UPMC HEALTH SYSTEM

Brain Trauma Research Center

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http://www.edc.gsph.pitt.edu/headinj/

June 10, 1999

Original: 2034
Bush
cc: Harris
Smith
Jewett
Markham
Sansusky
Legal

Elaine M. Terrell, MPH
Director, Head Injury Program
Division of Special Health Care Programs
Room 724, Health and Welfare Building
Harrisburg, PA 17120

RE: Proposed Rule Making: Department of Health: 28 PA. CODE CH, 4 Head Injury Program (as published in the Pennsylvania Bulletin (5/22/99); 29:(21);2671-8, 1999

Dear Ms. Terrell:

I carefully reviewed the Proposed Rulemaking to the Head Injury Program and have several concerns:

1. Page 2671, Section 4.4, Eligibility for services: The last paragraph on this page under this section indicates "...that the Department would deem a client ineligible if that client lacks the potential to benefit and to live more independently as a result of the services sought. This determination would be based upon the recommendations of the client's case manager and other neuropsychological evaluations." I am very concerned about this statement. Patients who suffer traumatic brain injury may not necessary progress in a consistent fashion in terms of their improvement. Indeed, some patients may plateau for several weeks and then begin to improve again. I am concerned that the regulations must stipulate a time period over which the patient must progress. I would recommend a three month time period. In addition, I strongly disagree that a non-medical doctor, and particularly a non-neurologic or brain injury medical doctor specialist be allowed to make this determination. Indeed, I strongly recommend that the determination of lack of progress be made only by a board-certified physiatrist, neurosurgeon or neurologist rather than the case manager. To do otherwise, I am afraid would be rather arbitrary and not provide for recognition of subtile changes in a patient's neurologic recovery.

2. Page 2672, Section 4.6, Duration of funding: Under this section, you state that "No client would receive more than 1 benefit year of rehabilitation. A benefit year would be defined as 12 consecutive months beginning on the date that HIP services are initially purchased for the client." Here I am concerned that there are a number of people in their 20's and 30's who may require up to 3 years to realize maximum benefit from aggressive rehabilitation therapy and I think that absolutely limiting their duration of

funding to 1 year would restrict the maximum potential recovery of those patients. In addition, there are some head injured patients who may initially benefit from a 6 week to 3 month course of inpatient rehabilitation therapy, then may be discharged either to home or a nursing home and at a later date have a spontaneous recovery to the extent that they would again benefit greatly from inpatient rehabilitation. Thus, I disagree with your requiring that it be a 12 consecutive months of funding.

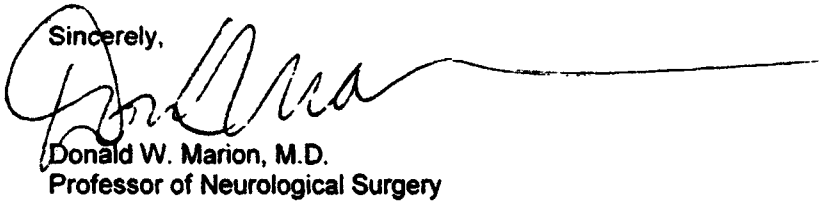
3. Page 2673, Section 4.10. Appeal procedures - C. Affected Persons: Under this section, you indicate that patients would be eligible if they are over the age of 21, but you do not indicate an older age limit. All scientifically conducted outcome studies of head injured patients indicate that elderly patients do not benefit meaningfully from aggressive inpatient rehabilitation. Indeed, the age threshold appears to be 55-60 years of age. I would strongly recommend that you provide a maximum age cut-off of 60-65 years of age. Doing so would hopefully save funding for younger individuals who are far more likely to benefit from organized inpatient rehabilitation and would not substantially change the ultimate outcomes for older individuals. As you undoubtably know, it is after all the younger individuals who are at far greater risk for severe traumatic brain injury and certainly those are the individuals that have the greatest loss of potential years of productive and meaningful life without the services of inpatient rehabilitation.

4. Page 2677, Annex A, Title 28, Section 4.9. Peer review - A. Purpose: In this section, you indicate that there will be a Head Injury Program Peer Review Committee charged with reviewing services and rehabilitation service plans for HIP clients. I strongly urge you to again appoint to that committee medical experts that are capable of understanding and assessing functional and neurologic progress of a head injured patient. The only appropriate subspecialties for such a committee, in my view, would be board certified physiatrists, neurosurgeons and neurologists. In the past, I have seen such committees composed of non-medical doctor social workers, psychologists, or medical doctors who are generalists or at best are internists. It think that this is inappropriate and leads to inaccurate assessments of neurologic progress of head injured individuals who otherwise could make a good recovery.

