA, PMS, PPS and the IRRC commented on prompt payment section.

ACEP, HAP, PCPA and PMS recommended explicitly stating in § 154.18 that the Department will conduct periodic evaluation to determine that plans are complying with the prompt payment requirements set forth in the act.

PCM recommended the Department closely scrutinized reimbursement issues to assure that plans are following prompt payment provisions set forth in the act and to identify any problem areas.

Additionally, ACEP and PMS suggested § 154.18 state the Department will conduct surveys to assure compliance with timely payment provisions.

ACEP and PMS also recommended § 154.18 explicitly state the Department possesses the authority to pursue disciplinary actions against plans that violate prompt payment provisions. ACEP and PMS recommended the Department develop a uniform complaint form and tracking system. ACEP and PMS also wanted the regulations to define a timely manner in which the plans notify the provider of the reasons underlying a suspension of a claim. PMS also recommended the plan notify the provider of any suspension of claims or situations affecting the processing of claims and the proposed time for the completion of claims processing. ACEP and PMS recommended the insurer notify the Department of any interruption of claims processing. ACEP and PMS would like the Department to pursue disciplinary measures against insurers that

consistently violate the timely payment provisions of the act. ACEP and PMS would like the Department to conduct a survey to determine compliance with timely payment provisions.

The Department agrees disciplinary actions, evaluations and surveys are necessary to assure compliance with the act. However, the Department already performs these tasks as part of its enforcement duties. To include these duties in this section is unnecessary and would be duplicative of the Department's existing enforcement authority.

HAP would also like § 154.18 to include a provision, which specifies prompt payment provisions, apply to out-of-network providers as well as participating providers.

Prompt payment provisions apply to health care providers whether they are participating or nonparticipating providers.

HAP would like the 45-day time period in subsection (a) to include uncontested portions of clean claims as well as clean claims. The IRRC also recommended revising subsection (a) to include this requirement.

The Department agrees with IRRC's and HAP's suggestion and has modified the language accordingly.

DVHC, DVH, HAP, and PMS requested clarification of when the 45-day time period begins. The IRRC reiterates their concerns and asks the Department provide clarification. DVHC and DVH would like the 45-day time period in subsection (a) to begin on the date the claim is received by the insurer. DVHC and DVH recommended a claim should be considered received three days after it is mailed in subsection (a). PMS suggested it begin on the day the claim was submitted by the provider.

The 45-day time frame begins on the date the plan receives the claim from the health care provider. Subsection (a) has been modified by deleting "clean" to clarify this requirement. Licensed insurers and managed care plans have an obligation to pay claims promptly, and where clean claims are not paid within 45 days, pay interest within 30 days of payment of the claim.

IFP recommended that subsection (a) be clarified to state that the prompt payment provisions apply only to health insurance claims and not to other types of insurance such as automobile and workers compensation.

The Department agrees with this comment and has modified subsection (a) to address it.

PPS would like to amend subsection (a) to allow for 3 business days past the mailing date of the date of receipt.

The act requires prompt payment based on the date of the licensed insurer's or managed care plan's receipt of a clean claim. This proposal is contrary to the act. No change has been made.

HAP and PACHA suggested clarifying the term "clean claim" and HAP recommended subsection (a) require plans to provide health care providers with the criteria used to classify a claim as clean. PPA suggested § 154.18 require plans to notify both enrollees and providers if a claim is clean or not. Additionally, PPA recommended § 154.18 require plans to notify providers of changes in claim submissions so providers know how to submit a clean claim.
The IRRC and PMS recommended requiring plans to notify providers of deficiencies that delay processing of a claim as well as notifying providers when a claim is suspended in subsection (a). PPA would like to extend the prompt payment rule to those insurance plans that the act expressly excludes from its definition.

HAP recommended a provision to subsection (b), which would require insurers to notify providers and enrollees of a claim status within 45 days of submission. MCAP recommended using language in the October 3, 1998 Statement of Policy rather than the current language in subsection (b).

While HAP believes that the Department has the statutory authority to require licensed insurers or managed care plans to notify providers that a claim is not a clean claim or the reasons it is not a clean claim, the Department does not believe it has the statutory authority to implement these proposed requirements. However, the Department does have the authority to require licensed insurers or managed care plans to provide health care providers with the criteria used to classify a claim as clean. This change was requested by HAP and has been made in the new subsection (e). In addition, (g)(1) requires licensed insurers and managed care plans to respond to health care providers inquiries regarding unpaid claims within a set timeframe.

Licensed insurers and managed care plans are urged to work together with providers to address issues related to payment of claims, in order to assure the provisions of the act are achieved.

Blair recommended using the highest WSJ national prime rate to determine the interest due to a health care provider on a clean claim in subsection (c). Blair also recommended adding an additional two-percent onto the interest rate in subsection (c) to cover administrative costs of providers and requiring providers to pay interest payments of less than $2.00. DVCH, DVH and DPW would like subsection (c) to specify a 10% interest payment be paid on a clean claim which is not paid within 45 days.

The interest rate and $2.00 minimum interest requirements are set by section 2166(a) of the act; therefore, the Department does not possess the statutory authority to change the interest rate.

