

PENNSYLVANIA ACADEMY OF FAMILY PHYSICIANS

August 27, 1999

RECEIVED

AUG 30 1999

VIA FACSIMILE (717) 705-3873  
AND U.S. MAIL

Office of Special Projects

Peter J. Salvatore  
Regulatory Coordinator  
Pennsylvania Insurance Department  
1326 Strawberry Square  
Harrisburg, PA 17120

Re: Insurance Department Proposed Regulations;  
Quality Health Care Accountability and Protection  
Act Implementation (Act 68 of 1998)

Dear Mr. Salvatore:

The Pennsylvania Academy of Family Physicians ("the Academy") represents approximately 4,500 physician members. The following comments are submitted in response to the Insurance Department's proposed regulations implementing Act 68 of 1998, the Quality Health Care Accountability and Protection Act, which were published at 29 *Pa. Bulletin* 4064-4071 (July 31, 1999).

**Definitions - § 154.2**

**Primary Care Provider** - The definition of this phrase in the proposed regulation tracks the statutory definition of the phrase. A potential ambiguity in that definition, however, should be addressed and resolved in the regulations.

The existing HMO regulations require HMOs to make available to each subscriber "a primary care **physician** to supervise and coordinate the health care of the subscriber." 28 Pa. Code § 9.75(c). Nothing in Act 68 changed the accessibility requirements under § 1555.1(b)(1)(i) of the HMO Act upon which § 9.75(c) was based. Accordingly, no authority exists in Act 68 to alter the primary care physician supervision and coordination requirement. Therefore, the regulations should clearly state that a "primary care **physician** shall supervise and coordinate the health care of an enrollee." Advanced practice nurses and physician assistants should not be expressly or impliedly

authorized in the regulations to possess supervisory and coordination authority or to practice independently of a primary care physician.

As § 2102 of Act 68 makes clear, Act 68 did not expand the scope of practice of any health care provider. Neither APNs nor PAs can practice independent of a primary care physician. Act 68 does not authorize substitution of a primary care physician with an APN or PA. Physician-approved protocols and standing orders, where appropriate, should guide the APN's or PA's approach to patient-described conditions. Standing orders should implement treatment following the diagnosis. An APN and a PA should be prohibited from being held out as a "primary care provider." Therefore, the regulations should define a "primary care provider" as "a physician who is Board certified or Board eligible in and limits his practice to family medicine, general internal medicine or pediatrics; or is a generalist physician who renders primary care at least 50% of the time in which he engages in the practice of medicine."

**Primary Care** – Act 68 mentions the phrase "primary care" several times, but fails to define this crucial term. The Academy believes the Insurance Department possesses regulatory authority to promulgate a definition of "primary care", and submits the following definition, which was developed and endorsed by both the American Academy of Family Physicians and PAFP, for adoption in the regulations:

**"Primary Care."** Care provided by physicians specifically trained for and skilled in comprehensive first contact and comprehensive continuing care for persons with any undiagnosed sign or symptom of health concern, the "undifferentiated" patient, not limited by problem origin, gender or diagnosis. The term includes health promotion, disease prevention, health maintenance, counseling, patient education, diagnosis and treatment of acute and chronic illnesses in a variety of health care settings, including office, inpatient, critical care, long-term care and home care. Primary care is performed and managed by a personal physician, utilizing other health professions, consultation and referral, as appropriate; provides patient advocacy in the health care system to accomplish cost-effective case management and care coordination of health care services; and promotes effective doctor-patient communication and encourages the role of the patient as a partner in health care.

#### **Direct Enrollee Access to OB/GYN - § 154.12**

**Enrollee Selection, Access to, Referral to, and Reimbursement for OB/GYN Services Provided by Family Physicians** – Under § 154.12, the proposed regulations largely restate the direct access to obstetrical and gynecological services under § 2111(7) of Act 68. Many of the Academy's Board certified family physicians are well trained in and

actively practice obstetrics and gynecology. In fact, JCAHO standards require each family practice residency to have one Board certified family physician teach OB/GYN in residency. Scores of family practice residents then provide OB/GYN services in active practice.

Moreover, § 2111(7) of Act 68, as well as Act 68's access to care requirements, **obligate** MCPs to permit enrollees to obtain direct access to OB/GYN services (regardless of the type of provider); to provide reimbursement coverage for such services; to allow self-referral to a family physician other than the patient's primary care physician for such services without prior approval from the enrollee's primary care provider; and, implicitly, to credential family physicians for the provision of OB/GYN services where they have obtained requisite training and experience. MCPs are routinely ignoring these obligations to the detriment of enrollees. Accordingly, § 154.12 should be amended to expressly include these rights inuring to the benefit of enrollees.

Furthermore, pursuant to § 2136(a)(14) of Act 68 (requiring MCPs to automatically publish the list of specialty providers by name, address and telephone number), MCPs should be expressly required to include family physicians with training and experience in OB/GYN on the *list of OB/GYN providers*. A specific provision should be added to the final form regulations clarifying this obligation.

Finally, when enrollees seek direct access to a specific OB/GYN provider, the regulations should specifically state that an MCP cannot penalize a family physician economically or in any other manner, including a negative credentialing decision, based upon an enrollee's direct access to OB/GYN services. A family physician's lack of control over an enrollee's direct access decision mandates this conclusion.

#### **Continuity of Care - § 154.15**

**Physician Rights** – Under § 154.15, the proposed regulations outline a series of obligations imposed on physicians if a patient chooses the continuity of care option. The regulations should make it clear that physicians possess *rights* under the Act as well as obligations. For example, under the continuity of care rules, a physician would have standing to initiate a utilization review challenge.

#### **Information for Enrollees - § 154.16**

**MCP Response Time and Delegation** – Act 68 is silent in terms of the amount of time an MCP has to provide information to enrollees and physicians under § 2136(a). The proposed regulations would allow MCPs 30 days to respond to an enrollee and 45 days to provide written information to physicians. *See* § 154.16(g)(3), (4). This is far too long. Time exigencies may drive the physician or patient's need to obtain crucial

information such as the definition of medical necessity required to be disclosed under § 2136(a)(1), utilization review dispute procedures under § 2136(a)(7), etc. The time limitation imposed on MCPs should be 15 days from the date of the written request. The 15 day limit should be applicable to both enrollees and physicians' requests.

The proposed regulations are also silent as to the time constraints imposed on MCPs to provide the information requested under § 2136(b). Enrollees are entitled to crucial information under this subsection, including for example whether a drug is included or excluded from coverage under § 2136(b)(5), drug formulary information under § 2136(b)(6), and physician credentialing processes under § 2136(b)(3). The same 15 day time constraint should be imposed on MCPs to respond to enrollees' requests under § 2136(b).

Finally, proposed § 154.16(e) appears to create some authority for an MCP to delegate its information disclosure obligation to a group policy holder or other designated entity. The Act provides no such delegation authority. Even if such authority to delegate is within the Insurance Department's realm of constitutional regulatory authority, § 154.16(e) should expressly state that the MCP retains responsibility for timely disclosure of the material requested.

#### **Complaints - § 154.17**

**Medical Necessity Parameters** - Act 68 does not contain an objective definition of the term "medical necessity." MCPs, however, must adopt and maintain a definition of medical necessity of their own. § 2111(3). MCPs must also disclose to enrollees and physicians the definition of medical necessity it utilizes. § 2136(1). If an MCP's contract prohibits or restricts disclosure of medically necessary and appropriate health care information by a physician, that provision is void and unenforceable. § 2113(b). The "gag clause" provisions in § 2113(c)(1)-(3) address the prohibition against squelching the disclosure of medically necessary information from physicians to patients. Thus, medical necessity definitions are an integral part of MCP operations, and (quite obviously) the physician's practice of medicine.

The provisions of Act 68 cited above permit the Insurance Department's regulation of the parameters of an acceptable "medical necessity" definition used by MCPs. In fact, Greg Martino testified to the House Insurance Committee that the Insurance Department already uses a series of "key characteristics" in determining whether to approve or disapprove an MCP's contract in terms of the medical necessity definition. The Academy has not seen those parameters, but believes medical necessity parameters should be included in the regulations.

The definition of medical necessity has emerged as one of the two most contentious issues in the managed care reform debate. States are beginning to enact statutory

definitions of this phrase. It is simply too important to patients (and physicians) to allow this crucial term to go undefined. Accordingly, the Academy believes the Insurance Department possesses sufficient statutory authority to include the following medical necessity definition parameters in its final form regulations, as follows:

- 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 the functioning of any body member.
- Objective clinical determinations which will be or are reasonably 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 must be taken into consideration.

These parameters strike the necessary balance between patient protection and utilization control. The Insurance Department should work collaboratively with the Department of Health to ensure that each agency's medical necessity contractual parameters are identical.

**"Hospitalist" Issue** - Some managed care companies are attempting to force family physicians to utilize "hospitalists" for their patients' hospital care. A "hospitalist" is generally defined as a physician who devotes the entirety of his or her practice to treating patients inside the hospital setting. Family physicians are well trained and have substantial knowledge and experience in practicing inpatient hospital medicine, and cannot and should not be mandated to utilize "hospitalists" for their patients' hospital care. A specific provision should be included in the regulations addressing this crucial issue.

**MCP Time to Make Denial Decision** - Act 68 is silent on the time required by an MCP to make a decision to deny payment as well as the amount of time an enrollee or physician has to assert a challenge to the MCP's denial decision. In § 154.17(e) of the proposed regulations, the Insurance Department proposes to allow an MCP to impose a

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minimum time period (30 days) for an enrollee to file a complaint. The proposed regulations, however, **impose no time limitations on an MCP to make the initial denial decision.** Because the Insurance Department has apparently seen fit to impose a time limitation on an enrollee, the same 30-day time limitation should be imposed upon an MCP. That is, an MCP should have only 30 days to deny payment for a particular treatment or service on the basis of a contract exclusion and non-covered benefit decision from the date the physician submitted the bill for payment.

Moreover, § 154.17(f) allows 5 days in addition to the statutory 30-day period in which the MCP must review a complaint. In fact, mail typically is delivered from one end of the Commonwealth to another in 2 days. The Pennsylvania Rules of Appellate Procedure only assume 3 days for mailing. *See* Pa. R.A.P. 121(e). The 5-day time limitation should be reduced to 2 days, or 3 days at the most. There is no valid factual basis to assume 5 days for mailing, and no legislative intent exists to support creation of the additional week for MCP compliance. These principles apply to the other subsections of § 154.17 where the 5-day rule is discussed.

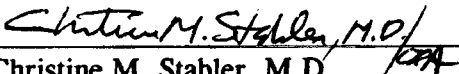
**Prompt Payment - § 154.18**

The requirement under § 154.18(e) that imposes the burden on *providers* to spend their resources to ascertain whether the MCP has sufficient documentation finds no basis in Act 68 and conflicts with the clean claim notion under HCFA regulations from which it was adapted. This provision should be stricken.

\* \* \* \*

Thank you for your consideration of the Academy's issues and concerns relating to these important public policy and legal matters. Should you have any questions, please contact us at your convenience.

Sincerely,

  
\_\_\_\_\_  
Christine M. Stabler, M.D.  
President

cc: PAFP Board of Directors  
PAFP Public Policy Commission  
Wanda D. Filer, M.D. - Chair, PAFP Public Policy Commission  
John S. Jordan, PAFP Executive Vice President  
Charles I. Artz, Esq. - PAFP General Counsel  
John A. Nikoloff - PAFP Lobbyist



**COMMONWEALTH OF PENNSYLVANIA  
INSURANCE DEPARTMENT**

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E-mail: psalvato@ins.state.pa.us

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August 30, 1999

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

ORIGINAL: 2046  
BUSH  
COPIES: Harris  
Jewett  
Markham  
Smith  
Wilmarth  
Sandusky

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

Dear Mr. Nyce:

Pursuant to Section 5(c) of the Regulatory Review Act, the Department is required to submit all comments on proposed regulations received during the public comment period to the Independent Regulatory Review Commission and the Legislative Standing Committees within 5 days.

Attached is a list of commentators that have submitted comment on the above-mentioned regulation and the respective comment that was received.