I appreciate the opportunity to comment on this Proposed Change in the Head Injury Program and would welcome the opportunity to testify before you or your Committee, speak with you on the phone, or provide further expert opinion among individuals from around the State who truly understand the long-term needs of patients with severe traumatic brain injury. I also welcome the opportunity from you to provide testimony from a number of my patients who have benefitted enormously from inpatient head injury rehabilitation and, one individual in particular, who is currently writing a book about her past experiences nine years after she was

rendered comatose from a severe traumatic brain injury and remained comatose for six months. Thank you again.

Sincerely,



Donald W. Marion, M.D.
Professor of Neurological Surgery
Director, Brain Trauma Research Center
Director, Center for Injury Research and Control

DWM/djk

UPMC HEALTH SYSTEM

Brain Trauma Research Center

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Manager. Focal Ischemia Project

June 10, 1999

Elaine M. Terrell, MPH
Director, Head Injury Program
Division of Special Health Care Programs
Room 724, Health and Welfare Building
Harrisburg, PA 17120

RE: Proposed Rule Making: Department of Health: 28 PA. CODE CH, 4 Head Injury Program (as published in the Pennsylvania Bulletin (5/22/99); 29:(21);2671-8, 1999

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I appreciate the opportunity to comment on this Proposed Change in the Head Injury Program and would welcome the opportunity to testify before you or your Committee, speak with you on the phone, or provide further expert opinion among individuals from around the State who truly understand the long-term needs of patients with severe traumatic brain injury. I also welcome the opportunity from you to provide testimony from a number of my patients who have benefitted enormously from inpatient head injury rehabilitation and, one individual in particular, who is currently writing a book about her past experiences nine years after she was

rendered comatose from a severe traumatic brain injury and remained comatose for six months. Thank you again.

Sincerely,

Donald W. Marion, M.D.
Professor of Neurological Surgery
Director, Brain Trauma Research Center
Director, Center for Injury Research and Control

DWM/djk

Original: 2034
Bush
cc: Harris
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Jewett
Markham
Sansusky
Legal

99 JUN 23 PM 3:37

DEPARTMENT OF HEALTH
...in pursuit of good health

(717) 772-4959

June 23, 1999

Mr. Robert E. Nyce
Executive Director
Independence Regulatory Review Commission
14th Floor, Harristown II
333 Market Street
Harrisburg, Pennsylvania 17101

RE: Proposed Regulations
Head Injury Program
No. 10-129

Dear Mr. Nyce:

The Pennsylvania Department of Health has recently received the enclosed public comments to the above-referenced regulations.

Sincerely,

Elaine M. Terrell, MPH

Elaine M. Terrell, MPH
Director, Head Injury Program
Division of Special Health Care Programs

EMT:cas

Enclosures

Original: 2034
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MECA United Cerebral Palsy
Serving Persons with Mental and Physical Challenges in Northwestern Pennsylvania
3745 West 12th Street • Erie, PA 16505 • 814-836-9113 • 800-950-6322 • FAX 814-833-3919

June 10, 1999

Elaine M. Terrell, MPH
Head Injury Program Director
Division of Special Health Care Programs
RM 724
Health & Welfare Building
Harrisburg, PA 17120

Dear Ms. Terrell,

In response to the Proposed Rulemaking in the Pennsylvania Bulletin (Vol. 29, No. 21), I would like to include written comments and suggestions for the program. We were given this information from a local state representative. As a Case Manager for MECA/UCP, Inc., I have specific concerns regarding the program and funding issues. My goals are finding & coordinating the best services in the area. Here are my concerns:

1.) That the Head Injury Program (HIP) has not accepted any new applicants for services in over one year. I receive phone calls from individuals, family members, or other social service agencies, regarding the need for case manager or financial assistance.

2.) That there is no education or training sessions for case managers to attend to improve knowledge and resource base. This would assist to generate new ideas or to help other case managers with more difficult cases. By having contact with other case managers we could get new information and assist each other regarding services in a particular area.

3.) Duration of funding should be person specific. Based on experience with persons who have suffered a brain injury, different people go through rehabilitation at a different speeds. Some need more time to recover, but may require numerous years of services before progress can be noted. One to two years are often not enough time to realize full recovery.

4.) Case manager should be reimbursed for travel time, especially those that cover multiple counties or travel great distances. (Example: I have two clients which are over 120 miles from my office, one in Clarion, PA & one in Beaver Falls, PA).

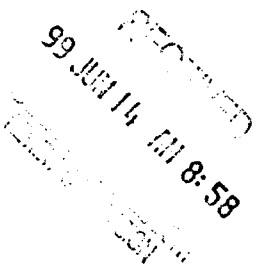
These concerns are addressed to maximize the services provided to the individuals and to assist them in regaining their full potential. I submit these concerns to assist with the planning of the proposed legislation.

Sincerely,

James Williams Jr, Med.