Highmark, KHPC, CBC, BCNE, IBC, MCAP opposed the requirement set forth in subsection (c) which requires plans to pay interest and claim payments simultaneously.

Section 2166(h) of the act requires interest to be added to the amount owed on any clean claim not paid within 45 days. The Department has determined that the interest may be

paid separately from the payment of the claim, however, any interest owed must be paid within 30 days of the payment of the claim.

Highmark, KHPC, MCAP and IBC disagreed with the splitting of claims into contested and uncontested portions in subsection (d). The IRRC reiterated the concerns raised by commentators and asked the Department to explain how classifying all claims that are paid as "clean claims" is consistent with the act.

Highmark, KHPC and IBC contend in their comments that if a claim is not submitted initially as a clean claim, it can never be considered a clean claim. This is contrary to letter and intent of the act. The Department believes that if a licensed insurer or managed care plan pays a claim, there must not have been any defect or impropriety in the claim and it is therefore a clean claim under the definition in the act.

Subsection (d) has been clarified to state that a contested claim is a claim for which required substantiating documentation "for the entire claim" 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. In addition, claims, which include uncontested portions, shall be paid on a timely basis. The contested portions of a paid claim can be filed with a licensed insurer or managed care plan for re-adjudication.

DVCH and DVH recommended revising subsection (d) to state the 45-day time period does not restart for claims that are re-adjudicated because of an insurer's error. IBC would like the Department to amend subsection (d) to clarify that the intention is that a new 45-day period for the prompt payment provision begins at the time the additional information is provided to the plan. KHPC would like to know if subsection (d) applies to claims that are re-adjudicated for reasons other than lack of information. KHPC believes subsection (d) presents serious implementation problems because the claims payment system does not contain enough detailed logic to measure re-adjudicated claims.

Subsection (d) has been modified to address IBC's comments by changing "the" 45 day period to "a new" 45 day period. In addition, claims, which include uncontested portions, shall be paid on a timely basis. The contested portions of a paid claim can be filed with a licensed insurer or managed care plan for re-adjudication. When re-adjudicated by a licensed insurer or managed care plan, that contested portion is provided with a new 45-day period.

MCAP would like the Department to reinsert language that states prompt payment provisions do not apply in instances whereby the insurer or managed care plan has not received premium payments during the period the health care service was provided. MCAP also believes it would be of no benefit to consumers and onerous for managed care plans to apply the Unfair Insurance Practices Act (UIPA)(40 P.S. 1171 et seq.) to claims submitted by out-of-network providers.

Licensed insurers and managed care plans are required to meet the "grace period" requirements of their enabling statutes and regulations in their enrollee or subscriber contracts. During the grace period coverage remains in effect even if no premium has been

paid. The Department has no statutory authority to exempt the prompt payment provisions if premiums have not been paid and a contract is still in effect. In addition, the provisions of section 2166 apply to all health care providers whether participating or non-participating while the UIPA applies to enrollees and subscribers.

Blair and PPS recommended the regulations mandate the insurer must respond to the provider's inquiry within 10 days in old subsection (e) (now subsection (f)). Blair would like all responses to be in writing. DVHC and DVH would like old subsection (e) to mandate a period of 7 days, which the insurer must respond to providers' request for information. PAFP would like subsection (e) deleted.

MCAP would like to amend old subsection (f) to prohibit providers from filing complaints prior to the end of the 45-day time limit. MCAP would like to delete paragraph (f)(1) and paragraph (f)(2) to ensure providers do not file complaints prior to the 45-day time limit set in the act.

IRRC raised several concerns with old subsection (e) (new subsection (f)). IRRC would like to know if the Department plans to dismiss a complaint submitted by a provider who did not make an inquiry with the plan? Also the IRRC would like to know how the Department is going to enforce this provision? IRRC also does not believe the regulation should include the term "should" since this implies the provision is optional and it is inappropriate to include optional language in a regulation. IRRC suggested it might be more appropriate to include this language in a policy statement. Also, although this section requires the plan to respond to an inquiry within a reasonable amount of time it does not specify "what is a reasonable amount of time." The IRRC recommended the Department specify what constitutes a reasonable amount of time. The IRRC also suggested including whether the plan must respond to the request in writing.

DVHC, DVH, HAP and PMS recommended revising subsection (f) to allow providers to submit "batch" complaints.

The Department believes the guidance in new subsection (f) is appropriate and has changed "should" first contact to "shall" first contact. The Department agrees with IRRC's suggestion of defining a time frame for licensed insurers or managed care plans to respond to inquiries. This response time is now set at 45 days of submission of the claim or within 30 days of the inquiry. Subsection (f) requires health care providers to contact licensed insurers and managed care plans regarding the status of an unpaid claim prior to contacting the Department subject to the provisions found in (g). The Department wants to allow licensed insurers and managed care plans flexibility in their response to providers' inquiries regarding the status of unpaid claims. This language will allow plans and licensed insurers to respond to inquiries either orally or in writing.

