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INDEPENDENT REGULATORY REVIEW COMMISSION

333 MARKET STREET, 14TH FLOOR, HARRISBURG, PA 17101

September 30, 1999

Honorable M. Diane Koken, Commissioner
Insurance Department
1326 Strawberry Square
Harrisburg, PA 17120

Re: IRRC Regulation #11-195 (#2046)
Insurance Department
Quality Health Care Accountability and Protection

Dear Commissioner Koken:

Enclosed are our Comments on the subject regulation. They are also available on our website at http://www.irrc.state.pa.us.

Our Comments list objections and suggestions for consideration when you prepare the final version of this regulation. We have also specified the regulatory criteria which have not been met. These Comments are not a formal approval or disapproval of the proposed version of this regulation.

If you would like to discuss these Comments, please contact Mary Lou Harris at 772-1284.

Sincerely,

Robert E. Nyce
Executive Director

REN:kcg
Enclosure
cc: Pete Salvatore
Office of General Counsel
Office of Attorney General
Pete Tartline

COMMENTS OF THE INDEPENDENT REGULATORY REVIEW COMMISSION

ON

INSURANCE DEPARTMENT REGULATION NO. 11-195

QUALITY HEALTH CARE ACCOUNTABILITY AND PROTECTION

SEPTEMBER 30, 1999

We have reviewed this proposed regulation from the Insurance Department (Department) and submit for your consideration the following objections and recommendations. Subsections 5.1(h) and 5.1(i) of the Regulatory Review Act (71 P.S. § 745.5a(h) and (i)) specify the criteria the Commission must employ to determine whether a regulation is in the public interest. In applying these criteria, our Comments address issues that relate to consistency with the statute and existing regulations, fiscal and economic impact, nature of reports and cost of preparation, need, reasonableness and clarity. We recommend that these Comments be carefully considered as you prepare the final-form regulation.

1. Section 154.1. Applicability and purpose. - Clarity.

Subsection (c)

Section 154.1 addresses the applicability and purpose of Act 68 of 1998 (Act). Subsection (c) of this section states:

> An entity subcontracting with a managed care plan to provide services to enrollees which issues subscriber contracts covering enrollees shall meet the requirements of the act and this chapter for services provided to those enrollees.

There are several concerns with Subsection (c). First, what is included in the term "entity?" Second, does the phrase "which issues subscriber contracts covering enrollees" refer to the managed care plan (Plan) or to the entity? Finally, if services are subcontracted for an exempt entity, but the subcontract is with a Plan, are these regulations applicable to the subcontracted services? We request the Department respond to these questions and revise Subsection (c) for clarity.

Subsection (d)

Subsection (d) provides that "cost plus products" or their equivalent must meet the requirements of the Act if they are issued by a Plan. What are "cost plus products?" We recommend the Department define or explain the term.

2. Section 154.2. Definitions. – Consistency with the statute, Need and Clarity.

This subsection contains 19 definitions, 13 of which come from the Act. We object to the reiteration of the statutory definitions. Instead, the Department should reference the definitions in Section 2102 of the Act.

Emergency service

The regulation's definition of "emergency service" mirrors the statutory definition in Section 2102 of the Act except that it adds the phrase "including a chronic condition." The reference to chronic condition refines the intent, and is consistent with the Act. However, the regulation should reference the statutory definition. Rather than revising the statutory definition, the Department could add a provision to Section 154.14 (relating to emergency services). That provision would clarify that the sudden onset of a chronic condition is included as one of the conditions requiring emergency service if the symptoms are severe and meet the "prudent layperson" test set forth in the Act.

Gatekeeper

Several commentators questioned, or had different interpretations of, this definition. The definition reads:

> *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 [emphasis added].

It is unclear whether this regulation will apply to Plans using a "passive" or "multiple-choice" gatekeeper structure. The Department should explain its intent. In addition, there are two related concerns. First, it is unclear whether the enrollee must select a primary care provider from a list approved by the Plan. Second, what is the purpose of the phrase "or the plan or an agent of the plan serving as the primary care provider?" The Department should clarify these portions of the definition.