James G. Williams, Jr., M. Ed.
MECA - Case Manager

Original: 2034
Bush
cc: Harris
Smith
Jewett
Markham



DEPARTMENT OF HEALTH
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(717) 772-4959

June 11, 1999

Mr. Robert E. Nyce
Executive Director
Independence Regulatory Review Commission
14th Floor, Harristown II
333 Market Street
Harrisburg, Pennsylvania 17101

RE: Proposed Regulations
Head Injury Program
No. 10-129

Dear Mr. Nyce:

The Pennsylvania Department of Health has recently received the enclosed public comments to the above-referenced regulations.

Sincerely,

Elaine M. Terrell, MPH

Elaine M. Terrell, MPH
Director, Head Injury Program
Division of Special Health Care Programs

EMT:cas

Enclosures

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PAYNE-SHOEMAKER BUILDING
240 NORTH THIRD STREET
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99 JUN 23 PM 3:37

June 21, 1999

Elaine M. Terrell, M.P.H., Director
Head Injury Program
Division of Special Health Care Programs
Room 724, Health & Welfare Building
Harrisburg, PA 17120

RE: Comments to Head Injury Program Regulations

Dear Ms. Terrell:

This firm represents one of the individuals that is currently enrolled as a recipient of the Head Injury Program (the "HIP"). On behalf of that individual, this letter provides you with comments on the proposed regulations of the Department of Health ("DOH") that were published in the May 22, 1999 *Pennsylvania Bulletin.*

Our comments are directed to: (1) the propriety of promulgating regulations at a time when the Commonwealth is evaluating whether the HIP should remain in DOH or be transferred to the Department of Public Welfare ("DPW"), and (2) the statutory authority for the regulations.

Timing of the Regulations

It is our understanding that there are a number of activities currently under way that would suggest a policy direction by the Commonwealth which would transfer the HIP program from DOH to DPW. In furtherance of this objective, we understand the following steps have or will be taken:

1. The Office of Social Programs, DPW is applying for a waiver from the Health Care Financing Administration that will permit the use of Medicaid funding for home and community-based head injury rehabilitation services;

2. Approximately $450,000 of state funds from the Emergency Medical Services Operating Fund ("EMSOF") will be transferred from DOH to DPW in the 1999-2000 fiscal year;

3. H.B.1467, which creates a head injury program in the Office of Social Programs of DPW, was introduced in the House by Representative Roy Cornell on May 6, 1999, and was referred to the House Health and Human Services Committee, also on May 6, 1999.

We have been told that the Medicaid waiver program is expected to begin in the 1999-2000 fiscal year. We understand that the EMSOF funds will be transferred from the Department to DPW to provide the State share for the Medicaid waiver program.

Because the Commonwealth appears to be moving in the direction of transferring responsibility for the HIP from DOH to DPW, the promulgation of the regulations by DOH at this time is particularly inopportune. DOH makes no mention of these other activities in the preamble to the regulations or how these activities might effect the proposed regulations.

Under the Regulatory Review Act, the Independent Regulatory Review Commission (the "IRRC") is charged with reviewing proposed regulations of the Commonwealth agencies and providing comments or objections to the agency. *See* Act of June 25, 1982, P.L. 633, No. 181, *as amended*, 71 P.S. § 745.1 *et seq.* The IRRC is required to consider a number of factors in deciding whether to approve or disapprove a final-form regulation, but it may not disapprove a final-form regulation or portion thereof if it does not raise its objection to the relevant portion of the regulation when it is initially proposed. *See* 71 P.S. 745.5(g). Thus, the criteria for disapproving a final-form regulation become relevant in the review of a proposed regulation.

One of the factors to be considered by the IRRC in approving or disapproving a regulation is whether the regulation "represents a policy decision of such a substantial nature that it requires legislative review." 71 P.S. § 745.5a(i)(4). Transfer of the HIP from DOH to DPW does present a substantial policy decision which deserves legislative review. In fact, that legislative review has begun through the introduction of H.B.1467 and its referral to the House Health and Human Services Committee. The publication of these regulations at this time ignores that overriding policy issue.

If the transfer of the HIP to DPW occurs, these regulations would be obsolete. On that basis alone, these regulations, as a whole, should be questioned by the IRRC, the House Committee on Health and Human Services and the Senate Committee on Public Health and Welfare. To be proposing regulations at this time, more than ten years after the passage of

legislation upon which DOH relies to promulgate these regulations and simultaneous with Representative Cornell's proposal to transfer the HIP to DPW, defies logic.

Statutory Authority for the Regulations

When reviewing regulations, the IRRC "shall, first and foremost, determine whether the agency has the statutory authority to promulgate the ....regulation and whether that regulation conforms to the intention of the General Assembly in the enactment of the statute upon which the regulation is based." 71 P.S. § 745.5a(h).