The Department strongly encourages licensed insurers and managed care plans to establish mechanisms for health care providers to inquire about the status of a claim. Providers seeking status of claims through inquiry to licensed insurers and managed care plans should receive replies within the timeframes required by the regulation. The Department has modified new (g)(1) to include the same timeframe established in (f) for licensed insurers and managed care plans to respond to a health care provider inquiries regarding

the status of unpaid claims. If that does not occur, (g)(1) also provides a mechanism whereby providers can inform the Department of a licensed insurer's or managed care plan's failure to respond.

The Department also agrees with allowing providers to file complaints individually or in batches and has modified (g) accordingly.

DVHC and DVH recommended removing the employer requirement in old paragraph (g)(3) (new paragraph (h)(3)) since the employer's name may not be available to the health care provider.

The Department agrees and has modified the subsection by clarifying that the employer information only has to be provided "if known".

MCAP would like paragraph (g)(4) to be amended to include the "member's identification number, provider identification number and the disputed amount."

The Department agrees regarding the provider identification number and has modified new paragraph (h)(1) accordingly. The Department has also added paragraph (h)(7) to allow the Department flexibility if it is determined that any additional information is necessary to review the complaint.

DVHC and DVH would like subsection (h) to be added to mandate the insure notify the policy hold and provider in writing if the plan determines it will not pay a portion of the claim. DVHC and DVH would like a subsection (i) to be added to required insurers to establish and maintain an adequate system for tracking claims. DVHC and DVH would like subsection (j) to be added to require insurers to publish guidelines on how the insurer conducts business. DVHC and DVH recommend addition subsection (k) to require prompt payment provision apply to out of area claim which are administered by licensed insurers and managed care plans.

The Department has no statutory authority over the requested changes in the commentators' proposed subsections (h), (i) and (j). The Department does not believe the proposed language in subsection (k) is necessary. No change has been made.

New section (i) has been added to clarify that the Department's authority under the statute is paramount, and that nothing in §154.18 shall be construed as preventing the Department from investigating a complaint where the health care provider has failed to contact the licensed insurer or managed care plan

General Comments

DPW, EPVA, KHPC, MCAP, PCPA, PHLP, and PPS submitted general comments.

DPW recommended reducing the number of references to the act throughout the document. In place of references, they suggested that the act's language be interpreted and clarified to make these regulations more user friendly.

The Department is following Legislative Reference Bureau requirements and the Governor's Executive Order 1996-1 to not repeat statutory language wholesale in a regulation. No changes have been made.

EPVA would like the Department to retain existing protections that are in Department of Health's 1991 Operational Guidelines.

These protections do not fall under the Department's authority. This is an issue to be addressed by the Department of Health.

KHPC fully agreed with the comments submitted by Highmark, Inc.

League recommended that the appeal processes in the act be simplified to assure that consumers can easily understand and make use of the mechanisms available to resolve disputes that might arise with their plans. The complicated processes defined by the act will be incomprehensible to most consumers and providers.

The regulations follow the appeal process set forth in the act. To change the appeal process would be outside the intent of the act and the department's statutory authority.

MCAP asked if managed care plans will be required to resubmit marketing and other materials for review upon final implementation of the regulations? If so, by what date would the managed care plans have to resubmit their documents for review? MCAP would also like the Fiscal Impact or Paperwork sections to include a statement that states, "Implementation of the act will impose significant additional costs on managed care plans in terms of material revisions, re-submissions, regulatory approvals, printing and distribution."

Managed care plans will be required to meet the filing requirements of Act 159 for all filings, including those under the authority of the act. **Implementation of the act may impose additional costs on managed care plan in terms of material revisions, resubmission of forms, printing and distribution. There are no costs associated with regulatory approval. It is the Department's position that the approval of this regulation will not have a significant monetary impact on the industry. Therefore, a change to the fiscal note concerning the implementation of the act is not appropriate coming from the Department, the fiscal note associated with the act, should be obtainable through the Legislative Reference Bureau.**

PCPA recommended the Department create and require standardized forms whenever possible.

The Department does not have the statutory authority to required plans to use standardized forms.

PHLP found it difficult to comment without knowing the Department of Health's proposed regulations.

The regulations drafted by the Department focus on the Department of Insurance's responsibilities and authority under the act.

PPS commented that although the act covers mental health care, it was drafted with the usual, non-mental health management protocols in mind. Believe an important function of the regulations is to make explicit the act's relationship and applicability to managed mental health services.

The provisions of the act and the regulations apply to all health care services not just specific subsets such as mental health services. No changes have been made.

Annex A

TITLE 31. INSURANCE

PART VIII. MISCELLANEOUS PROVISIONS

CHAPTER 154. QUALITY HEALTH CARE ACCOUNTABILITY AND PROTECTION

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 act. THE DEPARTMENT AND THE DEPARTMENT OF HEALTH BOTH HAVE REGULATORY AUTHORITY UNDER THE ACT. THIS CHAPTER DOES NOT APPLY TO

HEALTH CARE SERVICES AND CLAIMS PROCESSED UNDER AUTOMOBILE AND WORKER'S COMPENSATION POLICIES.