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

Sincerely yours,

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Peter J. Salvatore  
Regulatory Coordinator







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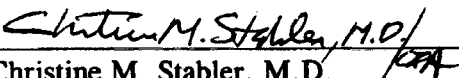
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Sincerely,

  
\_\_\_\_\_  
Christine M. Stabler, M.D. *CS*  
President

cc: PAFP Board of Directors  
PAFP Public Policy Commission  
Wanda D. Filer, M.D. - Chair, PAFP Public Policy Commission  
John S. Jordan, PAFP Executive Vice President  
Charles I. Artz, Esq. - PAFP General Counsel  
John A. Nikoloff - PAFP Lobbyist



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

ORIGINAL: 2046

BUSH

COPIES: Harris  
Jewett  
Markham  
Smith  
Wilmarth  
Sandusky

Re: Insurance Department  
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Peter J. Salvatore  
Regulatory Coordinator

**Comments on the regulation listed below have been received from the following:**

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

---

**Ms. Harriet Franklin**  
**Stevens & Lee**  
**One Glenhardie Corporate Center**  
**Wayne PA 19087-0236**

**Date Received      8/30/1999**

**Phone: (610) 293-5888 X00000**

**Email: hf@stevenslee.com@stevenslee.com**

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**Page 1**

**Date sent to Committes and IRRC      8/30/1999**

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**STEVENS & LEE**

A PROFESSIONAL CORPORATION

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99 SEP -1 AM 9:44

DIAL DIRECT

(610) 293-5888

email: hf@stevenslee.com@stevenslee.com

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Peter J. Salvatore, Regulatory Coordinator  
Pennsylvania Insurance Department  
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Harrisburg, PA 17120

Re: Quality Health Care Accountability and Protection Act  
Proposed Regulations

Dear Mr. Salvatore:

On behalf of our client, Community Medical Center, Scranton, Pennsylvania ("CMC"), we hereby submit these comments concerning the above-referenced proposed regulations which were published in the July 31, 1999 Pennsylvania Bulletin. CMC requests that the definition of utilization review set forth in proposed 31 Pa. Code §154.2 be clarified or modified for the following reasons.

Various managed care plan agreements require CMC, as the health care provider, to obtain prior authorization or pre-certification from the managed care plan or its utilization review agent before providing certain services. Pre-certification is, in effect, a form of prospective utilization review that can result in the denial of payment for health care services because all or part of the proposed services may not be authorized. In CMC's experience, some managed care plans have refused to issue written determinations regarding pre-certification decisions, thereby giving CMC no basis for appealing any adverse decision. Some managed care plans have refused to take any action on requests for pre-certification. In such cases CMC has no choice but to provide services which a patient's physician deems to be medically necessary, only to have the services denied as not pre-certified or to have them paid at lower rates than provided for in the plan's provider contract. It also leaves CMC without the ability to appeal to the managed care plan.

40 P.S. §991.2152(a)(6), governing operational standards for utilization review entities, requires utilization review "entities" to provide all decisions regarding prospective utilization review in writing within certain time guidelines. However, as currently defined in the proposed regulation, the term "utilization review" does not specifically mention pre-certification or prior authorization requests. The definition also addresses only utilization review decisions made by utilization review entities. Managed care plans that perform their own utilization review

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208 North Third Street, Suite 310, P.O. Box 12090, Harrisburg, PA 17108-2090 • 717-234-1250 Fax 717-234-1939

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Peter J. Salvatore, Regulatory Coordinator  
08/27/99  
Page 2

functions should be held to the same operational standards as utilization review entities with respect to providing written notice of determinations.

Therefore, CMC suggests the definition of utilization review in proposed 31 Pa. Code §154.2 be revised in the final regulations by the addition of the following underlined text:

*Utilization review--* A system of prospective, concurrent or retrospective utilization review, as defined by the act, performed by a utilization review entity or a managed care plan of the medical necessity and appropriateness of health care services prescribed, provided or proposed to be provided to an enrollee, including requests for pre-certification or prior authorization of health care services . . .

The remaining language of the definition would be unchanged.

By adding a specific reference to pre-certification, the regulations will ensure that such decisions must also be communicated in writing within 2 business days of receipt of all supporting information reasonably necessary to complete the review, in accordance with the requirements of Act 68.

In addition, to ensure that utilization review decisions involving pre-certification and prior authorization are subject to the grievance process provided for in Act 68, CMC requests that the definition of "grievance" in proposed 31 Pa. Code §154.2 be modified to make specific reference to pre-certification and prior authorization, by adding the following underlined language:

*Grievance--*

(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, including a decision involving pre-certification or prior authorization for services.

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Peter J. Salvatore, Regulatory Coordinator  
08/27/99  
Page 3

Thank you for this opportunity to submit these comments. Please contact me if you have any questions regarding CMC's comments or concerns.

Respectfully submitted,

STEVENS & LEE

A handwritten signature in cursive script that reads "Harriet Franklin" followed by a small flourish.

Harriet Franklin

cc: Paul Evers, Finance  
Community Medical Center



**COMMONWEALTH OF PENNSYLVANIA  
INSURANCE DEPARTMENT**

OFFICE OF SPECIAL PROJECTS  
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August 30, 1999

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

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

Dear Mr. Nyce:

Pursuant to Section 5(c) of the Regulatory Review Act, the Department is required to submit all comments on proposed regulations received during the public comment period to the Independent Regulatory Review Commission and the Legislative Standing Committees within 5 days.

Attached is a list of commentators that have submitted comment on the above-mentioned regulation and the respective comment that was received.

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

Sincerely yours,

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

Peter J. Salvatore  
Regulatory Coordinator

**Comments on the regulation listed below have been received from the following:**

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

---

**Mr. Robert Jones**

**DPW**

**2nd Floor, Beechmont Building**

**Harrisburg PA 17105-2675**

**Date Received      8/30/1999**

**Phone: (717) 772-7926 X00000**

**EMail:**

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**Ms. Suzanne Love**

**Director**

**DPW, Bureau of Policy, Budget and Planning**

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**Date Received      8/30/1999**

**Phone: (717) 772-6147 X00000**

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**Mr. Jerry Kopelman**

**Director**

**DPW, Bureau of Policy and Program Development**

**Beechmont Bldg**

**Harrisburg PA 17105-**

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**COMMONWEALTH OF PENNSYLVANIA  
DEPARTMENT OF PUBLIC WELFARE**

**SUBJECT:** Insurance Department; Proposed Regulations, Chapter 154

**TO:** Peter J. Salvatore  
Regulations Coordinator

**FROM:** Suzanne Love, Director  
Bureau of Policy Budget and Planning  
Office of Medical Assistance Programs

Jerry Kopelman, Director  
Bureau of Policy and Program Development  
Office of Mental Health and Substance Abuse Services

Thank you for the opportunity to review Chapter 154 of regulations proposed by the Insurance Department. We are providing the following comments:

1. Our overall recommendation is to reduce the number of references to the Act 68 throughout the document. The reader must, too often, refer to the Act 68 for details. In place of references, we suggest that the Act's language be interpreted and clarified to make these regulations more user friendly.

In addition, we suggest that some references to Act 68 are not necessary or confusing. For example, 154.14(a) refers to section 2101 of the Act for a definition of "Emergency Services". Definitions are found under section 2102 of the Act.

2. §154.1 Applicability and Purpose - We recommend clarification of paragraph (c). The word "entity" is too broadly used and it is difficult to determine if "subcontracting entity" refers to any subcontractor or a subcontracting Utilization Review/Managed Care Organization.
3. §154.2 Definitions – "Emergency Service" – Under (i) of the definition of "emergency service" the Insurance Department adds the phrase... "including a chronic condition,"... This wording is not

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found in the Act. We oppose this addition and recommend this phrase be deleted as unnecessary.

4. §154.2 Definitions – “Gatekeeper” – Behavioral Health specialty managed care plans do not use the primary care physician/primary care provider as gatekeeper. In addition, many HealthChoices plans do not understand the term “agent” as used in the definition. The definition of “gatekeeper” does not apply to Behavioral Health MCOs and we believe it is not necessary. We recommend it be deleted.
5. §154.2 Definitions – “Ongoing Course of Treatment” - We suggest that ongoing course of treatment is a valid concept. However, we recommend that it is better to incorporate it under §154.15, Continuity of Care, rather than as a definition.
6. §154.11(b)(1) needs further clarification so that the time limit is more than an across the board limitation. We suggest the following language... (1) 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.
7. §154.14(d)(1) Emergency Services. The timeframes in paragraph (d)(1) are open to interpretation. For example, should notification to an MCO for a Thursday admission take place Saturday or Monday? We recommend notification within 48 hours of admission, and delete the words...“or the next business day, or whichever period is greater.”
8. §154.15. Continuity of Care – 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. These regulations make no specific mention of the treatment plan. We recommend that this requirement be added. *Note: was it the intent of the DOI/DOH, to place this requirement in the DOH regulations only? Please clarify.*
9. §154.15. Continuity of Care. Act 68, Section 2117 (b) termination of a participating primary care provider for cause, (c) notification to the enrollee of a participating primary care provider’s termination and (f) services not covered in the plans terms and conditions, are not included in these regulations as specific subsections. We recommend that they be included as subsections.
10. §154.15(g). We recommend rewriting “terminating providers” to read “providers in the process of termination.”

11. §154.16. Information for Enrollees. Section 154.16 (a) references both required disclosures to enrollees and information to be provided to prospective enrollees and health care providers written requests. This subsection references Section 2136 (a) of the Act, which does not include the information to be released upon written request. We suggest that these regulations specify information that is to be released upon written request.
12. §154.16( c)(3). We suggest that the sentence beginning... “If applicable managed care plans...”, is not related to gag clauses and should either introduced as a separate paragraph under this subsection.
13. §154.16(g)(1) provide exceptions by permitting plans to provide summaries of required information during open enrollment periods. We suggest the following: (1) this subsection should be clearly identified as an “exception”; (2) we concur that a complete list of required information should be provided along with summary information; and (3) along with the complete list of required information, clear instructions should be provided which explain how to obtain the listed information, i.e. by calling a number in the member handbook or by providing a number to be used by prospective enrollees and providers.
14. §154.17 Complaints. We suggest that it is better to disseminate the information in Section 154.17(j) and (l) by bulletin or other means. If incorporated in regulation, any future changes must be done by amendment.
15. We suggest that the information contained in §154.17(k) would be more appropriate as an item in the preamble to regulations.
16. §154.18 Prompt Payment. Section 154.18 (c) provides clarification regarding the application of interest accrued from late payment of clean claims, but the amount of the interest due is not mentioned. We recommend stating that the interest due is 10% per year.

If you have any questions regarding our comments, please contact Mr. Robert Jones at 772-7926.





**COMMONWEALTH OF PENNSYLVANIA  
INSURANCE DEPARTMENT**

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August 31, 1999

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

ORIGINAL: 2046

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

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Dear Mr. Nyce:

Pursuant to Section 5(c) of the Regulatory Review Act, the Department is required to submit all comments on proposed regulations received during the public comment period to the Independent Regulatory Review Commission and the Legislative Standing Committees within 5 days.

Attached is a list of commentators that have submitted comment on the above-mentioned regulation and the respective comment that was received.

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

Sincerely yours,

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

Peter J. Salvatore  
Regulatory Coordinator



**Pennsylvania  
Psychiatric Society**

The Pennsylvania  
District Branch of the  
American Psychiatric Association

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[www.papsych.org](http://www.papsych.org)

Peter J. Salvatore, Regulatory Coordinator  
Department of Insurance  
1326 Strawberry Square  
Harrisburg, PA 17120

Dear Mr. Salvatore:

I am writing on behalf of President Lee C. Miller, MD, of the Pennsylvania Psychiatric Society, in regard to the Department of Insurance's proposed regulations for Act 68, as published in the *Pennsylvania Bulletin* July 31, 1999.

Although as physicians we are interested in numerous aspects of the legislation and regulations, our primary concern as *psychiatric* physicians is ensuring that the regulations clarify the Act's scope in relation to managed mental health services. Such services are often "carved out" of a health plan, either internally or by subcontract, and are subjected to separate and sometimes different managed care protocols than those related to the bulk of services covered by the health care plan.

A problem arises in that the Act clearly covers mental health care, but it was drafted with the usual, non-mental health management protocols in mind. We believe that an important function of the regulations is to make explicit the Act's relationship and applicability to managed mental health services which are "carved out," usually but not necessarily by subcontract. The object is to prevent the unintended exemption of managed mental health services by plans (and perhaps courts) through either simple confusion or a strict interpretation of regulatory language predicated on physical health protocols.

Happily, the proposed regulations represent a great improvement over earlier, non-published versions, demonstrating the Department's sensitivity to the issue. Nevertheless, the proposed regulations need further work in order to eliminate the danger of unintended consequences. Under the proposed rules, determining whether a particular plan is subject to the Act involves a very convoluted process. It first requires examination of § 154.1 (Applicability and Purpose), subsection (c). The next step is examination of the definition of "managed care plan," in § 154.2 (Definitions). That definition references "gatekeeper," whose definition references and requires an analysis of "primary care provider." "Primary care provider" in turn relies on the definition of "health care provider."

### Discussion and suggested solutions

#### § 154.1 Applicability and purpose

This section, in (c), represents a considerable improvement over earlier drafts in that it explicitly establishes applicability to entities which subcontract with managed care organizations.

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(1) Nevertheless, the construction of the sentence in (c) makes unclear whether the qualifying phrase "which issues subscriber contracts covering enrollees" refers to the managed care plan or the subcontractor. Subcontracting mental (behavioral) health organizations generally do not issue subscriber contracts. They provide services on behalf of managed care plans which issue subscriber contracts. Although this appears to be a technical matter, correcting the problem is essential if the ostensible purpose of subsection (c) is to be achieved.