We question the Department's authority to promulgate the regulations as proposed. The regulatory authority that flows from the statutory language is very limited. In fact the entire subsection that relates to this funding provides as follows:

> Twenty-five percent of the [EMSOF] fund shall be allocated to a Catastrophic Medical and Rehabilitation Fund for victims of trauma. The catastrophic fund shall be available to trauma victims to purchase medical, rehabilitation and attendant care services when all alternative financial resources have been exhausted. The Department may by regulation, prioritize the distribution of funds *by classification of traumatic injury.*

35 P.S. § 6934(e)(Emphasis supplied). The plain meaning of the legislation gives the Department only the ability to decide which *class or type* of traumatic injury it will fund, in order of priority. It does not provide the Department with the authority to develop detailed administrative regulations relating to operation of the HIP.

Clearly, when the General Assembly intends to delegate comprehensive authority to an agency to develop regulations, it does so through broad statutory language. *See, e.g.*, 35 P.S. § 448.803 (With respect to health care facility licensure, DOH "shall have the power and its duty shall be...to promulgate, after consultation with the policy board, the rules and regulations necessary to carry out the purposes and provisions of this chapter."); 35 P.S. § 449.5(b) (With respect to the collection of health care data, the Health Care Cost Containment Council "may, in a manner provided by law, promulgate rules and regulations necessary to carry out the purposes of this act."). In contrast, the General Assembly in this instance delegated a specific task to the DOH. DOH is permitted, but not mandated, to carry out this task through regulation. The General Assembly established a portion of the EMSOF to be used for victims of "trauma" generally. It then gave DOH the limited ability to decide through regulation what classes of traumatic injury should be funded.

DOH made the decision long ago to fund head injuries. The proposed regulations surpass that decision, however, and thus, DOH has exceeded its statutory authority. The level of detail present in these proposed regulations relating to administration of the HIP is not necessary or authorized. "When the words of a statute are clear and free from all ambiguity, the letter of it is not to be disregarded under the pretext of pursuing its spirit." 1 Pa.C.S.A. § 1921(b). In this instance, DOH has abandoned the clear meaning of the statute. Furthermore, it has taken this step when it is both unnecessary and untimely to do so.

Thank you for your consideration of these comments.

Respectfully,

Ruth E. Granfors

cc: The Honorable Senator Harold F. Mowery
The Honorable Senator Vincent J. Hughes
The Honorable Representative Dennis M. O'Brien
The Honorable Representative Frank L. Oliver
Robert E. Nyce, Executive Director,
Independent Regulatory Review Commission
Lori McLaughlin, Esq.

Original: 2034
Bush
cc: Harris
Smith
Jewett
Markham
Sandusky
Legal

99 JUN 23 PM 3:37

DEPARTMENT OF HEALTH
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(717) 772-4959

June 23, 1999

Mr. Robert E. Nyce
Executive Director
Independence Regulatory Review Commission
14th Floor, Harristown II
333 Market Street
Harrisburg, Pennsylvania 17101

RE: Proposed Regulations
Head Injury Program
No. 10-129

Dear Mr. Nyce:

The Pennsylvania Department of Health has recently received the enclosed public comments to the above-referenced regulations.

Sincerely,

Elaine M. Terrell, MPH

Elaine M. Terrell, MPH
Director, Head Injury Program
Division of Special Health Care Programs

EMT:cas

Enclosures

PERFORMANCE AUDIT OF THE HEALTH DEPARTMENT'S ADMINISTRATION OF THE PA HEAD INJURY PROGRAM

Original: 2034
Busa
cc: Original audit in file
Harris
Smith
Jewett
Markham
Sandusky, Legal

Original: 2034
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cc: Harris
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Sandusky
Legal

Ms. Elayne Klein
671 River Road
Yardley, Pa. 19067

June 21, 1999

Elaine M. Terrell, M.P.H., Director
Head Injury Program
Division of Special Health Care Programs
Room 724, Health & Welfare Building
Harrisburg, PA 17120

RE: Comments to Head Injury Program Regulations

Dear Ms. Terrell:

This letter provides you with comments on the proposed regulations for the Head Injury Program ("HIP") that were published in the May 22, 1999 Pennsylvania Bulletin. As you know, my son Scott Sarubin is currently a client of the HIP.

Initially, I want to convey how grateful we are for the HIP and the difference it has made in Scott's life. Scott suffered his severe traumatic injury in March, 1991. He became eligible for HIP rehabilitation funding in September 1992. Scott suffers from a number of problems due to his head injury that diminished his cognitive abilities. Scott's participation in the head injury rehabilitation program at Beechwood has transformed him. When he entered the program, Scott was disoriented, unable to walk independently, control emotional outbursts and panic attacks, stay focused on a task, follow a schedule, initiate tasks of daily living, focus his attention or write. Since being in the structured, therapeutic environment at Beechwood, he continues to learn compensatory strategies which have had a significant impact on his ever-improving growth and capabilities. Although Scott is still significantly impaired, he has learned to overcome many obstacles. He was able to walk down the aisle with a cane at his sister's wedding, recite a poem at his cousin's wedding, improve in his social interactions, begin relearning rudimentary computer skills, complete activities of daily living, work in a sheltered workshop, participate in a community learning workshop and become a valued member of his community skills group.