(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) An entity, INCLUDING AN INTEGRATED DELIVERY SYSTEM, subcontracting with a managed care plan to provide services to enrollees ~~which issues subscriber contracts covering enrollees~~ shall meet the requirements of the act and this chapter for services provided to those enrollees.

(d) ~~Cost plus products, or their equivalent,~~ POLICIES which partially insure an entity's risk, shall 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, 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).

ANCILLARY SERVICE PLAN—AS DEFINED IN SECTION 2102 OF THE ACT (40 P.S. § 991.2102).

Clean claim-- AS DEFINED IN SECTION 2102 OF THE ACT.

~~(i) 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.~~

~~(ii) The term does 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-- AS DEFINED IN SECTION 2102 OF THE ACT.

~~(i) 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 Department.~~

~~(ii) The term does not include a grievance.~~

Department--The Insurance Department of the Commonwealth.

Emergency service-- AS DEFINED IN SECTION 2102 OF THE ACT.

~~(i) 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, so 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 one of the following:~~

~~(A) 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.~~

~~(B) Serious impairment to bodily functions.~~

~~(C) Serious dysfunction of any bodily organ or part.~~

~~(ii) Emergency transportation and related emergency service provided by a licensed ambulance service constitutes an emergency service.~~

Enrollee--A policyholder, subscriber, covered person or other individual who is entitled to receive health care services under a managed care plan. FOR PURPOSES OF THE COMPLAINT AND GRIEVANCE PROCESSES, THE TERM SHALL INCLUDE PARENTS OF MINOR ENROLLEES AS WELL AS DESIGNEES OR LEGAL REPRESENTATIVES WHO ARE ENTITLED OR AUTHORIZED TO ACT ON

BEHALF OF AN ENROLLEE.

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 precondition to receiving the highest level of coverage available under the managed care plan.

Grievance-- AS DEFINED IN SECTION 2102 OF THE ACT.

~~(i) 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 does one of the following:~~

~~(A) Disapproves full or partial payment for a requested health care service.~~

~~(B) Approves the provision of a requested health care service for a lesser scope or duration than requested.~~

~~(C) Disapproves payment for the provision of a requested health care service but approves payment for the provision of an alternative health care service.~~

~~(ii) The term does not include a complaint.~~

Health care provider-- AS DEFINED IN SECTION 2102 OF THE ACT. ~~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 the 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-- AS DEFINED IN SECTION 2102 OF THE ACT. ~~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.~~

INTEGRATED DELIVERY SYSTEM (IDS)--

(i) A PARTNERSHIP, ASSOCIATION, CORPORATION OR OTHER LEGAL ENTITY WHICH:

(A) ENTERS INTO A CONTRACTUAL ARRANGEMENT WITH A MANAGED CARE PLAN;

(B) EMPLOYS OR HAS CONTRACTS WITH PROVIDERS (PARTICIPATING PROVIDERS);

(C) AND AGREES UNDER ITS ARRANGEMENTS WITH A MANAGED CARE PLAN TO:

(I) PROVIDE OR ARRANGE FOR THE PROVISION OF A DEFINED SET OF HEALTH CARE SERVICES TO MANAGED CARE PLAN MEMBERS COVERED UNDER A MANAGED CARE PLAN BENEFITS CONTRACT PRINCIPALLY THROUGH ITS PARTICIPATING PROVIDERS; AND

(II) ASSUME UNDER THE ARRANGEMENTS SOME RESPONSIBILITY FOR CONDUCT, IN CONJUNCTION WITH THE MANAGED CARE PLAN AND UNDER COMPLIANCE MONITORING OF THE MANAGED CARE PLAN'S, QUALITY ASSURANCE, UTILIZATION REVIEW, CREDENTIALING, PROVIDER RELATIONS, OR RELATED FUNCTIONS.

(ii) THE IDS MAY ALSO PERFORM CLAIMS PROCESSING AND OTHER FUNCTIONS.

Licensed insurer--An individual, corporation, association, partnership, reciprocal exchange, interinsurer, Lloyds insurer and other legal entity engaged in the business of

insurance, and fraternal benefit societies as defined in the Fraternal Benefits Societies Code (40 P. S. §§ 1142-101--1142-701), and preferred provider organizations as defined in section 630 of The Insurance Company Law of 1921 (40 P. S. § 764a) and 31 Pa Code § 152.2 (relating to definitions).

Managed care plan--

(i) 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 health care arranged through an entity operating under any of the following:

(A) Section 630 of The Insurance Company Law of 1921.

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

(C) The Fraternal Benefit Societies Code.

(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).

(ii) 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.

(iii) ~~The term does not include ancillary service plans as defined by the act or an indemnity arrangement which is primarily fee for service.~~ THE TERM INCLUDES MANAGED CARE PLANS THAT REQUIRE THE ENROLLEE TO OBTAIN A REFERRAL FROM ANY PRIMARY CARE PROVIDER IN ITS NETWORK AS A CONDITION TO RECEIVING THE HIGHEST LEVEL OF BENEFITS FOR SPECIALTY CARE.

