COMMENTS OF THE INDEPENDENT REGULATORY REVIEW COMMISSION

ON

DEPARTMENT OF HEALTH REGULATION NO. 10-129

HEAD INJURY PROGRAM

JULY 22, 1999

We have reviewed this proposed regulation from the Department of Health (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 statutory authority; fiscal impact; protection of the public health, safety and welfare; duplication of regulations; reasonableness; need; and clarity. We recommend that these Comments be carefully considered as you prepare the final-form regulation.

1. Enrollment status. - Clarity.

The regulation does not clearly state when an applicant becomes "enrolled" in the Head Injury Program (HIP). The term "enrollment" is used inconsistently throughout the regulation including the following:

- A "Client" is defined in Section 4.2 as an individual "enrolled" in the HIP.
- Time periods in Section 4.6 begin with the date of enrollment in the HIP.
- Section 4.7 of the regulation requires enrollment (i.e. client status) for payment for services, including assessments.
- Under Section 4.8, the provider has 30 days after enrollment to submit a rehabilitation service plan (plan).
- Section 4.10(a)(1) restricts administrative review to applicants.

These and other substantive provisions are tied to the date when an individual actually becomes enrolled. Does enrollment occur when an applicant is deemed eligible, when a plan is approved, or when services actually begin? The regulation should provide a clear distinction of when a person is considered to be enrolled in the HIP.

2. Financial eligibility for services. - Implementation procedures; Reasonableness; Fiscal impact; and Protection of the public health, safety and welfare.

The regulation requires an applicant to meet financial tests to be eligible for services. Subsection 4.4(a)(3) provides the following criterion: "The applicant exhausted all alternate financial resources to pay for services covered by HIP as determined in accordance with HIP financial eligibility criteria." We have two concerns with how financial eligibility for services will be determined.

First, the regulation does not include the "HIP financial eligibility criteria" which will be used to determine eligibility. It is our understanding from information provided by the Department that these financial criteria include measures such as discounting income up to 300% of the federal poverty line. However, these important criteria, used in determining an applicant's financial eligibility, must be included in the regulation in order to give adequate notice to applicants.

Our second concern is with the requirement that the client exhaust all alternative financial resources to pay for services covered by the HIP. The relationship between "exhausting all alternative resources" and "services covered by HIP" is unclear. For example, the definition of "alternative financial resources" includes income which is used for many needs, such as housing, food, or medical bills. The definition also includes interest payments, court awards, etc. Senator Vincent Hughes, Minority Chairman of the Senate Public Health and Welfare Committee, questions whether a client will be expected to be fully impoverished before obtaining the HIP services. The regulation does not clearly establish how an applicant's income will be reviewed to meet the financial eligibility criteria. We recommend the final-form regulation specify the income or assets the Department will consider in determining eligibility.

3. Clients currently enrolled in the HIP. - Protection of the public health safety and welfare; and Reasonableness of implementation procedures.

According to the Department, there are approximately 19 rehabilitation and 278 case management clients receiving services from the HIP. There are also 178 clients on the HIP waiting list. The proposed regulation does not address the status of these individuals once the regulations are promulgated.

The regulation should contain a provision that clearly states the status of those currently either enrolled in the program or on the waiting list. The provision should also outline the process of notifying these clients and applicants of the Department's change in policy regarding the HIP.

4. Section 4.2. Definitions. - Need; Duplication of regulations; and Clarity.

Case manager

This section defines "case manager" as an individual approved and assigned by the HIP to provide case management for a client. However, the proposal should describe the qualifications and the approval process to become a case manager. We recommend that a section be inserted in the regulation to clarify these two points.

Division

This definition reads: "The organizational unit, within the Department, having responsibility for the administration of the HIP." It is our understanding that the program will be administered through the Special Healthcare Programs Division. The definition should specify which division will be responsible.

Exhausted

This term is defined as the point when alternative financial resources for a HIP service have been denied or fully utilized. In light of **Comment #2** above, this definition may not be needed if the financial eligibility criteria are specified in more detail.