Solution: We suggest simply removing the phrase completely, as it doesn't seem to add any element not covered elsewhere.

(2) Second, the current wording in (c) fails to address another concern we expressed in earlier communications: managed mental health care delivered through subcontract to a plan which, except for the subcontracted portion, does not meet the definition of managed care plan.

The current regulation would appear to exempt those managed care services which are provided under a subcontract with fee-for-service or similar plans. This is of critical importance to mental health treatment, since some primarily fee-for-service plans subcontract with behavioral health organizations to tightly manage the mental health benefit. In most cases the subcontractors are the very same organizations, applying the same managed care techniques, which are covered under the regulations if the behavioral health organization is subcontracted to a "managed care plan" rather than a fee-for-service plan. The distinction, of course, is irrelevant to the subscriber who happens to encounter a mental health problem.

Solution: We suggest adding a subsection (c) to clarify that when an otherwise-exempt plan separately manages or subcontracts the management of certain conditions or types of conditions, the regulations will apply to that portion of the health care plan which functions as a managed care plan.

### § 154.2 Definitions

The definition of "managed care plan" is, of course central to the scope of the Act. The definition is even more critical if the Department agrees that the "carved out" portion of an otherwise exempt plan - or a free-standing behavioral health care plan - is covered when the carved-out portion meets the definition of "managed care plan," as we have suggested.

"Managed Care Plan" - On its own, the definition seems reasonable. However, it references the use of a "gatekeeper," so the definition of "gatekeeper" becomes critical.

"Gatekeeper" - This definition is very helpful in that it recognizes a plan, or its agent, as gatekeepers in addition to the more common understanding of a gatekeeper as a primary care physician serving as the source of basic care and referrals. Decisions about basic care and referrals for patients seeking mental health services are often made by someone other than the Primary Care Provider making those decisions for the patient's other health care needs.

However, since the definition of "gatekeeper" references "primary care providers," and plans and agents serving as primary care providers, it is necessary to examine the definition of "primary care provider" to make sure that what these behavioral health plans and agents actually do is consistent with the definition of "primary care provider."

"Primary Care Provider" - The definition of "primary care provider" is a "health care provider" who performs specific, listed activities. Plans and agents of the plan operating carved-out behavioral

health delivery systems are unlikely to meet the definition of "health care provider," a term restricted to facilities and individuals licensed to provide health care services. Health care plans are not so licensed, nor, necessarily, are their agents. This may not be problematic, since the gatekeeper definition covers plans and agents "serving as" the primary care provider. A common-sense reading would indicate that the plan or its agents would not need to meet the definition of "health care provider" in order to "serve" as the primary care provider for gatekeeping purposes.

We recommend and request, however, that the regulations clarify this point.

Second, and potentially more problematic, the functions used to define "primary care provider" are idiosyncratic to systems of care which seek to centralize responsibility or oversight of all of a patient's health care needs in one provider. When mental health care is carved out of that system and treated separately by a plan or subcontracted agent "acting as" the primary care provider, certain responsibilities associated with primary care providers are either absent or exist in a different form. For example, a behavioral health organization is not responsible for continuity of care in the manner of primary care providers who oversee all aspects of a patient's health, because the behavioral health organization only deals with one aspect of the patient's health. As another example, referrals are handled in a variety of ways.

Solution: Since the listed functions defining "primary care provider" are not exactly accurate as a description of the basic primary care function as it is performed in "carved out" behavioral health plans, we recommend that the regulations clarify that plans and their agents are deemed to be "serving as" the primary care provider when they perform any of the listed or similar functions under the "primary care provider" definition. An alternative solution would be a statement to the effect that plans and agents "serving as the primary care provider" need not strictly meet the definition of "primary care provider" in order to be considered gatekeepers.

#### § 154.11 Managed care plan requirements

Subsections (b) (1) and (2) allow managed care plans to establish time restrictions on approved treatment plans which include standing referrals, and requirements that treatment plans be periodically reviewed and re-approved by the plan. These practices are already common in the utilization management of behavioral health care. Unfortunately, the time restrictions and frequency of reviews are sometimes so excessive and burdensome that they discourage requests for treatment which would meet medical necessity criteria.

The regulation should be amended to include a reasonableness standard consistent with the standard of practice of the medical community.

#### § 154.15 Continuity of Care

Subsection (g) (6) allows managed care plans to require nonparticipating or terminating providers to give "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."

This subsection omits any requirement for patient permission. Although the Act itself requires managed care plans to adhere to all applicable laws and professional ethical standards regarding the confidentiality of records, this regulation, read out of context, will likely be used to improperly compel production of actual records without the informed, signed consent of the patient and other requirements

of federal and state law. Further, the plan's need to have a copy of the entire record, as opposed to the primary care provider's need, is questionable and problematic for many mental health patients.

We recommend that subsection (g) (6) be amended to include the patient's consent and adherence to all applicable laws, regulations, and professional ethical standards, as required by the Act. We also recommend that the requirement be restricted to the primary care physician or, in the case of specialty care, to the specialist who will be providing services to the enrollee - not to the plan itself.

#### § 154.18 Prompt payment

Subsection (a) requires insurers and plans to pay clean claims within 45 days of receipt of the clean claim. The regulations should describe some method for determining or assuming the date of receipt.

We recommend that subsection (a) be amended to allow the use of either three business days past the mailing date, or the date of receipt as indicated on the return-receipt from a certified mailing.

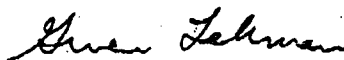
Subsection (e) requires providers to contact insurers to inquire about unpaid claims before filing a complaint with the Department. Although it is reasonable to require some good faith effort to resolve the matter prior to filing a complaint, it is not reasonable to place the entire burden on the provider. The provider, after all, is the one to whom something is owed.

We recommend that the regulations be amended to require insurers to notify providers of all deficiencies in their claims within ten working days of receipt. The regulation should specify that all deficiencies should be revealed at the same time, to avoid the all-too-frequent situation where a provider finds out a claim is deficient, fixes the problem, resubmits the bill, receives no payment, inquires again, and is told of another problem.

In support of our ten-day notification recommendation, we would point out that the "threat" of having to pay interest on unpaid clean claims is unlikely to help the private practitioner who sees many patients in the office and files a large number of small claims. Few of those claims are likely to reach the \$2 interest threshold (a \$100 claim paid one month late, at 10%, will incur less than \$1 in interest), but in the aggregate the physician may be owed thousands of dollars.

In closing, we want to thank the Department again for the sensitivity it has shown to the particular issues which we raised in the past, and to express our hope that our comments here will be useful in further refining the regulatory language to accomplish the stated purpose of the Act.

Sincerely yours,



Gwen Yackee Lehman  
Executive Director

cc: Lee C. Miller, MD  
John Jewett, IRRC  
The Honorable Nicholas Micozzie  
Gregory Martino, DOI

gyl/govt/68DOtrcp

National Association on Admin. Rules Review  
Mr. Frank J. Ertz Executive Director

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# Facsimile Cover Sheet



**To:** John H. Jewett.  
**Company:** IRRC  
**Phone:**  
**Fax:** 783-2664

**From:** Gwen Lehman  
**Company:** Pennsylvania Psychiatric Society  
**Phone:** 717-558-7750  
**Fax:** 717-558-7845

**Date:** Aug. 30, 1999  
**Pages including this cover page:** 5

**Comments:** These are the Pennsylvania Psychiatric Society's comments on the proposed regulations for Act 68. I am also sending a copy by mail.

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## Pennsylvania MEDICAL SOCIETY®

August 26, 1999

Mr. Peter J. Salvatore  
Regulatory Coordinator  
Department of Insurance  
1326 Strawberry Square  
Harrisburg, PA 17120

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JITENDRA M. DESAI, MD  
*Secretary*

ROGER F. MECUM  
*Executive Vice President*

Re: Pennsylvania Bulletin: Vol 29, July 31, 1999, Insurance Department: Quality Health Care  
Accountability and Protection; proposed regulations.

Dear Mr. Salvatore:

On behalf of the Pennsylvania Medical Society, the largest physician organization in the Commonwealth, I am submitting comments and recommendations related to the above captioned proposed regulations. These proposed regulations are intended to implement provisions of the Quality Health Care Accountability and Protection Act (Act 68 of 1998).

At the outset, I would like to compliment the Insurance Department for its openness during the drafting process and its willingness to share working drafts of the proposed regulations with interested stakeholders for input prior to submission for formal public comment through publication in the Pennsylvania Bulletin.

I will discuss first several issues which should be addressed in further detail in the regulations. I will also offer the Medical Society's comments and recommendations on specific sections of the proposed regulations.

### *§ 154.1 Applicability and Purpose*

Act 68 defines "managed care plans." The regulations repeat that definition and add examples. Unfortunately, there is no means for the Department to verify what entities are or aren't covered by the Act. The Medical Society was recently contacted by a physician's office who had received correspondence indicating that a number of their patient's employers "have elected not to abide by the provisions of Act 68." The Insurance Department was asked for clarification and was told that the employers named were in fact exempted from Act 68 either as self insured plans or as otherwise excluded because of federal (ERISA) protections.

The Department doesn't maintain a listing of plans or entities exempt from Act 68. Knowledge of the specific local employers mentioned in the correspondence enabled the Department to respond to the Society's inquiry.

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Office of Special Projects

**The Medical Society recommends that the Department identify plans and entities that it (the Department) believes should be included under Act 68. That list should be available to the public, including health care providers, upon request. The Department should also be required to determine what plans and entities are in fact exempt from the provisions of the Act.**

*§ 154.2 Definitions*

The Act defines "clean claim" as "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 payment being made on the claim."

The Medical Society is aware that, in other states where timely payments requirements similar to Act 68 have been legislated, there have been problems over the interpretation of what constitutes a clean claim. The Uniform Claim Form (Health Care Financing Administration (HCFA) 1500) has multiple lines for the physician to list services provided. Each of those services is a request for payment. What some insurers had done in other states is to suspend payment of a reported service but also not pay for other services listed on the same HCFA 1500.

The Department has attempted to correct that potential problem by including under section 154.18(d) language stating that "the prompt payment requirement of the Act also applies to the uncontested portion of a contested claim." The Medical Society thanks the Department for that language.

**The Medical Society would suggest that further clarification be included under the clean claim definition by stating that each service listed on the HCFA 1500 be considered a claim. The Society recommends the addition of the following language "a claim is (1) a bill for service (2) a line item of service or, (3) all services for one recipient within a bill.**

The Medical Society is also concerned that there is no stipulation requiring the payer to notify the provider that a claim has been suspended for lack of information, etc. Experiences in other states have been that the payer doesn't inform the provider that a claim is suspended as unclear or doesn't provide the reason(s) for the suspension.

**The Society believes that the Insurance regulations should require payers to notify providers in a timely manner, which should be defined, when a claim is suspended and provide all of the reasons for suspension, especially when there may be more than one reason.**

The requirements for provider access to the grievance process under the definition section, needs clarification. Normally, when a patient presents to a provider for treatment, he or she offers proof of insurance to be used to reimburse the provider for that care. The service is rendered and a claim is submitted for reimbursement. If the claim is subsequently challenged for medical necessity reasons, the provider should not be precluded from being able to defend the claim. The Society is concerned that the language of the statute and the regulations may be narrowly interpreted to require a written consent from the enrollee at the time the application for grievance is made. This would place an unnecessary burden on the provider and the patient, and may prevent the provider from pursuing a legitimate grievance. Securing a new consent from the patient could also delay the timing of the submission of the grievance.

**The Medical Society suggests that the consent to treatment approval by the patient be permitted to serve as authorization to pursue the claim with the patient's insurer in the event of a medical necessity denial.**

The Society doesn't object to informing the patient of the provider's intention to seek a grievance, both as continuation of the patient-physician relationship and to avoid duplicate filing of a grievance. The Society does object to an added requirement to seek the patient's consent to fight for payment of the provider's claim. Use of the consent to treatment or authorization by the patient to submit a claim for payment is not unlike the insurers' contention that submission of a claim by a subscriber authorizes the insurer to obtain information and to act to adjudicate that claim.

#### *§ 154.16 Information for Enrollees*

The next issue relates to requirements for disclosure of information for enrollees. Section 154.16 of the proposed regulations outlines the general disclosure requirements for enrollee information. Subsection (h) describes some of the specific information to be supplied to enrollees, prospective enrollees, and health care providers. Such information includes a description of emergency services, how to access care, etc.

The Medical Society believes that the list of information to be disclosed should include the plans' definition of "medical necessity," as approved by the Department of Health. Just as the definition of "emergency services" describes how such services are accessed, a medical necessity definition permits the enrollee and the provider to understand the rationale to be used by the plan to determine whether or not the care rendered was necessary.

**The Medical Society requests that the plan's definition of "medical necessity", as approved by the Department of Health, be disclosed to the enrollee and, upon request, to the health care provider.**

#### *§154.18 Prompt Payment*

Last but certainly not least, is the process for investigation and adjudication of complaints involving timely payment. As mentioned previously, other states which have implemented a timely payment requirement are having a variety of problems enforcing the provision.