(iv) 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.~~ A CONTINUOUS HEALTH CARE TREATMENT PROVIDED TO AN ENROLLEE BY A HEALTH CARE PROVIDER WHICH WAS INITIATED PRIOR TO AND THAT WILL CONTINUE AFTER THE PLAN'S TERMINATION OF A CONTRACT WITH A PARTICIPATING PROVIDER FOR REASONS OTHER THAN CAUSE OR THE ENROLLEE'S COVERAGE BY A MANAGED CARE PLAN AS A NEW ENROLLEE.

Plan-- AS DEFINED IN SECTION 2102 OF THE ACT. ~~A managed care plan.~~

Primary care provider--AS DEFINED IN SECTION 2102 OF THE ACT. ~~A health care provider who, within the scope of the provider's practice:~~

~~(i) Supervises, coordinates, prescribes or otherwise provides or proposes to provide health care services to an enrollee.~~

~~(ii) Initiates enrollee referral for specialist care.~~

~~(iii) Maintains continuity of enrollee care.~~

Prospective enrollee--For group contracts or policies, those persons eligible, BUT NOT YET ENROLLED, 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-- AS DEFINED IN SECTION 2102 OF THE ACT. ~~The health care providers designated by a managed care plan to provide health care services.~~

REFERRAL--AS DEFINED IN SECTION 2102 OF THE ACT.

Utilization review-- AS DEFINED IN SECTION 2102 OF THE ACT. ~~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:~~

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

~~(ii) 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-- AS DEFINED IN SECTION 2102 OF THE ACT. ~~An entity certified under section 2151 of the act (40 P. S. § 991.2151), which relates 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: contract endorsements, contract amendments and modification to the contract then in effect.

REQUIRED PROVISIONS AND ENROLLEE DISCLOSURES

§ 154.11. 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 APPROVAL FOR either:

(1) A standing referral to a specialist with clinical expertise in treating the disease or condition.

(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 subsection (a) may include:

(1) Time restrictions on approved treatment plans, AS SET FORTH IN SECTION 2111(6) OF THE ACT (40 P.S. § 991.2111(6)), which include standing referrals or specialist designations.

(2) Requirements that treatment plans be periodically reviewed and reapproved by the plan.

(3) Requirements that the specialist notify the enrollee's primary care provider of all care provided WITHIN 30 DAYS.

§ 154.12. 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. NO TIME RESTRICTIONS SHALL APPLY TO THE DIRECT ACCESSING OF THESE SERVICES BY ENROLLEES.

(b) A managed care plan may require ~~an~~ A PROVIDER OF obstetrical or gynecological ~~provider~~ SERVICES 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) A 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 the information within 30 days of the services being provided under procedures established by the managed care plan. FOR ROUTINE OBSTETRICAL SERVICES, AN INITIAL NOTIFICATION AND FINAL NOTIFICATION, SUBSEQUENT TO THE POSTPARTUM VISIT, SHALL MEET THE NOTIFICATION REQUIREMENTS.

~~(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.~~ MANAGED CARE PLANS SHALL NOT HAVE DIFFERENT REIMBURSEMENT LEVELS FOR COVERED SERVICES BECAUSE AN ENROLLEE OBTAINS THESE SERVICES THROUGH DIRECT ACCESS RATHER THAN WITH THE PRIOR APPROVAL OF A PRIMARY CARE PROVIDER.

§ 154.13. Managed care plan reporting of complaints and grievances.

(a) 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 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.~~

(b) MANAGED CARE PLANS SHALL REPORT THE INFORMATION IN SUBSECTION (A) TO THE DEPARTMENTS BASED ON THE FORMAT AS REQUIRED BY THE DEPARTMENTS.

(c) Notice of changes or amendments to the format ~~required by the Department~~ for reporting complaint and grievance information ~~to the Department~~ will be published BY THE DEPARTMENT in the *Pennsylvania Bulletin*. The notice will 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*.

§ 154.14. 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 section 2101.2 of the act (40 P. S. § 991.2102).

(b) Plans are required to pay all reasonably necessary costs FOR ENROLLEES MEETING THE PRUDENT LAYPERSON DEFINITION OF ~~associated with the~~ emergency services provided during the period of the emergency. INCLUDING EVALUATION, TESTING, AND IF NECESSARY, THE STABILIZATION OF THE CONDITION OF THE ENROLLEE.

(c) SUDDEN AND UNEXPECTED MEDICAL EVENTS INVOLVING A CHRONIC CONDITION WHICH MEET THE PRUDENT LAYPERSON REQUIREMENTS OF THE ACT SHALL BE CONSIDERED EMERGENCY SERVICES SUBJECT TO THE PROVISIONS OF THE ACT AND THIS CHAPTER.

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

(e)~~(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. AN EXCEPTION TO THIS REQUIREMENT WILL BE MADE WHERE THE MEDICAL CONDITION OF THE PATIENT PRECLUDES THE PROVIDER FROM ACCURATELY DETERMINING THE IDENTITY OF THE ENROLLEE'S MANAGED CARE PLANS WITHIN 48 HOURS OF ADMISSION.

(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.

(f)~~(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 in § 154.16(h) (relating to information for enrollees).