In light of our experience, we have the following comments regarding the HIP regulations. Our comments fall into primarily two categories: (1) comments on how the regulations can be improved; and (2) comments on whether any Department regulations are appropriate, given the significant and fundamental policy decisions being considered at the State level that may change the face of the HIP in the near future.

Our greatest concern is the inflexible one-year limit on rehabilitation services proposed at section 4.6 of the regulations. If there ever was an example of why the HIP

should consider some exception to this rigid proposal, Scott is that example. If Scott's services had ended after his first year, he would have developed to the point of requiring assistance in areas of ambulating, activities of daily living, all areas of cognitive functioning, socialization and vocational skills. We understand the desire of the Department of Health (the "Department") to provide benefits to as many individuals as possible, but we cannot see the benefit of operating the HIP in such a rigid manner that it would not take into account individual characteristics and progress of the clients beyond one year. For that reason, we suggest a modification of section 4.6 that would allow for an exception to the one year requirement if the client is continuing to make tangible concrete progress in rehabilitation.

Our second concern is related to the first. We are pleased to see that there is a two step appeal process for individuals who are denied or terminated from HIP participation. However, given the strict one year limit for benefits that is proposed in section 4.6, what sort of appeal is really available to an individual who is terminated after one year of rehabilitation services? The regulation is not clear in this respect. We suggest that section 4.10 explicitly indicate that an appellant may raise through the appeal proceedings reasons why an exception to the one year rehabilitation rule would be appropriate in that case. We suggest that this basis for appeal be specifically recognized in the regulation at both levels of the appeal, i.e., the administrative review process and the administrative hearing.

Our third concern relates to the lack of available alternatives for an individual that is required to transition from the HIP. Based on the Department's current one year rehabilitation requirement, many individuals who will be removed from HIP-funded rehabilitation will be facing inappropriate placement in a nursing home or back in the family home, neither of which generally provide the requisite combination of skills and socialization necessary for a young adult who requires significant assistance and continued rehabilitation and therapy in order to achieve his or her fullest potential. For example, to date, there has been no appropriate facility available to which Scott could be transferred if HIP rehabilitation benefits were no longer available to him.

We understand that the Pennsylvania Department of Public Welfare ("DPW") is seeking a waiver from the Health Care Financing Administration in order to use Title IXX Medicaid funding for head injured individuals, so that appropriate services and a proper placement may be available for individuals such as Scott. We applaud these efforts by the Commonwealth. However, we believe that these proposed regulations should not go into effect until the waiver program is in place.

Sincerely yours,

Elayne Klein

cc: ROBERT E. NYCE, EXEC. DIR.

Angela -

United Cerebral Palsy

Serving Persons with Mental and Physical Challenges in Northwestern Pennsylvania

3745 West 12th Street • Erie, PA 16505 • 814-836-9113 • 800-950-6322 • FAX 814-833-3919

June 10, 1999

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Rep. Linda Bebko-Jones
1st District Office
460 East 26th Street
Erie, PA 16504

Dear Rep. Bebko-Jones,

In regards to our meeting on 2/25/99, here are the changes for the Proposed Rulemaking in the Pennsylvania Bulletin (Vol. 29, No. 21), as it pertains to the PA Head Injury Program. Included in this letter are my concerns. These proposals were brought to my attention by a family member of one of my client's and not the PHIP. As a Case Manager for MECA/UCP, Inc., I have specific concerns regarding the program and funding issues. My goals are to find & coordinate the best services in the area. Here are my concerns:

1.) That the Head Injury Program (HIP) has not accepted any new applicants for services in over one year. I receive phone calls from individuals, family members, or other social service agencies, regarding the need for case manager or financial assistance.

2.) That there is no education or training sessions for case managers to attend to improve knowledge and resource base. This would assist to generate new ideas or to help other case managers with more difficult cases. By having contact with other case managers we could get new information and assist each other regarding services in a particular area.

3.) Duration of funding should be person specific. Based on experience with persons who have suffered a brain injury, different people go through rehabilitation at a different speeds. Some need more time to recover, but may require numerous years of services before progress can be noted. One to two years are often not enough time to realize full recovery.

4.) Case manager should be reimbursed for travel time, especially those that cover multiple counties or travel great distances. (Example: I have two clients which are over 120 miles from my office, one in Clarion, PA & one in Beaver Falls, PA).

5.) Our agency has not been reimbursed for services for over 6 months (we have not been payed for services from January, 1999 to present).

Enclosed is a copy of the Proposed Rulemaking. Laura Eaton (Executive Director) and I thought it would be a good idea for you to review these changes, to assist you in this legislation. These concerns are addressed to maximize the services provided to the individuals and to assist them in regaining their full potential.