Legal representative

This term is not defined in the regulations. However, it should be. In Section 4.8, Section 4.10, and other sections, the regulation refers to the applicant or client, or the parent, guardian, or representative of the applicant or client. Department staff indicated that the representative should be legally capable to make decisions for the applicant or client. This is especially important when the decisions for the applicant or client involve developing the plan or appealing an adverse initial review.

To clarify who can act on behalf of an applicant or client, we recommend the Department adopt a definition for the term "legal representative." The definition of "responsible person" in the Department's recently revised Long Term Care regulations at 28 Pa. Code Section 201.3 (Definitions) and 201.29(L) (Residents rights) is an example. With this definition in place, Sections 4.8 and 4.10 and other parts of the regulation, could simply include the phrase "applicant, client or legal representative" rather than a list of several terms such as "parent, guardian or representative." As noted in our Comments below, this phrase should also be included in Section 4.10, to clarify that a legal representative may seek administrative review and file an appeal on behalf of an applicant or client.

Consistent with our question in **Comment #6** of why eligibility is limited to applicants over 21 years of age, the definition of "legal representative" should include a reference to "minor."

Rehabilitation service plan

The last sentence of the definition of "rehabilitation service plan" states the purpose and function of the goals within the plan. These substantive provisions are not appropriate in a definition. Additionally, this sentence duplicates language concerning goals in Section 4.8(b). The Department should delete this sentence from the definition.

5. Section 4.3. HIP services and objectives. - Clarity.

Subsection 4.3(c) consists of a lengthy sentence describing how the Department will use the HIP Fund (Fund) to pay for clients' HIP services. The provision states that the Department "...will use the Fund to pay for clients' HIP services which would not otherwise be available to clients with traumatic brain injury who have exhausted alternative financial resources."

Under the eligibility requirements in Section 4.4(a)(3), an applicant must exhaust all financial resources to pay for services covered by the HIP. For an "applicant" to become a "client" they must have met the eligibility requirement. Because Section 4.3 addresses services and objectives for a "client," we question why the alternative financing provision is necessary in this section. For clarity, we recommend the Department delete the language that follows "clients' HIP services" unless the Department provides a reason to retain it.

6. Section 4.4. Eligibility for services. - Fiscal impact; Protection of public health, safety and welfare; Reasonableness; Need; and Clarity.

In Subsections (a) to (e), the phrase "the Department will deem" is used. Why is this phrase necessary? The regulation should simply state the eligibility and ineligibility criteria. For example, Subsection (a) could state "An applicant must meet the following conditions: .... "

Neither Subsection (a) nor (b) indicates that the Department will conduct evaluations to determine an applicant's initial eligibility and a client's continuing enrollment in the HIP. These evaluations are mentioned in Subsection 4.6(a). The language in Subsection 4.6(a) would be better placed in Section 4.4. The Department should also describe the procedures and standards it will use for these evaluations.

Subsection 4.4(a) Conditions.

Subsection (a) sets forth the basic conditions for eligibility. It includes four paragraphs that describe these conditions.

Subsection (a)(1) reads: "The applicant sustained a traumatic brain injury on or after July 3, 1985." The use of "on or after" is confusing and unnecessary. The Department should amend this subsection to read: "The applicant sustained a traumatic brain injury after July 2, 1985."

Subsection (a)(2) contains three residency requirements for eligibility. We question the requirement that the applicant must demonstrate the intent to maintain a permanent home in Pennsylvania for the indefinite future. It is unclear how the Department would enforce this requirement or why it is needed. The Department should either delete this requirement or justify its retention.

Subsection (a)(3) reads: "The applicant exhausted all alternate financial resources to pay for services covered by HIP as determined in accordance with HIP financial eligibility criteria." As discussed in **Comment #2**, the term "HIP financial eligibility criteria" is not defined in the proposal, nor does the proposal include any specific eligibility criteria. The proposal should describe this term and the criteria used in determining an applicant's eligibility.