§ 154.15. Continuity of care.

(a) Managed care plans are required to provide the option of continuity of care for enrollees when one of the following applies:

(1) A managed care plan terminates a contract with a participating provider for reasons other than for cause AS SET FORTH IN SECTION 2117(b) OF THE ACT (40 P.S. § 991.2117(b)) and the enrollee is then in an ongoing course of treatment with that provider.

(2) A new enrollee enters a managed care plan and is then in an ongoing course of treatment with a nonparticipating provider WHICH IS NOT OTHERWISE COVERED BY THE TERMINATED COVERAGE.

(b) A current enrollee shall be allowed to continue an ongoing course of treatment with a provider whose contract has been terminated BY THE PLAN for reasons other than for cause (AS SET FORTH IN SECTION 2117(b) OF THE ACT) 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) Nonparticipating and terminated providers ~~shall~~ MAY BE REQUIRED BY THE PLAN TO 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, one of the following conditions shall be met:

(1) All of the providers involved ~~shall~~ MAY BE REQUIRED BY THE PLAN TO agree to the plan's terms and conditions.

(2) Those providers who accept the plan's terms and conditions ~~shall~~ MAY BE REQUIRED BY THE PLAN TO 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 shall be covered by the managed care plan under the same terms and conditions as applicable for participating health care providers. To be eligible for payment by plans, providers shall 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 nonparticipating or terminating providers to agree to terms that include:

(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 referrals for specialty care, diagnostic testing and related services to the enrollee's current managed care plan's participating providers.~~

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

~~(6)~~(4) 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.

~~(7)~~(5) 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 nonparticipating providers to undergo the FULL 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~~ THE ENROLLEE HANDBOOK (IF PROVIDED TO THE ENROLLEE). This information and 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.

§ 154.16. Information for enrollees.

(a) Managed care plans shall provide the written information in section 2136(a) of the act (40 P. S. § 991.2136(a)), which relates required disclosures, to enrollees and, on written request, to prospective enrollees and health care providers.

(1) 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~~ SHALL be easily identifiable within the materials provided.

(2) THE WRITTEN INFORMATION TO BE PROVIDED BY MANAGED CARE PLANS TO ENROLLEES, PROSPECTIVE ENROLLEES AND HEALTH CARE

PROVIDERS SHALL BE SUBJECT TO THE FILING REQUIREMENTS UNDER ACT 159 OF 1996 (40 P.S. §§ 3801 - 3813) AND ALL OTHER APPLICABLE STATUTES AND REGULATIONS.

(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:

(1) The information REQUIRED BY (a) ~~specified in section 2136(a) of the act.~~

(2) A list by specialty of the name, address and telephone number of all participating health care providers WHICH AN ENROLLEE MAY HAVE ACCESS TO EITHER DIRECTLY OR THROUGH A REFERRAL. The list may be a separate document AND MAY BE A REGIONAL OR COUNTY DIRECTORY and shall be updated at least annually. IF A REGIONAL OR COUNTY DIRECTORY IS PROVIDED, ENROLLEES SHALL BE MADE AWARE THAT OTHER REGIONAL OR A FULL DIRECTORY IS AVAILABLE UPON REQUEST. 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)), which relates to a medical "gag clause" prohibition.

(4) 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 the services on moral or religious grounds.

(d) For the purposes of the specified disclosure statement required by section 2136(a)(1) of the act, subscriber and group master contracts and riders, amendments and endorsements, do not constitute "marketing materials" subject to the specified disclosure statement. FOR THE PURPOSES OF WRITTEN INFORMATION DISTRIBUTED TO

ENROLLEES OR POTENTIAL ENROLLEES, THE TERM "MARKETING MATERIALS" SHALL HAVE THE MEANING GIVEN TO WRITTEN INFORMATION IN THE TERM "ADVERTISEMENT" IN 31 PA. CODE § 51.1.

(e) For group contracts and policies, the managed care plan shall 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 shall 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 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 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 HAVE CHANGED or networks have SUBSTANTIALLY changed since the initial enrollment or last renewal, disclosure information SHALL ~~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 RECEIPT OF THE request for the information.

(3) Disclosure information requested by prospective enrollees shall be provided to prospective enrollees within 30 days of the date of the RECEIPT OF THE written request for the information.

(4) Disclosure information requested by health care providers shall be provided to health care providers within 45 days of the date of the RECEIPT OF THE written request for the 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," AS SET FORTH IN ~~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, upon written request by enrollees or prospective enrollees, shall provide written information as specified in section 2136(b) of the act. This information shall be easily understandable to the layperson.

§ 154.17. Complaints.

(a) Under the complaint process established by the act (40 P.S. §§ 991.2141 – 991.2143), the Department will consider complaints INCLUDING THOSE regarding issues of contract exclusions, ~~and~~ noncovered benefit disputes AND POTENTIAL VIOLATION OF INSURANCE STATUTES, INCLUDING THE UNFAIR INSURANCE PRACTICES ACT (40 P. S. §§ 1171.1--1171.15). THE ENROLLEE MAY BE REPRESENTED BY AN ATTORNEY OR OTHER INDIVIDUAL BEFORE THE DEPARTMENT. THE DEPARTMENT OF HEALTH WILL FOCUS ON COMPLAINT ISSUES INCLUDING THOSE INVOLVING ENROLLEE QUALITY OF CARE AND QUALITY OF SERVICE. 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 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.