Sincerely,

James Williams

James G. Williams, Jr., M. Ed.
MECA - Case Manager

reviewed 6/4

PROPOSED RULEMAKING

DEPARTMENT OF HEALTH

[28 PA. CODE CH. 4]
Head Injury Program

The Department of Health (Department) proposes to amend Part I (relating to general health) by adding Chapter 4 (relating to head injury program). Proposed Chapter 4 would set forth the rules and regulations governing the administration of the Head Injury Program (HIP), and describe the types of services available under the program. The regulations being proposed would also define the eligibility criteria that must be met by applicants for services and the scope of services available to eligible applicants. In addition, the proposed regulations would provide for an appeal mechanism which may be utilized by an applicant or client of HIP. The proposed chapter is to read as set forth in Annex A.

A. Purpose of the Proposed Regulations

1. *Statutory Background*

In 1985, the General Assembly passed legislation which created a Statewide emergency medical services system. This legislation known as the Emergency Medical Services Act (act) (35 P. S. §§ 6921—6938), provided for an Emergency Medical Services Operating Fund to be funded by a $10 fine to be levied on all moving traffic violations. The act further directed that 25% of the fund be allocated to a Catastrophic Medical and Rehabilitation Fund (Fund) for victims of trauma injuries to purchase medical, rehabilitative and attendant care services when all alternative financial resources were exhausted. The Department developed a program for victims of head trauma based on this Legislative directive, and labeled the program the "Head Injury Program."

In 1988, the General Assembly amended the act by the act of October 21, 1988 (P. L. 1055, No. 121). This amendment modified the type of traffic violations for which a $10 fine would be assessed and authorized the Department to prioritize, by regulation, the distribution of funds by classification of traumatic injury.

2. *Interim Guidelines*

Following the enactment of the act, the Department recognized that the size of the Fund would be insufficient to meet the needs of all victims of trauma in this Commonwealth. The Department, persuaded by Legislative debate, traumatic brain injury victims and advocacy organizations, decided to restrict access to the Fund solely to victims of traumatic head injury. It used the Fund to pay only for services which were directly related to the needs of persons due to traumatic head injury. On March 5, 1988, the Department formally announced how it intended to administer the Fund by distributing interim policies it had developed.

The interim policies announced that the Department intended to administer the Fund to pay for services provided to victims of traumatic head injury, and described the manner in which it intended HIP to operate. These policies, however, were not intended to preclude development of a program through further analysis based on actual experiences the Department and agencies in other states encountered in allocating limited resources to serve people who have sustained traumatic injuries. To this end, the Department began plans to replace the interim policies with program regulations.

The Department appointed a Citizens Advisory Committee (Committee) to review the interim policies and advise the Department on the development of program regulations. This Committee was composed of consumers of services associated with traumatic injuries, and representatives from the rehabilitation field. The proposed regulations are a product of the Committee's recommendations to the Department, the Department's experience in administering the Fund and the Department's assessment of what program services best serve the Legislative intent consistent with current fiscal constraints.

B. Summary of the Proposed Regulations

The proposed regulations adopt some of the limitations and restrictions that had been incorporated in the interim guidelines, such as restricting eligibility to individuals who sustained traumatic brain injuries on or after July 3, 1985, the effective date of the act. A brief description of the proposals follows.

Section 4.1. Scope and purpose.

This proposed section would describe the chapter's scope and purpose.

Section 4.2. Definitions.

This proposed section would define key phrases that would appear in the regulations, such as "alternative financial resources," "exhausted" and "traumatic brain injury."

Section 4.3. HIP services and objectives.

This proposed section, along with § 4.1 (relating to scope and purpose), would broadly explain the manner in which HIP is to be run and it would clarify how and for whom the program is to operate.

Section 4.4. Eligibility for services.

This proposed section would set forth eligibility criteria for applicants to HIP, as well as criteria for specific HIP services. HIP eligibility criteria for an applicant would be as follows: (1) sustained a traumatic brain injury on or after July 3, 1985; (2) have been a resident in this Commonwealth for 90 days at the time of the injury and at the time of application to HIP and have the intent to maintain a permanent home in this Commonwealth for the indefinite future; (3) have exhausted all alternative financial resources to pay for services covered by HIP; and (4) have reached 21 years of age.

It is proposed that the Fund be used to pay only for services to individuals who are 21 years of age and older, as individuals under 21 years of age are currently eligible to receive coverage for appropriate services from Medical Assistance and the Department of Education.

In addition to these criteria, specific conditions and impairments are listed in the proposed regulations which would exclude an otherwise-eligible applicant because those conditions would impede an individual's participation in or benefiting from services HIP provides. The proposed regulations provide that the Department would deem a client ineligible if that client lacks the potential to benefit and to live more independently as a result of the services sought. This determination would be based upon the recommendation of the client's case manager and other neuropsychological evaluations. The Department has exercised its discretion under section 1(c) of the act (35 P. S. § 6934) by developing a program which attempts to prioritize funds for those persons who have the ability

to progress in rehabilitation. It is the Department's position that the limited moneys available to it through the Fund should be used to rehabilitate as many individuals as possible given its limited resources, rather than to maintain a static number of persons with traumatic head injuries past the point where progress in rehabilitation can be made by those persons.