Managed care plan and Plan

Both of these definitions match the statutory definitions of the Act. The definition of "managed care plan" provides a detailed description of the types of plans covered by the Act. A "plan" is defined as "a managed care plan." However, both terms are used frequently throughout the regulation. "Plan" is not always used to replace the longer term. "Plan" should be used consistently in place of "Managed Care Plan."

Ongoing course of treatment

This definition reads:

Continuous health care treatment **which arises out of a single diagnosis** provided to an enrollee by a health care provider [emphasis added].

Commentators question the meaning and purpose of the phrase "which arises out of a single diagnosis." The term "ongoing course of treatment" is used in Section 154.15 (relating to continuity of care). The application of the "single diagnosis" phrase to Section 154.15 is unclear and may place needless limits on the applicability of this section.

Continuity of care is already limited to a 60-day transition period. In addition, continuity of care applies only to treatments started before the date the current enrollee was notified of the provider's termination or before the new enrollee's effective date of enrollment. If a treatment is based on a diagnosis made after these dates, then the continuity of care provisions of the Act do not apply. Therefore, the phrase "which arises out of a single diagnosis" is unclear and may be unnecessary.

Terms used in the regulation -- "Ancillary service plans" and "Referral"

Section 2102 of the Act contains definitions for "ancillary service plans" and "referral." The first term is used in the definition of "managed care plan." The second term, "referral," is also in other definitions and in other provisions of the regulation. The regulation does not define either of these terms, nor does it reference their statutory definitions. This section of the regulation should include references to the definitions of these two terms in Section 2102 of the Act.

3. "Enrollee," parent and legal representative. – Reasonableness, Consistency with the statute and Clarity.

The Act defines "enrollee" as "Any policyholder, subscriber, covered person or other individual who is entitled to receive health care services under a managed care plan." In addition, Subsection 2136(a)(8)(iii) of the Act requires that the Plans notify enrollees of "[t]he enrollee's right to designate a representative to participate in the complaint or grievance process as set forth in this article." It is unclear, however, who represents enrollees in contacting their Plans or for other procedures established by the Act. A minor or an incapacitated adult may have a parent, relative or legal representative act in the enrollee's behalf. The Department should explain how and when others, regardless of whether they are enrollees, may represent enrollees under the Act.

4. Section 154.11. Managed care plan requirements. – Reasonableness and Clarity.

Subsection (b)

In Subsection (b)(1), the Department introduces the phrase "approved treatment plans." This phrase is unclear. Section 2111(6) of the Act describes the process whereby a treatment

plan is approved by a Plan. For clarity, the Department should cross-reference Section 2111(6) of the Act in this subsection of the regulation.

Subsection (b)(3) requires that specialists notify the enrollee's primary care provider of all care provided to an enrollee. However, no time frame is given for that notification. For clarity, we ask the Department to consider adding a maximum time period within which the specialists must notify the enrollee's primary care provider.

5. Section 154.12. Direct enrollee access to obstetrical and gynecological services. – Clarity.

Subsection (a)

Subsection (a) states "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...." Commentators questioned whether there is a time limit on these services, as well as who can utilize them. Representative Patricia H. Vance also stated that clarification is needed regarding direct access to OB/GYN providers.

For clarity, the Department should state that these services are provided for enrollees, regardless of whether they are pregnant. Do enrollees have direct access as long as services are needed? If so, the Department should clarify that there are no time restrictions that apply to direct access to these services.

Subsection (d)

Subsection (d) states "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." Does this mean that self-referrals would be paid at the same rate as referred services?

6. Section 154.13. Managed care reporting of complaints and grievances. - Nature of Reports and Cost of Preparation, Reasonableness and Need.

Information format

Section 2111(13) of the Act requires Plans to report certain information to the Department of Health and the Insurance Department. The nature of the reports and the resulting cost of their preparation will be determined through regulation. Our concern is that Plans could be required to produce two separate reports with essentially the same content. We recognize that the Department of Health regulations implementing the Act have not yet been proposed. However, the Insurance Department and the Department of Health should coordinate the reporting requirements so that managed care organizations would be required to produce a single report that is sent to the two state agencies. When this final regulation is submitted, the Insurance Department should explain the nature of the reports, the expected cost of preparation, the reasonableness of and need for the format requirements in Section 154.13.