The first problem is determining when the 45 days begins. Is it the date the providers' office submits the claim, the date of receipt of the claim by the insurer, or the date the insurer determines the claim is "clean" and refers the claim for processing?

The Medical Society has suggested that the date starting the 45 day clock should be the date the claim was submitted by the provider. Allowance should be made for time of mail delivery, i.e. three days at either end of the process. Insurers should be required to give the provider notice of claims suspended and the reasons for suspension in a timely manner (may require Insurance Department to define "timely"). The time taken by the insurer for such notification should not be deducted from the 45 day limit.

I would like to recount a recent experience with the timely payment complaint process. I believe the experience points out problems which weren't anticipated when the language of Act 68 was crafted or when the Insurance Department developed its process for investigating timely payment complaints.

In May, the Medical Society became aware of a situation where a large health care insurer had experienced a major computer malfunction which prevented the insurer from entering new covered patients into the system, correctly identifying participating providers within the network, and processing claims. At the time we heard of the problem, many providers' claims were well over the 45 day time limit, some claims were over 5 months old.

The Society immediately informed the Insurance Department of the situation but were told that the complaints had to be filed by individual physicians. Further, complaints had to be for specific claims and not be submitted as a collective complaint representing numerous claims or providers.

Fortunately, several physicians had already written to the Insurance Commissioner and the investigations were undertaken.

Approximately one month later the insurer notified participating providers of their problem (to the Society's knowledge, the first acknowledgement of the problem since it occurred in early April) and the steps being taken to correct the problem. The notification gave no assurances as to when the problem would be corrected or how previously submitted claims would be processed or recreated if necessary.

My reason for citing this experience is to point out that more attention and resources from the Insurance Department are needed to aggressively deal with the timely payment problem. The insurer in question operates in over ½ of the state. The payment problems affected thousands of physicians and other provider practices. The delayed payments and associated interest due amounted to millions of dollars. The problems with past claims which were submitted during the malfunction may never be addressed. Claims for patients never entered into the system or from providers inaccurately identified as non network providers may not be settled or may have to be resubmitted. Calculations of correct payment and interest must be made and verified for accuracy. Correction of these problems demands the active involvement of the Department.

**The Medical Society recommends that the following remedies and solutions should be added to the Insurance regulations to correct problems which may arise in the implementation of Act 68:**

- A requirement for insurer notification of network and non-network providers of any suspension of claims or situations affecting processing of the claim. Notification must include a proposed time for completion of claim processing and what, if any, information from the provider is required

- A requirement for Insurer notification of the Insurance Department of any interruption of services including processing of claims.
- A requirement for uniformity of complaint submission (Development of a Department complaint form and complaint tracking mechanism is needed.)
- A requirement for regular communication between insurers and providers during any prolonged payment difficulties.
- Providing an opportunity to batch complaints related to the timely payment of claims by services and/or provider.
- Pursuit of penalties and other disciplinary actions against insurers with pattern of abuse of timely payment provisions.
- A survey, conducted by the Insurance Department, of insurers and providers to determine compliance with timely payment requirements.

The remainder of the Medical Society's comments relate to specific sections of the proposed regulations.

*154.12(b) Direct enrollee access to obstetrical and gynecological services.*

The Department has confused "enrollee access to ob/gyn services" with the providers' requirement for prior authorization of services.

**The Medical Society supports the Pennsylvania Section of the American College of Obstetricians in recommending that only services, such as reproductive endocrinology, gynecologic oncology, and maternal and fetal medicine, should have restrictions as to enrollee access.**

*154.12(c) Informing primary care providers within 30 days.*

The Medical Society believes that services other than those related to a pregnancy should be reported to the enrollee's primary care provider every 30 days. However, the report visits during pregnancy and related services would place an unnecessary reporting burden and would offer little usable information to the primary care provider.

**The Medical Society recommends that section 154.12 (c) be amended to require the obstetrician gynecologist to provide a report to the primary care provider which covers the duration of the enrollee's pregnancy following the postpartum visit. Other conditions not related to the pregnancy could be reported within 30 days.**

*154.15 (e) (2) AND (G) (5) Continuity of care and the use of participating providers.*

These subsections require clarification 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.

Situations may arise where the physician providing care under the continuity of care provision doesn't have privileges at a network facility approved by the enrollee's new plan. There may also be situations where the provider may be part of a highly specialized treatment

team or the provider may require a specific subspecialty referral or ancillary service which is not part of the plan's network.

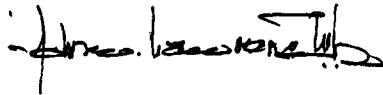
Subsections (e) (2) and (g) (5) would be restrictive and would preclude the enrollee from accessing appropriate care.

**The Medical Society recommends that Section 154.15 (e) (2) be amended by the addition of the following after the word "enrollees" consistent with the health care needs of the enrollee, as determined by the provider.**

**The Medical Society further recommends that Section 154.15 (g) (5) be deleted from the proposed regulations.**

The Pennsylvania Medical Society appreciates the opportunity to comment on these proposed regulations. If you have any questions or would like to discuss the Society's comments further, please contact Mr. Donald McCoy, the Society's Director of Policy and Regulatory Affairs.

Sincerely,



John W. Lawrence, MD  
President

Cc: Deputy Commissioner Gregg Martino  
The Honorable Nicholas Micozzie  
Independent Regulatory Review Commission

DNM/doc/cor/Salvatore



**COMMONWEALTH OF PENNSYLVANIA  
INSURANCE DEPARTMENT**

OFFICE OF SPECIAL PROJECTS  
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August 30, 1999

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

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

Dear Mr. Nyce:

Pursuant to Section 5(c) of the Regulatory Review Act, the Department is required to submit all comments on proposed regulations received during the public comment period to the Independent Regulatory Review Commission and the Legislative Standing Committees within 5 days.

Attached is a list of commentators that have submitted comment on the above-mentioned regulation and the respective comment that was received.

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

Sincerely yours,

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

Peter J. Salvatore  
Regulatory Coordinator



**Comments on the regulation listed below have been received from the following:**

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

---

**Ms. Ann S. Torregrossa , Esq.**  
**Pennsylvania Health Law Project**  
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**Philadelphia PA 19107-**

**Date Received      8/30/1999**

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August 30, 1999

VIA E-MAIL, FACSIMILE, AND U.S. MAIL

Peter J. Salvatore  
Regulatory Coordinator  
PA Department of Insurance  
1326 Strawberry Square  
Harrisburg, PA 17120

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AUG 30 1999

Office of Special Projects

Re: **Comments to Proposed Rules on Act 68  
31 PA Code Chapter 154**

Dear Mr. Salvatore,

Enclosed please find our comments to the Department's proposed rules regarding Quality Health Care Accountability and Protection published in the Pennsylvania Bulletin on July 31, 1999 at pages 4064-4071. We submit these comments on behalf of our clients, the Consumer Health Coalition and the Armstrong County Low-Income Rights Organization.

We have enclosed the following: (1) a summary of the aspects of the proposed regulations that we support and (2) a summary of the aspects of the proposed regulations which we believe need improvement along with line by line suggested revisions.

We want to note up front how difficult it is to comment on the Department's rules without knowing the content or the scope of the Department of Health's (hereinafter "DOH") proposed rules on the Act. Our office reviewed and commented on DOH's Draft Regulations and we find it confusing that the Department's proposed rules overlap and are inconsistent on their face with the DOH's draft regulations. For example, each Department has proposed different definitions for terms such as "complaint", "gatekeeper" and "utilization review". How and when will these differences be resolved? In addition, the format and organization of the Department's proposed rules is very different from that of the DOH draft regulations which makes it almost impossible to reconcile the two to determine if there are gaps, inconsistencies,

etc. We urge you to allow another opportunity for comment once the DOH and DOI proposed rules are combined and prior to their being finalized.

Please do not hesitate to call us with any questions.

Very Truly Yours,

Ann S. Torregrossa, Esq.  
Mike Campbell, Esq.  
Fran Chervenak, Esq.  
David Gates, Esq.  
Alissa Eden Halperin, J.D.  
Attorneys For The Consumer Health  
Coalition and The Armstrong County Low  
Income Rights Organization

**THE PENNSYLVANIA HEALTH LAW PROJECT'S COMMENTS TO THE  
DEPARTMENT OF INSURANCE'S PROPOSED REGULATIONS REGARDING  
QUALITY HEALTH CARE ACCOUNTABILITY AND PROTECTION PUBLISHED IN  
THE PENNSYLVANIA BULLETIN ON JULY 31, 1999 - FILED ON BEHALF OF OUR  
CLIENTS THE CONSUMER HEALTH COALITION AND THE ARMSTRONG  
COUNTY LOW INCOME RIGHTS ORGANIZATION**

**I. PROVISIONS OF THE DEPARTMENT OF INSURANCE'S ACT 68  
REGULATIONS THAT ARE BENEFICIAL TO CONSUMERS.**

The Department of Insurance's Proposed Regulations for Act 68 establish a framework of requirements to be followed by managed care plans and licensed insurers in their provision of health care services to enrollees and members. Regulations for Act 68 are of great importance to implement the consumer protections contained in the Managed Care Accountability Act.

The following proposed regulations are particularly important to properly implement Act 68's consumer protections and should be retained.

**1. Definitions.**

- Managed care plans that use "passive gatekeepers" are no longer excluded from the term "managed care plan" as they were in the draft regulations. As a result, those enrolled with "passive gatekeeper" plans will also be afforded the protections set forth in ACT 68.

**2. Section 154.12, Direct Enrollee Access to Obstetrical and Gynecological Services:**

- The enrollee's direct access to obstetrical and gynecological services as provided in the act appropriately include access to nurse midwives and other advance nursing practitioners. The regulations specify that services covered are not limited to routine visits but include visits for both wellness and for gynecological symptoms. These provisions are essential to assure direct access to early detection and prevention care for women and to prenatal care for expectant mothers.

**3. Section 154.14, Emergency Services:**

- This section requires that plans include in member handbooks and other enrollee materials information clearly indicating that prior contact with the plan is not required in an emergency situation. Clear language informing enrollees that there is no need to call their plan prior to seeking emergency services is an important part of preventing unnecessary delays or confusion to enrollees seeking and requiring emergency services.

**4. Section 154.15, Continuity of Care:**

- This section allows plans to extend transitional periods (where clinically appropriate), requires plans to forego credentialing of non-participating providers, and requires plans to provide non-participating providers with written plans to which they will be required to agree in writing. These provisions improve access to ongoing treatment allowing for the continuity of care required by the Act and eliminate health risks involved in interruptions in necessary treatment.

**5. Section 154.17, Complaints:**

- Section 154.17(a)(2) no longer classifies issues of experimental treatment as a complaint. This would provide an enrollee with the opportunity to proceed through an expedited grievance process and receive a decision on the issue within 5 days on life threatening issues. Clearly, the legislature did not intend for an enrollee in a life threatening situation to have to wait 30-40 days to have his or her complaint decided and, thus, classifying such disputes as grievances provides the enrollee with the protections intended in the act. Presumably this means that issues of experimental treatment will be listed in the Department of Health's regulations as appropriate for the grievance process.
- 154.17(f). The inclusion of the requirement that the notification to the enrollee include the procedure to file a request for a second level review is most important. Enrollees must be informed of their rights throughout each stage of the complaint process.
- The draft regulations had provided that managed care plans could require enrollees to utilize the internal and external grievance process before filing a court case. Recognizing that the Department had no legal authority for such a provision, and that it went well beyond the Act itself, the Department complied with its "strict constructionist" approach and deleted that language. What, if any, procedures a party must exhaust prior to proceeding with litigation is a matter best left to the courts.
- The 30 day time period for enrollees to file first and second level complaints is clarified now that the "5 day presumed delivery rule" has been deleted. The draft regulations had specified that a complaint was considered received by a plan 5 days after it was mailed. That presumption effectively reduced an enrollee's time to appeal from 30 to 25 days. The deletion of the presumed delivery rule leaves the 30 day time period intact. However, the rules must also clarify when the 30 day time period begins. (see below)

**II. PROVISIONS OF THE DEPARTMENT OF INSURANCE'S ACT 68 REGULATIONS THAT NEED REVISION TO EFFECTUATE THE GENERAL ASSEMBLY'S INTENT TO PROTECT AND BENEFIT CONSUMERS.**

**SECTION 154.2, DEFINITIONS**

This section of the proposed rules is absolutely necessary to provide greater clarity and understanding of both the Act and its intent, as well as to provide clear guidance of the Department's intent and expectations regarding these rules. Clear, accurate definitions are critical to proper and uniform implementation of the Act and its regulations.