(3) Problems relating to one or more of the following:

(i) Coordination of benefits.

(ii) Subrogation.

(iii) Conversion coverage.

(iv) Alleged nonpayment of premium.

(v) Dependent coverage.

(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, COMPLAINTS AND QUESTIONS regarding premium rate increases ~~do not constitute "appeals" and~~ may be filed with the Department without the necessity of following the plan's internal complaint process.

(d) ~~Managed care plans may establish time frames, of at least 30 days, for the filing of~~

~~complaints and grievances with the plan.~~ IF PLANS ESTABLISH TIMEFRAMES FOR THE FILING OF COMPLAINTS AND GRIEVANCES WITH THE PLAN, THEY SHALL ALLOW THE ENROLLEES AT LEAST 45 DAYS TO FILE A COMPLAINT OR GRIEVANCE FROM THE DATE OF THE OCCURRENCE OF THE ISSUE BEING COMPLAINED ABOUT OR THE DATE OF THE ENROLLEES RECEIPT OF NOTICE OF THE PLAN'S DECISION.

(e) Managed care plans shall complete the initial level of review of an enrollee complaint within 30 days of receipt of the complaint. The plan shall 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 shall complete the second level of review of an enrollee complaint within 45 days of receipt of the enrollee's request for review. THE ENROLLEE HAS THE RIGHT TO APPEAR BEFORE THE SECOND LEVEL REVIEW COMMITTEE. The plan shall 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 Department~~, or the Department of Health.~~

(g) ~~Enrollees~~ IN ORDER TO EXPEDITE THE COMPLAINT REVIEW PROCESS, ENROLLEES ~~shall~~ SHOULD follow and complete the plan's internal complaint process before filing an appeal of the complaint decision with the Department or the Department of Health. PURSUANT TO SECTION 2143 OF THE ACT (40 P.S. § 991.2143), THE DEPARTMENT MAY COMMUNICATE WITH THE APPROPRIATE PARTIES TO ASSIST IN THE RESOLUTION OF THE COMPLAINT.

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

(i) Appeals of complaints to the Department shall include THE FOLLOWING 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.

(6) WHETHER THE ENROLLEE WILL BE REPRESENTED BY AN ATTORNEY OR OTHER INDIVIDUAL BEFORE THE DEPARTMENT.

(J) THE DEPARTMENT SHALL NOTIFY THE PLAN IF A COMPLAINT APPEAL HAS BEEN FILED. THE PLAN SHALL PROVIDE COPIES OF ALL RECORDS FROM THE INITIAL AND SECOND LEVEL REVIEW TO THE DEPARTMENT. THIS INFORMATION SHALL BE PROVIDED TO THE DEPARTMENT WITHIN 30 DAYS OF THE DEPARTMENT'S NOTICE TO THE PLAN OF THE COMPLAINT APPEAL.

(K)~~(j)~~ IN THE EVENT AN APPEAL IS TRANSFERRED FROM THE DEPARTMENT TO THE DEPARTMENT OF HEALTH, THE ORIGINAL SUBMISSION DATE OF THE APPEAL WILL BE UTILIZED TO DETERMINE COMPLIANCE WITH THE FILING TIME FRAME IN ACCORDANCE WITH § 2142(a) OF THE ACT (40 P. S. § 991.2142(a)), WHICH RELATES TO THE APPEAL OF A COMPLAINT. ~~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~~ THE 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)), which relates to the appeal of a~~

~~complaint.~~

(L) THE DEPARTMENT SHALL PROVIDE THE MANAGED CARE PLAN AND THE ENROLLEE WITH A COPY OF THE FINAL DETERMINATION OF AN APPEALED COMPLAINT.

~~(k) The Department and the Department of Health share the statutory responsibility to regulate the enrollee and managed care plan complaint process. The Department will focus on the review of cases which concern the potential violation of insurance statutes, including 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.~~

(M)~~(l)~~ Complaint appeals under subsection (i) may be filed with the Department at the following address:

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

§ 154.18. Prompt payment.

(a) Licensed insurers and managed care plans shall pay clean claims AND THE UNCONTESTED PORTIONS OF A CONTESTED CLAIM (PURSUANT TO (D)) 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. THE PROMPT PAYMENT PROVISION APPLIES ONLY TO CLAIMS SUBMITTED UNDER HEALTH INSURANCE POLICIES, EXCLUDING AREAS SUCH AS AUTOMOBILE AND WORKER'S COMPENSATION POLICIES.