Subsection (a)

Subsection (a) repeats the statutory requirement for information which includes the number, type and disposition of all complaints and grievances filed with the Plan. The requirement in the regulation for the "number, type and disposition" of complaints and grievances is vague. For example, does "type" refer to complaint or grievance, or does it differentiate between the "type" of services, such as access to obstetrical and gynecological services, emergency services, and continuity of care? The Department should provide guidance in the regulation regarding what information it will require.

The last sentence of Subsection (a) is a format requirement. It should be moved to Subsection (b) along with the possible amendments or changes to format requirements.

7. Section 154.14. Emergency Services. – Clarity.

Subsection (a)

The citation to Section 2101 to the Act in this section is incorrect. The correct citation is to Section 2102. The Department should correct this citation in the final-form regulation.

Subsection (b)

Subsection (b) does not state when the "period of the emergency" ends. Does it end when the attending physician stabilizes the patient's condition? This should be clarified.

The same subsection states, "Plans are required to pay all reasonably necessary costs associated with the emergency services...." The Department should specify the criteria it will use to determine what it will consider to be "reasonably necessary costs". Greater clarity would be achieved if the Department specified what is intended by the term "reasonably necessary." For example, does it include all services provided during "the period of the emergency?"

Subsection (d)

Subsection (d)(1) states "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."

Commentators questioned what happens if this provision cannot be met due to extraordinary circumstances. If extraordinary circumstances prevail, will claims filed for the emergency services rendered be paid by the Plan? We ask the Department to clarify this subsection to allow for further review of the claim to protect the patient from expenses and additional charges.

8. Section 154.15. Continuity of care. – Consistency with the statute, Reasonableness and Clarity.

Subsections (a)(1) and (b)

These subsections reference termination "other than for cause." Section 2117(b) of the Act lists examples of for cause terminations. To improve clarity, we suggest the Department include a reference to Section 2117(b) of the Act.

Subsection (e)

Subsections (e) and (e)(1) state that nonparticipating and terminated providers *shall* agree to the Plan's terms and conditions. However, Section 2117(e) of the Act states that a Plan *may* require a nonparticipating provider to meet the same terms and conditions as a participating provider. The use of "shall" in the proposed regulation is inconsistent with the statute and negates the flexibility provided by the Act. For consistency with the Act, these subsections should be revised to reflect that providers shall be required to agree to the same terms and conditions as the Plan's participating providers if the Plan specifically imposes such a requirement.

Subsection (e)(2) requires providers who accept the Plan's terms and conditions to utilize participating providers for all other health services provided to the enrollees. Section 2117(e) of the Act permits a Plan to require nonparticipating providers to meet the same terms and conditions as participating providers. The regulation is inconsistent with the Act because it imposes this requirement in every instance. The regulation should be revised to reflect that a Plan *may* impose the requirement contained in Subsection (e)(2).

Subsection (i)

This subsection requires written disclosure of continuity of care benefit requirements in subscriber and master group contracts and in "all other appropriate documents." It is unclear if "all other appropriate documents" refers to Plan marketing materials distributed to enrollees or to documents distributed to providers. The Department should clarify this phrase in the final regulation.

This subsection also requires certain information to be provided to terminated or terminating and nonparticipating providers within 10 days after an enrollee requests continuity of care benefits. The Department should clarify if "10 days" refers to business or calendar days.

9. Section 154.16. Information for enrollees. – Fiscal impact, Reasonableness, Consistency with existing regulations and the statute and Clarity.

There is a concern with the completeness and clarity of Section 154.16. With few exceptions, the section merely references or paraphrases the requirements in Section 2136 of the Act. It does not provide any additional guidance or details concerning the implementation of the required information disclosures. One example is Subparagraph 2136(a)(8)(i) of the Act. That section of the Act requires the Plans to give enrollees a summary of the procedures for filing a

complaint or grievance as set forth in the Act. Nothing in this section addresses this summary's content. Allowing each Plan to write its own summary without further regulatory requirements will lead to unnecessary confusion. Other examples of the need for detail are discussed below. The regulation should provide more direction concerning this summary and other requirements in Section 2136 of the Act.