**A. The regulations need further clarification to protect consumers.**

1. The definition of “ongoing course of treatment” excludes a course of treatment for a combination of impairments/diagnosis. The definition is not as clear, and is inexplicably narrower than the previous definition found in the draft regulations. There is no reason to confine the definition to treatment which “arises out of a single diagnosis” and thereby eliminate a course of treatment for dual diagnoses or a combination of impairments/diagnoses. The previous definition offered in the draft regulations should be adopted.
2. The definition of “enrollee” could preclude parents, attorneys, or others to act on behalf of the enrollee to protect his/her rights. The definition of “enrollee” should be expanded to include parents designees or legal representatives. This clarity is needed to reflect and acknowledge the reality that when the rules state “an enrollee” may request something (i.e. a standing referral), or do something (i.e. file a complaint), the actor or requestor will often be someone who is not a member of the plan but is someone legally entitled to act on behalf of the member.
3. The definition of “gatekeeper” is unclear. The definition of “gatekeeper” must be clarified. At the end of the definition, the Department includes the phrase “as a precondition to receiving the highest level of coverage available under the managed care plan”. The meaning of that phrase is not clear and it therefore adds considerable ambiguity to the definition. The phrase, particularly the reference to “the highest level of coverage available”, should either be clarified or deleted.

**B. The regulations fail to ensure proper implementation of the Act**

1. The definition of “complaint” should be amended to include not only a dispute or objection regarding a participating health care provider, but also “a plan authorized non-participating provider”. Enrollees may be receiving services from an out of network provider which have been authorized by their managed care plan. In such cases, enrollees should be able to file a complaint regarding that provider as well. Under the Act, those non participating providers are required to agree to the same terms and conditions as the plan requires of its participating providers. Sec. 2117(E)
2. Grievances are under the jurisdiction of the Department of Health. It has issued draft proposed regulations defining “grievance” (which differs from the Department’s proposed definition) and other regulatory provisions relating to grievances. Accordingly, there is no reason to include grievance provisions in the Department’s rules. To avoid conflict and confusion, the definition of “grievance” in the proposed rules should be withdrawn.

## **SUGGESTED REGULATORY LANGUAGE CHANGES**

### **FOR SECTION 154.2, DEFINITIONS**

The proposed regulations should be revised and amended as follows (new language is in bold):

#### **154.2, Definitions.**

***Cause-*** the reason or reasons a managed care plan is terminating a contract with a participating health care provider which constitute serious grounds for the contract termination, including breach of contract, fraud, criminal activity or posing a danger to an enrollee or the health, safety or welfare of the public as determined by the plan. This definition only applies to continuity of care issues under Sec. 154.15 and is not intended to apply to other legal issues between the managed care plan and the provider such as issues relating to excess provider capacity or expiration of the contract term.

***Complaint-*** (i) A dispute or objection regarding a participating health care provider, or a plan authorized non-participating 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.

***Enrollee-***A policyholder, subscriber, covered person or other individual who is entitled to receive health care services under a managed care plan. 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-*** (i) As provided in section 2161 of the act (40 P.S. sec 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.~~

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

~~*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 health care service provided to an enrollee by a health care provider which was initiated prior to either (i) a managed care plan's termination of its contract with the provider for reasons other than cause as defined by these regulations, or (ii) the enrollee's entrance into a managed care plan as a new member, and will be continuing after the occurrence of (i) or (ii).~~

### **SECTION 154.11. STANDING REFERRALS**

For persons with life-threatening, degenerative or disabling conditions, the Standing Referral Section of Act 68 is one of utmost importance. This provision was adopted by the General Assembly to cure the many barriers faced by persons needing ongoing specialist care when plans require repeated prior authorizations and PCP referrals which delay or deny needed care. For instance, immediate access to ongoing specialist care for persons with life threatening conditions such as HIV/AIDS is essential when opportunistic infections threaten their lives. The proposed regulations do not ensure or require the access to standing referrals that the General Assembly intended in Act 68.

**A. Section 2111(6) of the Act should be governed by DOH regulations, not those of DOI.**

- 1. DOH has the expertise to monitor compliance with this Section.** The Department of Health, not the Department of Insurance, should oversee access to specialist care for persons with life-threatening conditions. The Department of Insurance is not equipped to deal with the medical and quality of care issues that are involved with monitoring plan compliance with the standing referral requirements of Act 68. They do not have the expertise to review disputes about whether a condition is life-threatening, or so degenerative or disabling that standing specialist care is needed.
- 2. An expedited grievance process is needed in life-threatening situations.** Disputes between plans and enrollees seeking specialist care under Section 2111(6) should be governed by the grievance process, not the complaint process. This would permit expedited appeals in life-threatening situations where the denial of this kind of specialist care further jeopardizes the life of the enrollee. If this provision is left with DOI and the complaint process, it will take several months before the Department of Insurance would receive the issue for review.



3. Denials by plans of standing referrals will generally be based on medical necessity and thus should be under DOH and the grievance process. Most denials by the plan of requests for standing referrals will be based on a determination by the plan that such a referral is not medically necessary. Therefore the DOH monitoring and grievance process should be used.

**B. The proposed regulations do not contain reasonable regulatory requirements to ensure that plans properly implement and evenly provide standing referrals as required by Section 2111(6) of Act 68.**

1. The proposed regulations require no review of the managed care procedures for approval of requests for standing referrals to determine if they comply with Section 2111(6) of the Act. Our experience under the Department of Welfare's HealthChoices SE Program shows the need for a level playing field for all plans and clear, uniform procedures and criteria on such an important issue as whether persons with special needs can obtain regular specialist care. Under the HealthChoices Program, plans were required to allow persons with special conditions best managed by a specialist, apply to have a specialist as PCP and the requests were to be granted if the condition was best managed by a specialist. After one year's operation of the HealthChoices SE Program, DPW found that two of the four licensed HMOs were not following the procedure at all and thus no special needs persons in those plans had been granted specialists as PCPs. Of the two other plans, one plan had granted 285 requests and the other only 2. To implement the standing referral section of Action 68, it is absolutely imperative that Plans be required to submit their standing referral procedures for review to DOH and to report annually the number of requests received and the number of requests denied.
2. The proposed regulations require no standards for the procedure plans will use for requests for standing referrals or specialist coordination.
  - a. There are no timeframes for decisions. There are no timeframes during which a plan must respond to such a request. This can lead to the same result that occurred in two of the HealthChoices plans. Plans need simply not respond to a request and there will be no denial from which to appeal. Nonetheless, enrollees with life-threatening and other qualifying conditions will go without the specialist services mandated by Act 68. Requests for standing referrals should be made within 5 business days or sooner, given the serious, ongoing need for specialist care that those making the request may have.
  - b. There is no standard criteria plans must use to determine if a request for standing referral should be granted. Plans could determine criteria that no enrollee could meet, thus avoiding the requirements of Act 68. Plans should be required to grant standing referrals to specialists or care coordination by specialists where the enrollee has a condition as described by Section

2111(6) and this condition needs involvement by the specialist to best manage the condition of the enrollee.

- c. There is no requirement of disclosure of the criteria for approval. Enrollees cannot possibly present evidence of the need of a standing referral if the elements that must be established are secret.
- d. There is no requirement of a written decision and notification of the right and the means to file a grievance. Any denial of a request for standing referral is a denial of care, and enrollees should be advised of how to appeal such a denial.
- e. There is no requirement of approval by the enrollee, PCP and specialist of a treatment plan as is require by the Act. Section 2111(6) of the Act states:  
The referral to or designation of a specialist shall be pursuant to a treatment plan approved by the managed care plan, in consultation with the primary care provider, the enrollee, and, as appropriate, the specialist.  
This provision should be contained in the regulations.

**C. The proposed regulations impose barriers to standing referrals not permitted by the Act. Instead of proposing regulations that further the legislative intention of this section, the proposed regulations permit plans to impose additional, burdensome barriers to enrollees not permitted by Act 68.**

1. Time restrictions on Standing Referrals should only be allowed in limited circumstances. Section 154.11(b)(1) allows plans to impose time restrictions on the standing referrals. There is no requirement that these time restrictions be reasonable or based on a determination of an estimated time when a standing referral may no longer needed. Plans could set such short time restrictions for standing referrals that they would no longer be standing. The final regulations should not permit time restrictions for standing referrals unless there is some basis to believe that the enrollee will no longer qualify for or need a standing referral at the end of the time period. The final regulations should place limits on the frequency of review and reapproval.
2. Unlimited periodic review and reapproval of treatment plans by the plans thwarts enrollee access to specialists provided in the Act. The proposed regulations permit plans to review and disapprove treatment plans, including the provision of the standing referral, as often as they wish. This could result in a situation that is no better than that which Section 2111(6) sought to cure. Plans could review treatment plans every five days, could require burdensome documentation from specialists and enrollees, over and over again and could thereby thwart the access to standing specialist referrals and their treatment called for by the Act.

The Standing Referral proposed regulations negate the protections bestowed by Act 68 for persons with serious ongoing health care needs best managed by a specialist. It is essential

that the regulations be drastically changed if managed care plans are to be safe places for persons with serious chronic conditions to receive health care in Pennsylvania.

### **SUGGESTED REGULATORY LANGUAGE CHANGES**

#### **FOR SECTION 154.11, MANAGED CARE PLAN REQUIREMENTS**

The proposed regulations should be revised and amended as follows (new language is in bold):

**This section, § 154.11. Managed care plan requirements, should be included in the Department of Health's Regulation, not the Department of Insurance.**

- (a) Managed care plans shall adopt and maintain procedures by which an enrollee with a life-threatening, degenerative or disabling disease or condition shall, upon request, receive an evaluation, and, if the plan's established standards are met, be permitted to receive either:
  - (1) A standing referral to a specialist with clinical expertise in treating the disease or condition.
  - (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) 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.**
  - (2) Requirements that treatment plans be periodically reviewed and reapproved by the plan **based on a reasonable determination of when noteworthy changes in conditions can be anticipated that would merit such a review and reapproval.**
  - (3) Requirements that the specialist notify the enrollee's primary care provider of all care provided **at reasonable intervals.**
- (c) **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.**
- (d) **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.**

- (e) **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.**

**154.12 (DIRECT ENROLLEE ACCESS TO OB/GYN SERVICES)**

The Direct Enrollee Access to OB/GYN Services Section of Act 68 is an important section for women. This provision was adopted by the General Assembly to insure achievement of the highest possible levels of prenatal care, early detection and prevention, and overall female reproductive health. The General Assembly perceived the prior obstacles of indirect access to OB/GYN services as injurious to consumers and unnecessary impediments to accessing necessary care. The proposed regulations do not ensure the full extent of direct access intended by the General Assembly.

- A. **The proposed regulations place limitations on Direct Enrollee Access to Obstetrical and Gynecological Services that are not permitted by Act 68.**
1. **Prior authorization may only be required for services that are outside the scope of practice for an OB/GYN.** This section requires prior authorization for some OB/GYN services. The proposed regulations state "A managed care plan may require an obstetrical or gynecological provider to obtain prior authorization for selected services such as diagnostic testing or subspecialty care - for example, reproductive endocrinology, oncologic gynecology and maternal and fetal medicine." This provision is contrary to §2111(7) of the Act which only allows MCOs to require prior authorization where the services are outside the scope of practice for an OB/GYN. These services, although ambiguously stated, are well within the scope of practice of an OB/GYN and, thus, prior authorization may not be required. In order to insure achievement of the highest possible levels of prenatal care, early detection and prevention, and overall female reproductive health, all obstacles to such care must be eliminated as called for by §2111 of the Act.
  2. **DOH has the expertise to resolve disputes over whether services are outside the scope of practice for an OB/GYN.** The Department of Insurance is not equipped to deal with the medical and quality of care issues involved in determining whether services are outside the scope of practice for an OB/GYN. Department staff do not have the expertise. Accordingly, 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.
  3. **Consumers may be improperly charged for directly obtained OB/GYN services.** This section requires the provider to notify the enrollee's PCP of the provision of obstetrical or gynecological services within 30 days of the services being provided to the enrollee. The regulations should provide that enrollees must be held

harmless for any provider charges denied by their plan as a result of the OB/GYN's failure to notify the patient's plan as required by this section. Enrollees have no control over whether their OB/GYN reports services in a timely manner.

4. The requirement that providers report within 30 days after each service provided is burdensome and inconsistent with the lump sum payment method. Where an enrollee has been receiving ongoing treatment or services, a provider may communicate with the plan once every 60 days to provide information on all health care services provided to the enrollee within the prior 60 days. This keeps the plan informed of services being provided but limits the cumbersome nature of requiring providers to report after each service during a pregnancy, for example.
5. The regulations do not set forth the level of coverage for direct referral to non-participating providers. The draft regulations provide that "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." The previous draft stated, "if an enrollee utilizes a non-participating provider for these services, the services may be covered at the lower self-referred benefit level." This provision should be retained to ensure plans which permit the option of direct referral to non-participating providers, cover those services at the appropriate level.

**B. Limitations placed on services must be disclosed to enrollees.**

1. Any permissible limitations must be disclosed. The Act and Proposed Regulations limit direct enrollee access to Obstetrical and Gynecological Services to services by participating providers. 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 154.16(h). Any materials describing this direct access must inform enrollees of this limitation.