Subsection (a)(4) provides an age limit for applicants. To be eligible for the HIP, an applicant must be 21 years of age or older. The Department has stated that people under 21 years of age are eligible to receive coverage for services through programs administered by the Departments of Education (Education), Labor and Industry (L&I), and Public Welfare (DPW). Commentators noted that people less than 21 years of age do not automatically receive services from these other programs. The Department indicated that the HIP previously had clients under the age of 21 years. However, these clients were eventually transferred to other programs. Since Subsection 4.4(a)(3) requires that an applicant exhaust all alternate financial resources to be eligible for HIP services, the Department should clarify the need for the age limit in Subsection 4.4(a)(4). The Department should also explain how the programs provided by Education, L&I, and DPW are appropriate alternatives to the HIP for people under 21 years of age.

Subsection 4.4(b) Eligibility.

Subsection (b) states that an applicant will be eligible for HIP services only if the Department determines that the applicant has the potential to benefit from the services. There are two concerns with this subsection. First, the phrase "and other neuropsychological evaluations as deemed appropriate by the Department" is confusing and unclear. It is our understanding that the Department intends each applicant to undergo at least one neuropsychological evaluation. The regulation should clearly establish this requirement.

Second, commentators expressed concern with what appeared to be an undue emphasis placed on the case manager's recommendation. They indicated that a board-certified physician, neurosurgeon, or neurologist should also be involved in the evaluation process to determine the

potential benefit of HIP services to an applicant. The Department should respond to these concerns by clearly establishing the procedures for eligibility determinations.

In 1991, the Legislative Budget and Finance Committee (LB&FC) produced a report on the HIP. It included a detailed description of the case manager's duties in reviewing applicants' diagnostic information for completeness and developing recommendations. The LB&FC's description can be found in Appendix A of its report entitled "Performance Audit of the Health Department's Administration of the PA Head Injury Program" dated June 1991. The Department should clarify the case manager's current role in its determination of an applicant's potential to benefit from HIP services. In addition, the Department should describe what is included in a neuropsychological evaluation. The Department should also explain how applicants' medical histories would be utilized in the evaluation and determination process. Medical histories should include the prognoses provided by physicians, neurosurgeons, or neurologists.

Subsection 4.4(c) Ineligibility due to impairment.

Subsection (c) states that an applicant will be ineligible for HIP services if the applicant's impairment is the result of one or more of the listed conditions.

Two areas in the subsection raise questions. First, one of the conditions leading to ineligibility in Paragraph (c)(4) is "significant preexisting psychiatric, organic or degenerative brain disorders." Who makes the determination that the impairment is the result of a preexisting condition?

Second, the Department should define the term "cerebral vascular accident" used in Paragraph (c)(5). *Stedman's Medical Dictionary* (Williams & Wilkins, 1982) lists a similar term "cerebrovascular accident" under the term "accident" and defines it as "an obsolete and inappropriate term for stroke."

Subsection 4.4(f) Notification of eligibility.

Subsection (f) states that the Department will notify an applicant of eligibility within 30 days from the date of receipt of a complete application. The provision raises three questions. First, how will the date when an application is complete be determined and recorded? Second, why doesn't the subsection also require notification of ineligibility? This written notice should include the reason(s) the applicant is ineligible and a reference to Section 4.10 relating to appeals. Finally, is the notice of eligibility considered to be the starting date for enrollment?

7. Section 4.5. Payment for services. - Fiscal impact and Clarity.

Subsection (b) states that HIP will maintain a waiting list. It is not clear how this list would be prioritized (i.e., by date of application, or degree of injury); the need to reapply once an applicant is on the list; and the priority assigned to a re-applicant. The purpose for, and protocols surrounding, the waiting list should be further defined in the final-form rulemaking.

Subsection (f) is unclear regarding conditions for which payment may be discontinued. In Paragraph (2), how and when are the maximum funds available for treating the client determined?

Paragraph (4) does not specify what amounts of alternative financial resources or services would result in the discontinuation of HIP services. What if some minor amount of alternative

resources becomes available? Or what if certain services could be obtained from another source? The regulation should specify some reasonable threshold at which alternative finances would result in discontinuing HIP services.