(b) For purposes of prompt payment, a claim shall be deemed to have been "paid" upon one of the following:

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

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

(c) 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~~ WITHIN 30 DAYS OF THE payment of the claim. Interest owed of less than $2 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~~ A NEW 45-day period for the prompt payment provision begins again at the time additional information prompting the readjudication is provided to the plan. Additional moneys 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 required substantiating documentation FOR THE ENTIRE CLAIM 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) LICENSED INSURERS AND MANAGED CARE PLANS SHALL PROVIDE WRITTEN DISCLOSURE TO HEALTH CARE PROVIDERS OF ALL THE DATA ELEMENTS NECESSARY TO INSURE THAT A CLAIM IS WITHOUT DEFECT OR IMPROPRIETY AND MEETS THE DEFINITION OF CLEAN CLAIM UNDER THE ACT.

(1) LICENSED INSURERS AND MANAGED CARE PLANS SHALL PROVIDE THIS INFORMATION TO CURRENTLY PARTICIPATING HEALTH CARE PROVIDERS WITHIN 30 DAYS OF THE EFFECTIVE DATE OF THIS CHAPTER. FOR HEALTH CARE PROVIDERS ENTERING INTO A PARTICIPATION AGREEMENT WITH THE LICENSED INSURER OR MANAGED CARE PLAN AFTER THE EFFECTIVE DATE OF THIS CHAPTER, THE LICENSED INSURER OR MANAGED CARE PLAN SHALL PROVIDE THIS INFORMATION WITHIN 30 DAYS OF THE PARTIES ENTERING INTO A PARTICIPATION AGREEMENT. IF ANY CHANGES ARE MADE TO THE REQUIRED DATA ELEMENTS, THIS INFORMATION SHALL BE PROVIDED TO PARTICIPATING HEALTH CARE PROVIDERS AT LEAST 30 DAYS BEFORE THE EFFECTIVE DATE OF THE CHANGE OR CHANGES.

(2) FOR NON-PARTICIPATING HEALTH CARE PROVIDERS, A LICENSED INSURER OR MANAGED CARE PLAN SHALL PROVIDE THIS INFORMATION WITHIN 45 DAYS OF AN ORAL OR WRITTEN REQUEST FROM THE HEALTH CARE PROVIDER.

(F)~~(e)~~ Prior to filing a complaint with the 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 SHALL ~~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~~ 45 DAYS OF SUBMISSION OF THE CLAIM OR WITHIN 30 DAYS OF THE INQUIRY, IF THE INQUIRY IS MADE AFTER THE 45-DAY PERIOD.

(G)~~(f)~~ Health care providers may file a complaint, EITHER INDIVIDUALLY OR IN BATCHES, with the 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 one of

the following applies:

(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~~ 45 DAYS OF SUBMISSION OF THE CLAIM OR WITHIN 30 DAYS OF THE INQUIRY, IF THE INQUIRY IS MADE AFTER THE 45-DAY PERIOD.

(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.

(H)~~(g)~~ Complaints to the 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, IDENTIFICATION NUMBER, address and daytime telephone number and the claim number.

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

(3) The name of the patient and employer (IF KNOWN).

(4) The dates of service and the dates the claims were submitted to the licensed insurer or managed care plan.

(5) 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.

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

(7) ANY ADDITIONAL INFORMATION PERTINENT TO THE COMPLAINT AS REQUESTED BY THE COMMISSIONER.

(I) NOTHING IN THIS SECTION SHALL BE CONSTRUED AS PREVENTING THE DEPARTMENT FROM INVESTIGATING A COMPLAINT WHERE THE HEALTH

CARE PROVIDER HAS FAILED TO CONTACT THE LICENSED INSURER OR MANAGED CARE PLAN AS PROVIDED FOR IN (F).

PART X. HEALTH MAINTENANCE ORGANIZATIONS

CHAPTER 301. HEALTH MAINTENANCE ORGANIZATIONS

(*Editor's Note*: Chapter 301, Subchapter J is proposed to be deleted. For the text of the existing statement of policy, see 31 Pa. Code pages 301-33 to 301-41, serial pages (249129) to (249137).)

Subchapter J. (Reserved)

§§ 301.401--301.403. (Reserved).

§§ 301.411--301.416. (Reserved).

[Pa.B. Doc. No. 99-1228. Filed for public inspection July 30, 1999, 9:00 a.m.]

COMMONWEALTH OF PENNSYLVANIA
INSURANCE DEPARTMENT
OFFICE OF SPECIAL PROJECTS
1326 Strawberry Square
Harrisburg, PA 17120

Phone: (717) 787-4429
Fax: (717) 772-1969
E-mail: psalvato@ins.state.pa.us

January 24, 2000

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 5a(c) of the Regulatory Review Act, enclosed for your information and review is final form 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. This regulation is 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 being 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,

Peter J. Salvatore

Peter J. Salvatore
Regulatory Coordinator

11-195f

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

RECEIVED
2000 JAN 24 AM 9:50
INDEPENDENT REGULATORY REVIEW COMMISSION

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

TYPE OF REGULATION

Proposed Regulation

X 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
1-24-00	M. Kaplagen	HOUSE COMMITTEE ON INSURANCE
1/24/00	Denise Patton	SENATE COMMITTEE ON BANKING & INSURANCE
1/24/00	D. Gelnett	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL
		LEGISLATIVE REFERENCE BUREAU

January 21, 2000