**SUGGESTED REGULATORY LANGUAGE CHANGES**

**FOR SECTION 154.12, DIRECT ENROLLEE ACCESS TO OBSTETRICAL AND GYNECOLOGICAL SERVICES.**

The proposed regulations should be revised and amended as follows (new language is in bold):

**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. Any written materials describing this direct access in accordance with §154.16(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.

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

(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. 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.

(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. If an enrollee utilizes a non-participating provider for these services, the services may be covered at the lower self-referred benefit level.

### **SECTION 154.13: PLAN REPORTING OF COMPLAINTS AND GRIEVANCES**

The filing of grievances and complaints are one of the most important indicators of the kinds of problems that enrollees are having with their managed care plans. This is critical information that is necessary for both departments to effectively monitor the managed care plan's compliance with Act 68. The General Assembly recognized this and required detailed reporting by all managed care plans of grievance and complaint information to the Departments of Health and Insurance. Section 2111(13) of Act 68 requires managed care

plans to report information to the Department of Health and the Department of Insurance with respect to the number, type and disposition of all complaints and grievances filed with the managed care plan. Section 154.13 of the draft regulations only requires plans to report complaint and grievance information utilizing the format utilized to report information prior to the effective date of the act.

**A. Utilization of the old reporting format does not comply with Act 68 requirements for the following reasons:**

1. The old report only went to the Department of Health. Information needs to go to both the Department of Health and the Department of Insurance.
2. The old report collected different information and is not appropriate for Section 2111(13) data collection purposes. Before Act 68 a complaint was entirely different than it is after Act 68. The old form does not indicate how many cases were appealed to the independent utilization review entity and the disposition of that appeal. Information should also be collected on the number of expedited grievances and their disposition.
3. The old report did not collect information on the type of complaint or grievance; just on the gross number. The General Assembly intended the Departments to utilize the reports of grievances by type required by Section 2111(13) of the Act to monitor for compliance with the various provisions of the Act. The previous report format did not collect this information by type of problem, but solely by gross number and whether the ultimate outcome was in favor of the enrollee or plan. The regulations must be changed to collect data by type of grievance, e.g., continuity of care, direct access to OBGYN, failure to provide information, etc.
4. The old report did not collect specific information on the disposition of the complaint or grievance. To be useful to Departmental monitoring, more detailed information is needed as to the disposition by type of problem.
5. The old report collected grievance information by plan, not by product line. It is critical that plans be required to report Section 2111(13) specific grievance and complaint information by product line, not by plan. This is particularly important to assist the Departments in monitoring whether the licensed HMOs are properly overseeing the unlicensed integrated delivery systems that often are at risk for health care provision. For instance, Independence Blue Cross is permitted to report consolidated grievance and complaint information under the old report format. It is impossible to determine which of the reported grievance or complaints are for the subcontracted mandatory Medicaid managed care contract to Keystone Mercy, which is an unlicensed managed care organization at financial risk for providing care to over 200,000 low income Pennsylvanians. It is critical that the Departments have this information to monitor whether these unlicensed, at risk organizations are complying with Act 68.

Now that Pennsylvania has a new bifurcated complaint and grievance process, it is critical that both Departments receive the specific detailed information mandated by Act 68 to enable them to monitor plan and integrated delivery system compliance with Act 68 and other licensure requirements.

### **SUGGESTED REGULATORY LANGUAGE CHANGES**

#### **FOR SECTION § 154.13. MANAGED CARE PLAN REPORTING OF COMPLAINTS AND GRIEVANCES.**

The proposed regulations should be revised and amended as follows (new language is in bold):

#### **§ 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.~~ **annually 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.**

(b) Notice of changes or amendments to the format required by the Department for reporting complaint and grievance information to the Department will be published 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)**

At the sudden onset of acute symptoms or severe pain, it is essential that an enrollee be able to directly and immediately access emergency services. This is why the Emergency Services Section of Act 68 is of grave import. The General Assembly adopted it to eliminate and to prevent obstacles to emergency services in potentially life threatening situations. In order to prevent obstacles or delays in enrollee receipt of emergency services, the regulations



must ensure and require the access to such services that the General Assembly intended in Act 68.

**A. The proposed regulations place limitations on Emergency Services that are not permitted by Act 68.**

1. The Proposed Regulations fail to require plans to use the exact Emergency Service definition in Act 68. The Draft regulations included the following provision (as 154.12(a)): "The act requires managed care plans to pay for emergency services based on the definition of emergency services set forth in the act and this chapter. 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." This language is missing from the proposed rule. While the Proposed Regulations state that "Managed care plans are prohibited from requiring that enrollees or health care providers obtain prior authorization for emergency services as defined by section 2101 of the act ...", specifically spelling out the definition in the regulations, as was done in the draft, can only help insure that the legislative intent be accomplished. The General Assembly clearly intended that it's definition of emergency services be specifically utilized. Permitting plans to use their own "concept of a prudent layperson" could lead to definitions of emergency service contrary to the Act.
2. The regulations must clearly mandate each plan to determine whether the costs of emergency services were reasonably necessary at the time of the emergency. Although the proposed regulations indicate that plans are to pay for reasonably necessary services, the regulations must clearly spell out that plans must pay for those services perceived to be reasonably necessary at the time of the presenting symptoms. Plans must be required to look to the presenting symptoms and emergency services provided from the perspective of the emergency service provider at the time of the presenting symptoms or else plans may employ 20/20 hindsight to assess what services were reasonably necessary and thus, deny payment for services that were reasonable and appropriate at the time.
3. The Proposed Regulations could lead to improper charges to enrollees for Emergency Services. The proposed regulation requires the provider to notify the enrollee's managed care plan of the provision of emergency services within 48 hours of the enrollee's admission to the hospital. The regulations should require providers to hold enrollees harmless for any provider charges that the enrollee's managed care plan denies as a result of the emergency provider's failure to notify the enrollee's plan as required by this section.

4. Enrollees must be fully informed in writing of their rights to emergency services. The proposed regulation requires managed care plans to "supply enrollees, 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)." In order to eliminate unnecessary obstacles and delays to enrollee receipt of emergency services, the proposed regulations should be changed to require that the information be provided promptly in writing and available in languages other than English. The regulations should further require accommodations to be made to provide this information in other forms to individuals with disabilities. Additionally, this information must incorporate the definition of emergency services set forth in the Act and not, as suggested by Proposed Regulation 154.16(h)(2), a definition consistent with the Act.

### SUGGESTED REGULATORY LANGUAGE CHANGES

#### FOR SECTION 154.14. EMERGENCY SERVICES

The proposed regulations should be revised and amended as follows (new language is in bold):

#### **§ 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 of the act (40 P. S. § 991.2102). **This section and section 154.2 of these regulations define emergency services as:**

- (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.**

- (b) **Plans are required to pay all costs for all services reasonably necessary at the time of the presenting symptoms which were ~~reasonably necessary costs~~ associated with the emergency and provided during the period of the emergency.**

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

- (d) The emergency health care provider shall notify the enrollee's managed care plan of the provision of emergency services and the condition of the enrollee upon discharge.
- (1) If the enrollee is admitted to a hospital or other health care facility, the emergency health care provider shall notify the enrollee's managed care plan of the emergency services delivered within 48 hours or on the next business day, whichever is later.
  - (2) If the enrollee is not admitted to a hospital or other health care facility, the claim for reimbursement for emergency services provided shall serve as notice to the enrollee's managed care plan of the emergency services provided by the emergency health care provider.
  - (3) **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.**
- (e) Managed care plans shall supply each enrollee, and upon written request, each prospective enrollee or health care provider, with written the information concerning emergency services **along with the information provided to enrollees under §154.16 in §-154.16(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.**

#### **SECTION 154.15. CONTINUITY OF CARE**

The continuity of care provisions are particularly important provisions of the Act. They reflect the legislature's awareness of the realities of the current managed care marketplace including: that plan provider networks are constantly changing, that enrollees can voluntarily choose to switch to managed care plans, that plans can choose to terminate providers from their networks, and that oftentimes changing plans is something enrollees must do due to changes in employment benefits, switching jobs, etc. At the same time, in adopting these provisions the General Assembly clearly indicated its primary concern is that a consumer's ongoing treatment not be interrupted and critically important health care needs not be jeopardized. As a result, the legislature guaranteed a minimum of 60 day transition period to enable consumers to continue to receive care from non-participating providers when the plan terminates a provider (for reasons other than "cause") or when the consumer is pregnant/in an ongoing course of treatment. In addition, the General Assembly attempted to eliminate any barriers to providing this ongoing treatment and clarified the relationship between the treating provider and the managed care plan. The proposed regulations do not go far enough to ensure that this consumer protection is uniformly implemented.

- A. **The regulations fail to provide sufficient guidance to assure the continuity of care protections are known and clearly understood.**

1. The regulation provides no guidance on terminations "for cause". The proposed regulations state that managed care plans must provide continuity of care to consumers in the situation where a managed care plan terminates a provider's contract for reasons other than "cause" but provides no definition of "cause". Sec. 2117(B) of the Act provides some guidance in this matter, but the regulation is silent. 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 Act 68 will be thwarted.
  2. The regulations fail to require any notice to enrollees of a need to change providers. Sec. 2117 of the Act requires that when a managed care plan terminates a contract with a primary care provider, it must give notice of the termination to every member served by the provider and also ask each member to choose another primary care provider. This is a critical consumer protection provision contained in the Act and it must be included in the Department's rules.
  3. The regulations fail to require plans to assist consumers in a course of treatment in arranging alternative care. Where a provider's contract is terminated, regardless of whether for cause, the plan must be required to take affirmative steps to ensure that the enrollee's course of treatment is not interrupted. The plan must also be required to assist the enrollee in finding a new provider. The provider's termination is not the fault of the enrollee and, thus, the enrollee should not suffer as a result of the termination.
- B. **The regulations fail to ensure that plans act promptly to permit service to enrollees by non-participating providers.**
1. The providers giving continuity of care services must agree to the same managed care plan terms that apply to participating providers. By the same token, the managed care plans should be required to take immediate action to enable those providers to abide by the plan's terms and conditions, including promptly processing any paperwork needed for the non-participating provider to be recognized by the plan. Plans should be required to take any necessary actions within 5 business days to enable a non-participating provider to serve an enrollee.

#### **SUGGESTED REGULATORY LANGUAGE CHANGES**

#### **FOR SECTION 154.15, CONTINUITY OF CARE**

The proposed regulations should be revised and amended as follows (new language is in bold):

**Sec. 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 defined in Sec. 154.2, and the enrollee is then in an ongoing course of treatment with that provider.
  - (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.**
  - (3) A new enrollee enters a managed care plan and is then in an ongoing course of treatment with a non-participating provider.
- (b) A current enrollee shall be allowed to continue an ongoing course of treatment with a provider whose contract has been terminated for reasons other than for cause, as defined in Sec. 154.2, for a transitional period of up to sixty days from the date, etc
- (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. **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.**
- (g) Managed care plans may require non-participating or terminating providers to agree to terms that include:
- (1) **Complying with the plan's third party liability (TPL) policies.**
  - (2) ~~(1)~~ **Accepting the plan's payment as payment in full for covered services, without balance billing, except for permitted deductibles, copayments or coinsurance.**
- (renumber the rest of this section accordingly)**
- (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 **including the managed care plan's marketing materials**

**and member handbooks.** This information and other information necessary to provide continuity of care services shall also be provided in written form to terminated or terminating and non-participating providers within 10 days of notice to the plan that an enrollee is requesting continuity of care benefits.

### **SECTION 154.16. INFORMATION FOR ENROLLEES & PROSPECTIVE ENROLLEES**

In order to protect their interests, consumers must have access to information about their health care coverage including what to do if they are denied prescribed care, what the financial incentives of their health care providers might be, what copayments they may face, etc. To best select between managed care plans, prospective enrollees need to have the information to evaluate differences in coverage, provider network, drug coverage, etc. In recognition of this, the General Assembly included Section 2136 of Act 68, which requires comprehensive disclosure by plans to enrollees and prospective enrollees.

**A. Mandated Automatic Disclosure.** Section 2136(A) lists 15 important categories of written information that “a managed care plan shall supply each enrollee and, upon written request, each prospective enrollee or health care provider”. The proposed regulations are deficient as follows:

1. The regulations fail to list the information to be disclosed or to provide clarifying language on what is to be provided for that particular category of written information. The regulations should list the 15 categories of information and should add clarifying information, where appropriate, so that all plans provide an equal level of information.
2. The regulations fail to define a reading level for disclosed information to ensure compliance with the Act’s requirement that the information “be easily understandable by the layperson. This permits huge variation in ease of understanding of the disclosed written materials from plan to plan. One could have written materials understandable by college lay graduates, another by Ph.D. lay graduates, etc. The Department, not the plans, should designate a reading level for disclosed written materials that are understandable by most Pennsylvanians, i.e. a 4th - 5th grade level.
3. The Department, not the plans, should determine if the materials are easily understandable to laypersons. Plans should be required to submit materials to the Department to review and approve of the materials for compliance with Act 68 and for ease of understanding.