Paragraph (5) would result in stopping payments if "...it is no longer feasible to implement a rehabilitation service plan." Who makes these determinations, and how will the patient be notified? We request the Department include provisions to clarify the process and conditions under which it would discontinue payment for the plan.

8. Section 4.6. Duration of funding. - Fiscal impact; Protection of public health, safety and welfare; Reasonableness; and Clarity.

The Preamble states the Department's intent is to protect the financial integrity of the Fund and to provide services to as many individuals as possible. In addition to limitations in Section 4.6, a periodic review or audit of program expenditures would ensure the limited dollars in the Fund are being used as efficiently as possible to meet the program goals. The Department should explain how it will review the program expenditures to protect the financial integrity of the Fund.

Subsection (a), dealing with initial eligibility and continuing enrollment, is not germane to this section. We recommend that this paragraph be placed in Section 4.4 (Eligibility for services). Additionally, evaluations to determine continuing enrollment should also be discussed at the beginning of Section 4.5(f) (Payment for services).

Subsections (b) and (c) state time limits for HIP participation of 12 consecutive months for rehabilitation and 18 consecutive months for case management. We have three questions regarding these time limits. First, page nine of the Preamble states data shows the average client completes a rehabilitation program in one to three years. Why then, is it appropriate to limit rehabilitation in the HIP to one year under Subsection (b)?

Second, why is it necessary to limit services to consecutive months? If the patient had to discontinue services due to an illness such as pneumonia, would the time limit for services continue?

Finally, the regulation defines time limits. However, the regulation does not specify a maximum dollar limit in the regulation. Does the Department intend to use a per client funding cap? If so, the Department should specify this maximum limit in the regulation.

9. Section 4.7. Services eligible for payment. - Clarity.

The opening sentence of this section appears to limit payment to "clients." Subsection (1) (Assessments) would be for applicants, not necessarily clients. These provisions should be revised for consistency.

Subsection (4) (Rehabilitation services) contains two references to the "appropriate National accrediting body" as approved by the Department. It is unclear what these accrediting bodies are and how the public could find the list of approved accrediting bodies. The regulation should include the accrediting bodies or state how a list of approved accrediting bodies could be obtained.

10. Section 4.8. Rehabilitation service plan. – Reasonableness and Clarity.

Subsection 4.8(a)

Subsection (a) requires the plan to be submitted to HIP for approval within 30 days after the date the client is enrolled in HIP. We have two concerns with Subsection (a).

First, there is no time limit placed on HIP to approve or disapprove the plan. In contrast, Subsection 4.4(f) directs the Department to notify an applicant within 30 days of eligibility for HIP services. The Department should specify in the regulation how long HIP has to approve or disapprove a plan.

Second, rehabilitation services are limited by Section 4.6 to 12 months, beginning with the date of the client's enrollment in HIP. Subsection (a) of Section 4.8 uses the same starting date to develop a plan. A client would lose significant and valuable rehabilitation time while waiting for approval. The regulation should be revised to provide that the 12 consecutive months for service begins when actual services are commenced.

Subsection 4.8(c)

Subsection (c) requires a procedure for evaluation of progress, but does not specify the content of the procedure. The result of an evaluation is significant. An evaluation could result in modifying the plan under Subsection (d), or discontinuing services under Section 4.5(f). The regulation should specify the minimum requirements the procedure for evaluation of progress must include.

Subsection 4.8(d)

Subsection (d) allows modification of the plan. Subsection (a) requires joint development of a plan by the provider, case manager, client or client's representative. It also requires the HIP's approval of the plan. Subsection (b) states that the plan must contain certain components including specific goals, necessary services, timeframes and financial responsibilities. In contrast, the scope of modifications that could occur under Subsection (d) is unclear. There is also no indication of whether client involvement or the HIP approval is required.

As written, the regulation could allow modification of any aspect of the plan. The Department should specify which components of the plan listed in Subsection (b) could be modified, whether joint development would be required, who can make modifications to the plan and whether the HIP's approval would be required.

11. Section 4.10. Appeal procedures. - Statutory authority; Fiscal impact; Protection of public health, safety and welfare; Reasonableness; Need; and Clarity.