This proposed section would also exclude from HIP an applicant who fails to complete an assignment agreement with the Department, assigning the Department rights of future or expected monetary awards, accruing to the applicant due to the applicant's traumatic brain injury, to cover the cost of HIP services provided. This language would permit the Department to recoup any improperly spent funds, and to obtain some reimbursement for funds spent on clients who might have initially had no alternative resources, but who have become eligible for those resources during the course of services. Recouping these moneys will enable the Department to stretch further the moneys available to it for this program and to provide services to more eligible persons.

Section 4.5. Payment for services.

This proposed section would state that the Department will give written authorization to both the client and provider as to the specific HIP services for which a client is eligible and the maximum funding available to the client for those services. This proposed section would also provide a list of conditions which may trigger termination from HIP. For instance, HIP will pay for services until a client: (1) exhausts the maximum funds available to the client during a benefit year; (2) reaches the maximum duration for HIP services; (3) gains access to alternative financial resources; or (4) undergoes a change affecting the client's clinical condition which affects eligibility or execution of a service plan. Again, the provisions will enable the Department to prioritize need, and to provide services to more individuals.

This proposed section would also make clear that the Department has the right to choose subrogation to obtain payments owed a client. This ability will enable the Department to utilize existing funds for the benefit of more clients.

Section 4.6. Duration of funding.

This proposed section would set forth strict time limitations for HIP funding. No client would receive more than 1 benefit year of rehabilitation. A benefit year would be defined as 12 consecutive months beginning on the date that HIP services are initially purchased for the client. Case management services would be limited to 18 consecutive months. These durational limits would represent a significant departure from past HIP practices. The 1988 policies under which HIP was instituted had no durational limits. Subsequent policies made known to applicants, clients and providers included durational limits of 2 years for rehabilitation services and a maximum of 3 years for case management (also referred to as case coordination). The Department, however, believes that the limitations in these proposed regulations are appropriate based upon the numbers of persons potentially eligible for HIP services during a time when those services are of maximum benefit. The Department also believes that these limitations will protect the fiscal integrity of the Fund and HIP's ability to provide services for as many eligible individuals as possible, during the window of opportunity for maximum benefit to those individuals.

Data pertaining to treatment of victims of head trauma reflect that the average client completes a postacute traumatic brain injury rehabilitation program in 1 years. Thus, the 1-year funding limit is establishe coincide with the needs of both existing and new cl while operating within budgetary limitations. This restriction should ensure that moneys will be avai from the Fund so new victims of head trauma wi afforded an opportunity to receive services from v they may benefit.

The proposed regulations also provide that the De ment will give prior notification to all clients of H the date that their funding for HIP services will t nate.

Section 4.7. Services eligible for payment.

This proposed section would describe the specific vices covered by the categories of services in (relating to HIP services and objectives) and as categories are defined in § 4.2 (relating to definiti This proposed section would also emphasize case mar ment as an important service to be provided immedi upon a determination of eligibility for HIP. Case mar ment requirements would emphasize, but not be lir to, the development of a rehabilitation service pla each eligible client.

Rehabilitation services are designed to be part o continuum of treatment with the goal of transitionir individual to independent living in the individual's or community; transitioning an individual to meani activity or vocational training; and transitioning an vidual to appropriate living and service arrangen once the client has met the goals established in rehabilitation service plan.

The case manager is required to have certain qual tions under this proposed section: a minimum of 2 of experience in traumatic head injury case manage at least a bachelor's degree in nursing, education, work, psychology or a rehabilitation field; and a kn edge of services and facilities available in the geogr area of practice.

Section 4.8. Rehabilitation service plan.

This proposed section would describe the develop of a rehabilitation service plan required for each c and prescribe the elements which must be part of plan. A rehabilitation service plan is a document identifies the specific goals for the client's rehabilit and the expected time frames for the achievement of goal. The rehabilitation service plan is of vital impor in charting the client's progress in meeting goals.

Section 4.9. Peer review.

This proposed section would describe the establish of a peer review committee to conduct a review of ser and rehabilitation plans for HIP clients. The membe the HIP Peer Review Committee would be appoint serve 3-year terms. Members could not serve consec terms. The HIP Peer Review Committee would r cases on a quarterly basis and, within 30 days review, provide recommendations for all ongoing ser Members of the Committee who would have a confl interest if they would participate in the review particular case would not be permitted to participa that review. The Department would notify the Comm of all actions taken on the recommendations o Committee.

Section 4.10. Appeal procedures.