4. Materials should be required to be provided in alternative formats for persons who are visually impaired.
5. Materials should be required to be provided for persons who read and understand a different language. Section 2136(A)(5) of the Act requires plans to provide: “a description of how the managed care plan addresses the needs of non-English speaking enrollees.” The regulations need to specify how that is done to ensure that information is provided to non-English enrollees in an effective manner across all plans.
6. The regulations permit plans to determine the format to disclose enrollee information and when the information is to be provided. Plans could bury this information in contracts given only to employers and could provide bits and pieces of the information throughout the contract term, or wait until the end of the contract to provide it. This would not allow the information to be accessible to enrollees during the term of their health care coverage. It is clearly the intention of the General Assembly that each and every enrollee be given this information at time of enrollment so that they may have it available to consult should questions or problems arise. The regulations should require that plans provide enrollees with the complete information required by Section 2136(A)(5) in an easy to understand member handbook within 30 days of enrollment in the plan. Section 154.16(g)(2) indicates that “following initial enrollment, or upon renewal, if benefits or networks have changed since the initial enrollment or last renewal, disclosure information should be provided to enrollees within 30 days of the effective date of the contract or policy, renewal date of coverage, if appropriate, or the date of request for the information.” There are several problems with this statement: (1) This provision says the plans “should” provide it rather than “shall” provide. It is therefore unenforceable. (2) This provision does not require that all of the information required by the Act be provided. (3) The information need only be provided if benefits or networks have changed, but not if any of the other required disclosure elements have changed. Complete information must be provided in member handbooks at initial enrollment and at each renewal date of coverage.

**B. Mandated Disclosure Upon Written Request: Section 2136(B) of the Act specifies what information must be provided to enrollees and prospective enrollees upon written request. The proposed regulations regarding this section should be modified as follows:**

1. Section 154.16(c)(2) requires plans to provide annual provider directories, but does not require designation of those that refuse to perform certain services on moral or religious grounds. This information should be required to avoid consumers and providers wasting their time with futile appointments.

2. Section 154.16(c)(e) allows either the managed care plan or the group policyholder to provide the information for group contracts. Group policyholders may not have much of the information, such as whether a drug is contained on a drug formulary, etc. Prospective enrollees could be ping ponged back and forth, never receiving the needed information in a timely fashion. The regulations should make clear that the plan is responsible for promptly disclosing any information required under 2136(b) that the group holder might not have.
3. Section 154.16(g)(4) states that disclosure information requested by health care providers shall be provided within 45 days of the request. Often health care providers need information promptly to care for their patients, i.e., whether a drug is covered on the formulary, whether prior authorization is needed. Language should be added to this section, “or earlier if needed by the health care provider to provide services to a plan enrollee.”
4. Section 154.16(h)) does not require plans to make reasonable accommodations for persons with disabilities who are unable to make their request in writing as required by the Americans with Disabilities Act.

### **SUGGESTED REGULATORY LANGUAGE CHANGES**

#### **FOR SECTION 154.16, INFORMATION FOR ENROLLEES**

The proposed regulations should be revised and amended as follows (new language is in bold):

#### **§ 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. **Specifically this includes: ( list from Act 68.) Managed care plans shall provide ~~may determine the format for disclosure of~~ the required information to enrollees in the member handbook within 30 days of enrollment or contract renewal and to prospective enrollees’ in a prospective enrollee packet. If the information is also disclosed through materials such as subscriber contracts, schedules of benefits and enrollee handbooks, the information should be easily identifiable within the materials provided. Materials must be available in alternative formats for persons who are visually impaired and plans must make reasonable accommodations to prospective enrollees with disabilities requesting the disclosure information.**
- (b) The information disclosed to enrollees, prospective enrollees and health care providers shall be easily understandable to the layperson and at no more than a fifth grade reading level



**and must be available in a translated version for enrollees or prospective enrollees who read a language other than English.**

- (c) The written disclosure of information shall include:
  - (1) The information 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. The list may be a separate document and shall be updated at least annually. If a list of participating providers for only a specific type of provider or service is provided, it shall include all participating providers authorized to provide those services. **If providers refuse to perform certain services on moral or religious grounds this should be designated for each such provider.**
  - (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. 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.
- (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 policyholder or another entity to provide the information to prospective enrollees on behalf of the managed care plan. **The managed care plan is responsible for promptly disclosing any information required under 2136(b) that the group policyholder has been unable to provide the prospective enrollee.**
- (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, **and how that information can be obtained.** The listed information shall be made available to enrollees and prospective enrollees upon request.
  - (2) Following initial enrollment, or upon renewal, ~~if benefits or networks have changed since the initial enrollment or last renewal,~~ **all disclosure information should shall be provided** to enrollees within 30 days of the effective date of the contract or policy, renewal date of coverage, if appropriate, or the date of request for the information.
  - (3) Disclosure information requested by prospective enrollees shall be provided to prospective enrollees within 30 days of the date of the written request for the information,

- or earlier if necessary to permit review by the prospective enrollee during the open enrollment period.**
- (4) Disclosure information requested by health care providers shall be provided to health care providers within 45 days of the date of the written request for the information **or earlier if needed by the provider to provide needed services to a plan enrollee.**
  - (h) Managed care plans shall supply each enrollee, and upon written request, each prospective enrollee or health care provider, with the following information which shall be contained and incorporated into subscriber and master group contracts and all other appropriate documents:
    - (1) A description of the procedures for providing emergency services 24 hours a day.
    - (2) A definition of "emergency services," consistent with the act.
    - (3) Notice that emergency services are not subject to prior approval.
    - (4) The enrollee's financial and other responsibilities regarding emergency services, including the receipt of these services outside the managed care plan's service area.
  - (i) Managed care plans, 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 **and at no more than a fifth grade reading level and must be available in a translated version for enrollees and prospective enrollees who read a language other than English. All disclosure information governed by this section shall be submitted to the Department for approval within 30 days of the effective date of these regulations and annually thereafter.**

### **SECTION 154.17 COMPLAINTS**

The Complaint provisions of the proposed rule are extremely critical to any consumer in this state who receives his/her health care through a managed care plan. The General Assembly recognized the absolute need to establish an internal process within the health plan that would allow consumers to be able to dispute coverage, operations or management policies of their managed care plans. Complaint issues may involve life and death matters. In coordination of care disputes with parties disagreeing over who is responsible for care, members could be totally deprived of life sustaining treatment. In disputes over entitlement to, or the extent of dependent coverage, children could be totally denied access to any medical care. For many consumers these complaint procedures would be the only avenue available to address their problems and/or concerns with how they were being treated by their managed care plan or whether they were receiving the level of coverage or benefits they were contractually entitled to receive. Obviously it is as important to consumers to have an excellent complaint process available as it is to have an excellent grievance process.

To ensure that the complaint procedures would be fair and uniform for consumers statewide, and not up to the discretion of individual plans, the legislature took pains to clearly detail many of the procedural protections it intended be in place. These included describing the make-up of the decisionmaking committee at each level of appeal, and the timeframes for each level of appeal. Clearly, the legislature intended there to be little, if any difference from one managed care plan to another regarding how complaints were to be handled and dealt

with. The proposed regulations do not ensure the fairness of or the uniformity within the complaint process that the General Assembly intended in Act 68.

**A. 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 a major loss of current consumer protections.**

1. The proposed regulation fails to spell out the details of precisely how the complaint process will work. The Complaint section of the proposed regulations are appallingly vague and totally silent on what the first and the second level review will consist of or how the plan will proceed at that level. A consumer could read the regulations and still have no idea who is deciding a complaint at any given stage, whether he/she has the option of meeting with the decision maker, what the meeting will be like, etc.
2. Very few of the procedural safeguards from the DOH Operational Standards have been incorporated into the proposed regulation.
  - a. Those Guidelines have been in existence for almost 10 years providing clear guidance regarding DOH expectations of fundamental fairness in the complaint and grievance process. Their continued relevance and the clear intent that their consumer protections remained in tact with Act 68 was affirmed when the Guidelines were specifically continued in DOH's Statement of Policy during the pendency of this rulemaking process.
  - b. Inexplicably, the Department incorporated only a few of the procedural protections detailed in the DOH guidelines. Dozens of critical protections that have ensured fundamental fairness to consumers when disputing their health plan's actions or decisions are not even mentioned. This includes all of the guidelines established by the DOH to assure fundamental fairness at the second level complaint review. The redrafted regulations which follow incorporate all of the standards established by the DOH. The procedural provisions highlighted by an asterisk indicate those longstanding consumer protections which will be lost unless the Department specifically incorporates them into its regulations. They include such important protections as:
    - requiring the opportunity of the enrollee to attend the second level review to present his/her positions, instead of relying on a paper review;
    - requiring the plan to notify the enrollee in writing of the complaint process and the timeframes at each step of the appeal including his/her right to have a non-involved staff person assist him/her;
    - requiring complaint decisions to contain a statement of the decisionmakers' understanding of the appeal and the facts as well as references to the evidence of records which supports the decision;

- requiring the plan to consider an enrollee's request to postpone a scheduled second level review for just cause;
  - requiring the members of the plan's second level review committee to remain unbiased, to make their decisions based solely on information and materials presented, and to conduct a fair and equitable hearing regardless of the enrollee's presence or absence from the review hearing;
  - requiring expedited review in life-threatening situations; and
  - requiring a record of second level review proceedings for Department review on appeal,
- c. Nothing in the General Assembly's actions indicated that it intended any loss of current procedural protections for HMO members to occur with the passage of Act 68. As written, the proposed regulations represent a major step backward in this state's protection of health care consumers and in ensuring fundamental fairness in disputes between managed care members and their health plans. Without substantial changes in the proposed regulations, consumers will stand little chance of having a meaningful review of their coverage issues or an opportunity to adequately develop the record of their complaint for review by the Department. The Department must add the many additional consumer safeguards in the complaint process similar to those set out in the DOH draft proposed regulations to ensure those previous procedural safeguards are maintained by the managed care plans.

3. The proposed regulations fail to provide for an expedited complaint process. As described above, disputes over coverage or managed care plan operations can involve life-threatening situations in which time is of the essence and a member cannot wait 30-40 days to have their complaint decided by the plan. Under the DOH Operational Standards to assure fundamental fairness to HMO members, an expedited process has been available to address these emergency issues. Inexplicably, the proposed regulations make no provision for an expedited complaint process. In passing Act 68, the General Assembly did not intend to diminish or take away any existing consumer procedural protections. As a result, the proposed regulations must be revised to provide for an expedited complaint process when the circumstances demand it.

**B. The regulations fail to provide the guidance necessary to ensure uniformity among health plan practices.**

1. The proposed regulations do not resolve the issues of whether an enrollee's 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 a grievance. The Statement of Policy of the Departments of Insurance and Health are not in agreement on these matters and it is imperative that the regulations provide clarity and guidance on how the appeals are to be classified. These

appeals will typically turn on issues of medical necessity and appropriateness and not on "the coverage, operations or management policies" of a plan. Please note that standing referrals have to be covered, and specialists are to be authorized to perform and coordinate primary care, where the enrollee's health situation meets the requirements of §2111(6) of the Act. Therefore, we urge you to clarify that such appeals are not to be classified as complaint but are instead grievances. The DOH proposed regulations should also clarify that such appeals are classified as grievances. This would be consistent with DOH's Statement of Policy at Sec. 9.504(b)(2)(viii).

2. The proposed regulations provide no mechanism for when a consumer and his/her managed care plan disagree over whether an appeal is a complaint or a grievance, or over how the appeal is being handled (for example, compliance with timelines or notice requirements). There must be a quick, independent means of resolving such disputes as is set forth in the DOH draft proposed regulations at 9.27 and 9.30. The Department's regulations should set out a process and require that plans notify their enrollees of the process available.
3. The proposed regulations provide no penalty for an HMO's failure to issue a decision within the timeframe allotted. For MA recipients in mandatory managed care, HMOs are required to issue complaint/grievance decisions within 30 days of filing. Yet the results of the clinical reviews for HealthChoices-SE revealed that HMOs consistently failed to meet this timeframe and months went by before complaints/grievances were decided and communicated to the health plan member. Given that experience, it is critical that there be a clear penalty for a managed care plan's failure to issue a decision in a timely manner. The regulations should be revised to provide that if a plan fails to issue a decision on a complaint within 30 days, the relief sought by the member in the complaint must be granted.

**C. The regulations go beyond the Act to make the appeal process more burdensome for consumers.**

1. The proposed regulations continue to place the unreasonable burden on the consumer to include the correspondence and decisions from the health plan regarding the complaint when appealing to the Insurance Department. The Department of Health in its Statement of Policy only requires the enrollee to include in an appeal, "the enrollee's name, address and telephone number, identification of the managed care plan, the enrollee's plan ID number, and a brief description of the issue being appealed...." Sec. 9.503(d). The statute does not specify that the enrollee is responsible for transmitting the records. This is an unreasonable burden and may pose a barrier to an enrollee continuing

an appeal in that he/she is likely not to have received many of the records relating to the complaint, or may have failed to keep copies of correspondence or decisions that were received. In fact, the managed care plan is the more logical choice for transmitting the records as they would have all the records.