Subsection (a)

There are three concerns with Subsection 154.16(a). First, it states that Plans "shall provide the written information in section 2136(a) of the act (40 P.S. § 2136(a))...." This same directive is repeated later in Subsection 154.16(c)(1), which requires that the written disclosure include the information specified in section 2136(a). This repetition is unnecessary. The Department should explain the need for this repetition or delete one of the subsections.

Second, Subsection 154.16(a) allows the Plans to determine the format for disclosure of the required information. However, some guidance would be useful for proper implementation of the Act. The use of common formats would assist consumers in comparing the more than 14 different types of detailed information required by the Act. This regulation should include basic standards for the format and content of the disclosure documents required by the Act and provide for departmental review. This process could be similar to existing regulations for advertising at 31 Pa. Code Chapter 51.

Third, the last sentence of Subsection 154.16(a) discusses the disclosure of the required information "through materials such as subscriber contracts, schedules of benefits and enrollee handbooks." It states that "the information **should** be easily identifiable within the materials provided" [emphasis added]. As written, this provision is not a mandate. It is unenforceable and should not be in the regulation. If the provision is intended to be advisory, it may be more appropriate to a guidance document. If it is intended to be a requirement, the word "should" needs to be replaced with "shall."

Subsection (b)

Subsection 2136(a) of the Act states that the required information "shall be easily understandable by the layperson." Subsection 154.16(b) repeats this standard in the regulation. The standard is similar to existing regulations at 31 Pa. Code § 51.21. Unlike existing provisions, there is no indication in the proposed regulation that the Department will review the information disclosures. The regulation should provide for departmental review.

Subsection (c)

Elements of Subsections 154.16(c)(1) and (2) duplicate Subsection 154.16(a). This repetition is unnecessary. The Department should delete the portions of these subsections that duplicate Subsection 154.16(a).

In addition, several commentators have expressed concern with the disclosure requirement imposed by Subsection 154.16(c)(2). It is virtually identical to Subsection 2136(a)(14) of the Act. It requires the Plans to provide an annual listing of "all participating health care providers." The statutory definition of health care providers is inclusive. It reads:

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

The Plans and others have expressed concerns over the costs of compiling lists of every participating provider in a Plan that covers several counties or is statewide. In addition, they question whether the list should include all the personnel, such as nurses, pharmacists and other professionals, at a Plan's participating facilities.

Because the disclosure requirement is intended for the enrollees' benefit, the Department should explain how it intends to implement this requirement. Directives on what and who must be in the lists of participating providers should be set forth in this regulation.

Finally, the second sentence in Subsection 154.16(c)(3) requires a disclosure to be included in specific documents including "subscriber contracts, schedule of benefits and other appropriate material." This provision is out of place in Subsection 154.16(c), which is a list of items to be included in a document described as the "written disclosure of information." Therefore, the second sentence of Subsection 154.16(c)(3) should be moved to a new, separate subsection.

Subsection (d)

Subsection (d) identifies specific types of contractual documents that do not constitute "marketing materials" for the purposes of Subsection 2136(a)(1) of the Act. The regulation does not define "marketing materials." Existing provisions in the Department's regulations at 31 Pa. Code § 51.1 include comprehensive definitions of "advertisement" and "publication." This proposed regulation could use similar language to define "marketing materials."

Subsection (g)(2)

This subsection states that the required disclosure information "**should** be provided to enrollees within 30 days of the effective date of the contract or policy, renewal date of coverage..." [emphasis added]. As discussed in Subsection (a) above, this provision is not written as a mandate. Thus, it is unenforceable. However, Section 2136 of the Act requires that Plans disclose this information to enrollees. Therefore, the word "should" needs to be replaced with "shall."

Subsection (h)

The main paragraph ends with the words "and all other appropriate documents." What documents are covered by this term?

In addition, Subparagraph 154.16(h)(2) uses the phrase "consistent with the act." The same phrase in Subsection 2136(a)(9)(i) of the Act reads: "A definition of emergency services

as set forth in this article." Hence, the phrase "consistent with" should be replaced with "as set forth in."