We have several concerns with respect to this section. Our concerns are outlined below.

Subsection 4.10(a) Administrative review.

Subsections 4.10(a)(1) - (2) are confusing. First, there is a discrepancy between the two subsections. Subsection 4.10(a)(1) states that an "applicant" may file the request for an administrative review. However, Subsection 4.10(a)(2) states that the "applicant or client" must file a request for an administrative review within 30 days of the date of the eligibility

determination. Why does the first subsection reference only an "applicant" and not also a "client," while the second subsection includes both?

Second, both subsections limit a request for an administrative review to the issue of the HIP eligibility determinations. What elements in the HIP eligibility determinations are subject to review or appeal?

Third, there is no time limit for administrative review. To insure an expeditious resolution of adverse determinations, the Department should impose a time limit on its internal review. Finally, the regulation does not indicate who is involved in an administrative review or whether the applicant or client may attend or participate in an administrative review. This should be clarified.

Subsection 4.10(b) Administrative hearing.

We have several concerns with this subsection. First, as noted above, the regulation does not indicate which issues may be appealed. Examples of other decisions or determinations that could be subject to appeal include the following:

1. The determination under Section 4.5 of the specific condition or impairment deemed eligible for treatment.
2. The determination under Section 4.5 whether the client has the potential to benefit from treatment and live more independently as a result of services.
3. The maximum allocation of funds under Section 4.5.
4. The duration of funding under Section 4.6.
5. The services eligible for payment under Section 4.7.
6. The modification of the plan under Section 4.8.

Second, it is unclear whether a person may immediately appeal an adverse determination or whether the person must first request an administrative review. The Preamble of this proposed rulemaking explains that an applicant or client must first request an administrative review. If the person is not satisfied with the results, the person may then appeal. This would lead to the scheduling of an administrative hearing. However, this two-step process is not clear in the regulation. Subsections 4.10(b)(1) - (2) do not mention the need for an administrative review before filing for a hearing. They simply state that the Division will advise the person of the right to appeal an adverse decision within 15 days of the mailing of that decision.

The regulation should clarify that an applicant or client must first complete the administrative review process before he can file an appeal. A solid start towards clarifying this two-step sequence would be to place the procedures for the administrative review and the hearing into two separate sections.

As noted above, Subsection 4.10(b)(2) gives an applicant or client 15 days to file an appeal. This period begins on the date that the Division mails its decision to the applicant or client. Depending on the postal service's efficiency in delivering the decision, the period in which an applicant or client may file an appeal could shrink dramatically. In order to account for unforeseeable postal delays, the rule should provide that three days should be added to the time required for filing an appeal when the decision is sent by mail.

Third, the regulation should insure that hearing locations are accessible to applicants or clients. Senator Hughes suggests that the regulation include a provision similar to one proposed for the Women, Infants and Children (WIC) program. The provision requires that the hearing

location be accessible to the applicant or client. We agree that accessibility to a hearing location would be important to the HIP population.

Fourth, the Subsection 4.10(b)(4)(ii)(B) indicates that an applicant or client may be represented at a formal hearing by a relative, friend or another person of the applicant's, or client's choice. Allowing a non-lawyer to represent another individual constitutes the unlawful practice of law, prohibited by 42 Pa.C.S. § 2524. An administrative agency does not have the authority to permit a practice that is prohibited by the Judicial Code. (see *Westmoreland County v. Rodgers, et al., 693 A.2d 996 (1997); Kohlman v. Western Pennsylvania Hospital, 652 A.2d 849 (1994), petition for allowance of appeal denied, 663 A.2d692 (1995)).*

Fifth, this section does not clarify that a legal representative may seek administrative review and file an appeal on behalf of an applicant or client. As noted in **Comment #3** above, this section should contain a reference to "legal representative," which should be a defined term.

Finally, will HIP services and funding continue during the pendency of a review or hearing? If not, the regulation should include a specific time limit for the administrative review. Also, the regulation should provide that immediately upon issuance of a favorable decision, services will be reinstated for the time remaining of the 12 month period based upon the date on which services are terminated.