### **SUGGESTED REGULATORY LANGUAGE CHANGES**

#### **FOR SECTION 154.17, COMPLAINTS**

The proposed regulations should be revised and amended as follows (new language is in bold):

#### **Sec. 154.17 Complaints**

(a) Under the complaint process established by the act, the Department will consider complaints regarding issues of contract exclusions and noncovered benefit disputes. The grievance process, which is administered by the Department of Health, includes review of the medical necessity and appropriateness of services otherwise covered by a managed care plan, **for example, denials of standing referrals or denials of requests for specialists to provide or coordinate primary care services.** 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 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) \* **The managed care plan must adopt a policy to routinely advise dissatisfied enrollees of their rights under the complaint/grievance process over the telephone and advise them how to file a complaint/grievance.**
- (e) Managed care plans may establish time frames, of at least 30 days, for the filing of complaints and grievances with the plan. **The time frames shall run from the date of occurrence of the issue being complained about or from the date of an enrollee’s receipt of a notice from the plan concerning the issue being complained about.**
- (f) **Complaints versus grievances. In recognition that disputes between enrollees and managed care plans generally involve two disparate positions and in consideration that the plan is the party with the responsibility to designate an appeal as either a complaint or a grievance, the plan shall ensure that its classification of the appeal as either a complaint or a grievance is not done with the intent to affect or deny due process to the enrollee. If there is any doubt as to whether the appeal is a complaint or a grievance, the plan shall consult immediately, or no later than five business days from receipt of the appeal, with the Department and the Department of Health as to the most appropriate classification. Enrollees who feel their appeal is misclassified may also independently contact the Department and the Department of Health directly for consideration or intervention with the plan, if necessary. If the Department determines that a grievance has been improperly classified as a complaint, the Department will notify the plan and the enrollee of such and the case will be redirected to the appropriate level grievance review and any filing fees shall be waived by the plan. If the Department determines that a complaint has been improperly classified as a grievance, the Department will notify the plan and the enrollee of such and the case will be redirected to the appropriate level complaint review. The Department will monitor plan reporting of complaints and grievances and may conduct audits and surveys to verify compliance.**
- (g) **First level review. The enrollee may file a written or oral complaint with the plan and may provide written data or other material in support of the complaint. Enrollees should be automatically provided with a copy of their oral complaint as transcribed by**

the plan. The enrollee should indicate the specific remedy or corrective action being sought. The plan must acknowledge receipt of the complaint to the enrollee within two (2) working days and \*must send their enrollee a brochure describing the complaint process along with the timeframes. The first level review committee shall include one or more individuals employed by the plan and \*a record of the persons participating shall be maintained. \*The committee shall not include any person previously involved in the determination.

\* Indicates a consumer protection found in the Department of Health's Grievance Systems Operational Standards For Fundamental Fairness for HMO Members but not found in Act 68.

(h) ~~(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:

- (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 rationale for the decision
- (3) \* Reference to any evidence or documentation that supports the committee's conclusions;
- (4) and the procedure to file a request for a second level review of the decision of the ~~initial review committee.~~ \* including the timeframe in which such request must be made.

If a managed care plan fails to notify the enrollee of its decision within 35 days of receipt of a complaint, the managed care plan must provide the enrollee with the relief sought in his/her complaint.

- (i) A managed care plan may not use the timeframe or procedures of the complaint process to avoid the medical decision process or to discourage or prevent the member from receiving medically necessary care in a timely manner. When the dispute is recognized by the HMO or the member as involving care which is alleged to be medically necessary and pressing, but not yet rendered, the plan must render a written decision within 48 hours. This decision must be signed by the Medical Director. If the member appeals this decision, the review may begin at the second level complaint review process. The availability of this expedited complaint process must be made known to all members in all written descriptions of the complaint process. If a member contacts the Department directly, Department staff will immediately contact the plan and request an expedited review of the complaint by the Plan's Medical Director.
- (j) Upon request, a review of the decision of the initial review committee shall be conducted by a second level review committee. The enrollee must be given written



notice of his/her right to appear before the committee. The second level review committee shall consist of three or more individuals who did not participate in the initial review. At least one-third of the committee cannot be employed by the managed care plan and should be plan enrollees or representatives of plan enrollees. \* The committee may not include anyone previously involved in the complaint.

**(k) Second level review process.**

- (1) \*The deliberation of the second level review committee, including the enrollee's and the provider's comments and all written submissions, shall either be transcribed or summarized and maintained as part of the appeal record. \*The plan shall provide reasonable flexibility in terms of time and travel distances when scheduling a second level hearing to facilitate the attendee's attendance and \*will notify the enrollee in writing, at least fifteen (15) days in advance, of the date and time of the hearing. The plan shall notify the attendee of his/her right to participate in the second level review hearing by telephone. \*The plan shall also provide the enrollee with a written description of the second level review committee's procedures so as to permit the enrollee to be prepared for the hearing and must readvise the enrollee of his/her right: (i) to have a non-involved staff person assist him/her in preparing for the second level review hearing; and (ii) to submit written material in support of his/her claim. \*Enrollee requests for hearing postponement (for just cause) must also be considered. \*"Just cause" may include an enrollee's inability to locate a representative or other individual in time to assist with the hearing, an inability to obtain necessary documents or medical records in time for the hearing, or the unavailability of a physician or other expert needed to provide testimony at the hearing. \*The enrollee's right to a fair and equitable hearing may not be made conditional on his/her attendance at the hearing. \*Regardless of the enrollee's presence, or lack of, the hearing must be conducted in the same manner. If an enrollee cannot appear in person at the informal hearing, the enrollee should be provided the opportunity to communicate with the review committee by telephone or other appropriate means.**
- (2) \*Members of the second level review committee may not discuss matters brought before the committee, or be present at such discussions prior to the second level review hearing. \*The written decision of the first level review committee shall be the basis for the deliberation of the second level review committee. Attendance at the second level review hearing shall be limited to members of the review committee, the enrollee and/or enrollee representatives, the enrollee's provider or applicable witnesses, and appropriate plan representatives. \*All persons attending and their respective roles at the hearing shall be identified for the enrollee.**
- (3) \*If any attorney representing the plan is present at the hearing, the primary purpose of the attorney shall be to represent the interests of the impartial second level review committee in insuring that a fundamentally fair hearing takes place and all issues in dispute are adequately addressed. \*The attorney is prohibited**

from arguing or representing the plan staff position in the dispute. \*If the plan desires to have an attorney present to represent the interests of the staff, then it must also make available another attorney to represent and assist the second level review committee.

- (4) The objective is to keep the second level review committee hearing informal and impartial so as not to be intimidating to the enrollee. \*Formal rules of evidence are not appropriate, and the enrollee may arrange for a physician or other expert to testify on his/her behalf.
- (5) \*A member of the plan staff previously involved in and knowledgeable about the appeal should present and summarize the plan staff's rationale for recommending that the denial be affirmed by the second level review committee. \*The written decision of the first level review committee shall be the basis for the rationale for recommending the affirmation of the plan's denial. \*Both the enrollee and members of the second level review committee have the right to question plan staff concerning the dispute. \*The enrollee must then be given an opportunity to present his/her side of the dispute as well as ask questions of the plan staff person presenting the plan's position.
- (6) The members of the second level review committee must provide a fair and equitable process to every enrollee. \*The members of the second level review committee shall have the duty to be unbiased in their review and decision and must consider the dispute based solely on the material and presentations made during the second level review hearing. \*The decision of the second level review committee shall be binding unless appealed by the enrollee.
- (l) ~~(f)~~ Managed care plans shall complete the second level of review of an enrollee complaint and render a decision within 45 days of the receipt of the enrollee's request for review. The plan shall notify the enrollee and the health care provider of the committee's decision in writing within five 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.~~ the notice shall 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 and rationale;
  - (3) Reference to any evidence or documentation which supports the committee's conclusions;
  - (4) A statement of the enrollee's right to appeal to the Department or the Department of Health, including the timeframes in which such request must be made, and the addresses and telephone numbers of each agency.

(m)~~(g)~~-Enrollees shall 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.

(n) **External review of a complaint decision.** ~~(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. Enrollees will be informed in writing by the managed care plan that the request must include, at a minimum: the enrollee's name; address and telephone number; identification of the managed care plan; the enrollee's plan ID number; a brief description of the issue being appealed, and any correspondence from the plan the enrollee may have concerning the issue.

~~(i)~~ Appeals of complaints to the Department shall include information such as:

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

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

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

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

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

**(1) Upon receipt of the appeal, the Department or the Department of Health shall verify that the appeal was submitted within 15 days from the enrollee's receipt of the notice of the decision by the second level review committee.**

**(2) Regardless of the agency receiving the request, the complaint shall be entered into a single tracking system established jointly by the Department and the Department of Health.**

**(3) ~~(j)~~ Within ten business days of receipt of the appeal the Department shall determine the appropriate agency for the review. If the Department believes that the appeal more appropriately relates to issues and matters under the jurisdiction of the Department of Health-for example, an issue involving quality of care- the Department will notify the enrollee 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. Secs. 1171.1-1171.15), which relates to the appeal of a complaint. The Departments will meet the sixty day timeframe allowed for external grievance reviews.**

**(4) All records from the first and second level review committee proceedings shall be transmitted to the appropriate Department by the plan.**

**(5) The Department, or the Department of Health may, at its sole discretion, hold a hearing concerning the complaint. The enrollee may be represented by an attorney or other individual before the Departments.**

**(o) ~~(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. sec. 1171.1-1171.15). The Department of Health will focus on complaint issues primarily involving enrollee quality of care and quality of service.**

**(p) ~~(j)~~-Complaint appeals under subsection ~~(i)~~ (k) may be filed with the Department at the following address :**

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



# PENNSYLVANIA COMMUNITY PROVIDERS ASSOCIATION

2400 Park Drive • Harrisburg, PA 17110-9303

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Raymond R. Webb, Jr., LSW

August 30, 1999

Peter J. Salvatore  
Department of Insurance  
Regulatory Coordinator  
1326 Strawberry Square  
Harrisburg, PA 17120

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Dear Mr. Salvatore:

Thank you for the opportunity to comment on the proposed regulations implementing Act 68 of 1998. My comments are submitted on behalf of the Pennsylvania Community Providers Association, which represents over 240 agencies in Pennsylvania that provide mental health, mental retardation, addictive disease, and other human services.

We realize that the department can only work with the basic framework handed to it by the General Assembly, and appreciate your efforts to make these regulations live up to Act 68's title: *Quality Health Care Accountability and Protection*.

### General comments

Our association was encouraged by the remarks of the Department of Insurance's representative Greg Martino at the August 23, 1999 meeting of the House Insurance Committee. Mr. Martino stated that all managed care entities will be covered by Act 68.

Whenever possible, we urge the department to create and require standardized forms or formats for reporting data, complaints, and other relevant information. A good managed care system can only be built with informed consumers, and the current diversity of forms among plans makes it difficult for regulators to obtain comparable data and for consumers to adequately compare plans.

### 154.18 Prompt payment

As providers of service, our members have been most directly affected by problems with prompt payment of claims. Administrators tell us that their largest single increase in expenditures under managed care is for clerical staff

*"PCPA promotes a community-based, responsive and viable system of agencies providing quality services for individuals receiving mental health, mental retardation, addictive disease and other related human services"*

to chase down payments. Andrew Wigglesworth, representing the Delaware Valley Health Care Council and the Hospital and Healthsystem Association of Pennsylvania, testified at the Insurance Committee meeting that there is \$1.6 billion in outstanding payments due from managed care entities in southeastern Pennsylvania every day, with approximately 50% of that amount 60 days or more past due.

We urge the department to track reimbursement issues carefully to assure that providers are promptly and appropriately paid. Mr. Martino noted that the department will be carrying out market conduct examinations, and we urge you to do this on a timely and frequent basis so that problem areas can be quickly identified and addressed. The current definition of *clean claim* is quite broad, and, therefore, will need close scrutiny to assure compliance.

Again, thank you for this opportunity to provide input on the development of the Act 68 regulations. If I can provide any additional information or assistance, please contact me.

Sincerely,

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C. Lu Conser, MPH  
Director of Government Relations

cc: James Smith, Independent Regulatory Review Commission





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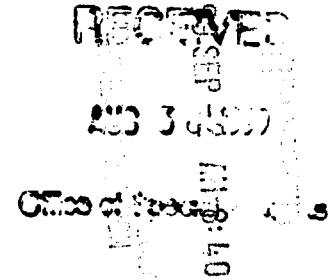
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C. Lu Conser, MPH  
Director of Government Relations

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