Special provisions for the disabled

Subsection 2136(a)(13) requires that a Plan's disclosure information include a description of the procedures that an enrollee with a life-threatening, degenerative or disabling disease or condition must follow and satisfy to be eligible for referral to a specialist or designation of a specialist to provide and coordinate treatment. In addition, Subsection 2111(11) of the Act requires the Plans to "ensure that there are participating health care providers that are physically accessible to people with disabilities and can communicate with individuals with sensory disabilities in accordance with Title III of the Americans with Disabilities Act of 1990."

The Act requires that information and services be provided for people with disabilities. The regulation should require that the information be provided in formats or via communication systems that are accessible to people with disabilities including people with sensory disabilities.

10. Section 154.17. Complaints. - Consistency with the statute, Economic Impact, Need and Clarity

Enrollee's right to designate a representative

Section 2136(a)(8)(iii) of the Act requires the Plan to disclose "the enrollee's right to designate a representative to participate in the complaint or grievance process as set forth in this article." Section 2142(c) of the Act regarding the appeal process states "the enrollee may be represented by an attorney or other individual before the appropriate department." The right to designate a representative is an important one, particularly for minors or when an enrollee is encumbered by health problems. The Department should add a subsection to Section 154.17 that explains the enrollee's right to designate a representative.

Separation of responsibilities

The Act has separate requirements for the Plan's internal complaint process located in Section 2141 of the Act, and the Department's responsibilities for appeal of a complaint in Section 2142 of the Act, and complaint resolution in Section 2143 of the Act. However, the regulation combines these requirements into one section. This diminishes the clarity of the regulation. The Department should consider separate subsections for the Department's responsibilities and for the Plans' responsibilities.

Subsection (a)

We have three concerns with Subsection (a). First, Subsection (a) begins with the phrase "Under the complaint process established by the act...." For clarity, the Department should cite the specific sections in the Act.

Second, this section states "the Department will consider complaints..." and later provides examples of "the types of complaints which may be filed with the Department...." This may

cause confusion with the Plan's internal complaint process. The Department can consider an appeal of a decision from the internal complaint process, or can facilitate resolution of a complaint. The Department should rewrite these provisions to more clearly state its responsibilities.

Finally, the scope of Subsection (a) is narrower than the definition of "complaint" in the Act and Section 154.2. One commentator questioned whether complaints could also include problems relating to submission requirements. The Department should expand Subsection (a) to provide further guidance on the coverage, operations and management policies that are within the scope of complaints.

Subsection (c)

Subsection (c) states "inquiries regarding premium rate increases do not constitute appeals" and may be filed directly with the Department. We have two questions on this subsection. First, is the term "inquiries" the appropriate term, or does this subsection pertain to complaints?

Second, it is unclear why the phrase "do not constitute appeals" is needed. The Department should explain what it means by this language.

Subsection (d)

Subsection (d) states Plans *may* establish time frames of at least 30 days for the filing of complaints and grievances. The intent of Subsection (d) is unclear. Does the Plan have an option to establish time frames? Is the intent to give the enrollee a minimum of 30 days to file a complaint or grievance?

Additionally, when would the 30-day time period start? The Department should clarify these points in its final submission.

Subsection (f)

Section 2141(c)(2) of the Act requires a written notification to the enrollee of the right to appear before the second level review committee. Subsection (f) does not include this requirement. The Department should add it.

Subsection (f) ends with the phrase "or the Department of Health." It is unclear why this phrase is needed in the Insurance Department's regulations.

Subsection (g)

Subsection (g) requires an enrollee to complete the internal complaint process before filing an appeal of the Plan's decision with the Department. Section 2143 of the Act allows the Department to assist in the resolution of a complaint any time during the complaint process. There may be circumstances where an enrollee would legitimately contact the Department before a decision was issued. For example, if a Plan is not responsive within the time frames of Subsections (e) and (f), it would appear appropriate for an enrollee to contact the Department.

The Department should explain the need for Subsection (g). If it is retained, the Department should include or reference the provisions of Section 2143 of the Act.

Subsection (i)

We have four concerns with Subsection (i). First, Subsection (i) states "Appeals of complaints to the Department shall include information such as...." The phrase "information such as" implies the information listed in Paragraphs (1) to (5) is optional. The Department should delete the phrase "information such as" and replace it with "the following information...."

Second, Section 2142(b) of the Act requires all records from the initial review and second level review to be transmitted to the Department "in the manner prescribed." The regulation does not prescribe how these records are to be transmitted to the Department. It should.

Third, the Plan would have conducted the reviews and kept the records. Why, then, does Paragraph (i)(5) require the enrollee to provide correspondence and decisions from the Plan regarding the complaint? The enrollee would presumably have to get the documents from the Plan and then duplicate them. The Department should explain why it is appropriate to require this information from the enrollee rather than from the Plan.

Finally, Section 2142(c) of the Act allows an enrollee to be represented by an attorney or other individual. If the enrollee elects to be represented by an attorney or other individual, the Department would also need that information. The Department should add a Paragraph (6) to get the appropriate information in the event the enrollee is represented by an attorney or other individual.

Subsection (k)

The intent of Subsection (k) is not clear. It contains no substantive provisions and appears to duplicate the provisions of Subsection (a). The Department should delete Subsection (k) or combine it with Subsection (a).

11. Section 154.18. Prompt payment. – Consistency with the statute, Reasonableness and Clarity.

Subsection (a)

This subsection requires clean claims to be paid "within 45 days of the licensed insurer's or managed care plan's receipt of the clean claim from the health care provider." Commentators have several questions about what constitutes a Plan's receipt of a clean claim. Specifically, is "receipt" the date the Plan determines the claim is clean, or is it simply the date the claim is received by the Plan? If it is the date the Plan receives the claim, does the postmark establish the receipt date? We request the Department clarify in the final regulation when the 45-day time period begins.

Health care providers have commented that insurers and Plans should be required to notify providers of deficiencies which would delay processing of a claim. This would allow the

provider to respond to the problem and receive timely payment of the claim. Absent this notification, the provider will be unaware of a problem until receipt of a rejection notice.

It is reasonable to advise a provider when a claim is suspended. This would help ensure timely resolution of the problem causing the suspension. In addition, such notification may reduce the number of inquiries from providers on the status of claims, as provided for in Subsection (e). Therefore, the Department should consider including provisions for notifying providers of claim deficiencies.

Subsection (d)

This subsections states "Claims paid by a licensed insurer or managed care plan are considered clean claims and are subject to the interest provisions of the act." Several commentators object to this provision as a broadening of the intent of the definition of "clean claim" contained in the Act. The commentators assert that if a claim is held awaiting further documentation, it is not a clean claim, even if it is paid after all the information is received. We request the Department explain how this provision is consistent with the Act.

This subsection further states that "The prompt payment requirement of the act also applies to the uncontested portion of a contested claim." For consistency, the Department should revise Subsection (a) to include the requirement that the uncontested portion of a contested claim shall be paid within 45 days of receipt of the claim.

Subsection (e)

We have several concerns with this subsection. First, it states the provider ***should*** contact the insurer or Plan before filing a complaint with the Department. It is unclear how the Department would enforce this provision. Section 2143 of the Act allows the Department to assist in the resolution of a complaint at any time during the complaint process. Would the Department dismiss any complaint submitted by a provider who did not first make an inquiry with the insurer or Plan?

Furthermore, the term "should" is nonregulatory language which indicates that this provision is optional. It is inappropriate to include optional provisions in a regulation. If the intent of this provision is to advise providers of the Department's preference in the administration of complaints, it may be more appropriate to include this information in a policy statement.

In addition, this subsection requires the Plan or insurer to respond to a provider's inquiry within "a reasonable period of time." The regulation does not specify what is a "reasonable period of time." This is significant because Subsection (f)(1) authorizes a provider to file a complaint with the Department if the insurer or Plan does not respond to an inquiry regarding the status of an unpaid claim "within a reasonable period of time." We suggest the Department specify the time period within which an insurer or Plan must respond to a provider's inquiry.

Finally, the regulation does not specify if the insurer or Plan must respond to the provider's inquiry in writing. The Department should clarify its intent in the final regulation.