This proposed section would contain a two-tiered a mechanism which protects the interests of both appli

and clients. The first level would consist of an internal administrative review of certain HIP office decisions. The second would involve a formal hearing procedure for appeals of administrative reviews.

An applicant or client may first appeal HIP office decisions relating to eligibility for HIP services by notifying the Division of Special Health Care Programs (Division) that the client is seeking an appeal with the Department. The Division would conduct the administrative review, and a review of the averments and supporting documentation provided by the applicant or client to refute the determination.

The Division's decision would constitute HIP's final determination, but not necessarily the final decision of the Department. An individual could appeal the Division's final determination to the agency head by seeking a formal administrative hearing. The hearing would be conducted in accordance with 1 Pa. Code Chapters 33 and 35 (relating to documentary filings; and formal proceedings), except where those rules are inconsistent with the regulations. This second mechanism would be available only for appeals of decisions pertaining to eligibility for services.

If a hearing is sought, the agency head would designate an impartial hearing officer to preside at a hearing and to render a decision based exclusively upon the hearing record. The applicant or client or his representative would be required to appear at the hearing unless the hearing officer finds he has good cause not to attend. Failure to do so would result in dismissal of the appeal by the Department with prejudice. Once a decision is made, a participant in the hearing could file a brief with the agency head, in which the participant takes exception to the hearing officer's findings or conclusions. If no brief on exceptions is filed within the time allowed, the hearing officer's decision would become final. When briefs are filed, the agency head would be required to consider the brief on exceptions, review the record along with the hearing officer's decision, and accept or reject that decision. The agency head would be required to issue an adjudication and order.

The Department believes that this procedure offers applicants and clients ample and appropriate opportunities to challenge HIP decisions in which the individuals may have a protected interest. At the same time, this process will not unduly hinder the functioning of HIP.

C. Affected Persons

The proposed regulations will affect individuals who are enrolled or seek enrollment in HIP who: (1) sustained a traumatic brain injury on or after July 3, 1985; (2) have been a resident in this Commonwealth for 90 days (both at the time of the injury and the time of application to HIP), and have the intent to maintain a permanent home in this Commonwealth for the indefinite future; (3) have exhausted all alternative financial resources to pay for services covered by HIP; and (4) have reached the age of 21. They will also affect service providers caring for the individuals.

D. Fiscal Impact

1. *Commonwealth*

Implementation of the proposed regulations will entail administrative costs associated with contract development, data analysis, fiscal monitoring and other program activities. HIP does currently have similar administrative costs from current program operations. These proposed regulations are intended to channel the bulk of nonadministrative funding into services for clients who are able to make progress as a result of those services.

2. *Political Subdivisions.*

There should be no cost to political subdivisions.

3. *Private Sector.*

HIP requires that providers of residential rehabilitation services are accredited by an appropriate National accrediting body as approved by the Department. Providers of outpatient, day or home and community-based services must be accredited by an appropriate National accrediting body as approved by the Department.

4. *General Public*

That portion of the general public suffering from traumatic head injuries, and their families, will be affected by the adoption of these proposed regulations. The restructuring of priorities under these proposed regulations will undoubtedly remove funds from some clients currently receiving moneys but who are not making rehabilitative progress with services provided with those moneys. These individuals will be required to find other funding sources for maintenance. The limited funds available for HIP necessitate some realignment of funding, and section 14(e) of the act provides the Department with the discretion to make that realignment.

E. Paperwork Requirements

The Department will require providers to submit periodic patient status reports.

Persons seeking to apply to HIP for themselves or others will be required to complete an application and to provide verifying documentation.

F. Effectiveness/Sunset Date

The proposed regulations will become effective upon publication of final-form regulations in the *Pennsylvania Bulletin*. No sunset date has been assigned. The regulations will be evaluated on an ongoing basis by the Department.

G. Statutory Authority

Under section 14(e) of the act, the Department is expressly authorized to promulgate regulations prioritizing distribution of moneys in the Fund by classification of traumatic injury.

H. Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a), on April 27, 1999, the Department submitted a copy of these proposed regulations, to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House Committee on Health and Human Services and the Senate Committee on Public Health and Welfare. In addition to submitting the proposed regulations, the Department has provided IRRC and the Committees with a copy of a detailed Regulatory Analysis Form prepared by the Department in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

If IRRC has objections to any portion of the proposed regulations, it will notify the Department by July 8, 1999. The notification shall specify the regulatory review criteria which have not been met by that portion. The Regulatory Review Act specifies detailed procedures for review prior to final publication of the regulations, by the Department, the General Assembly and the Governor of objections raised.

I. Contact Person

Interested persons are invited to submit written comments, suggestions or objections regarding the proposed regulations to Elaine M. Terrell, M.P.H., Director, Head Injury Program, Division of Special Health Care Programs, Room 724, Health and Welfare Building, Harrisburg, PA 17120, (717) 772-4959, within 30 days after publication of this proposed rulemaking in the *Pennsylvania Bulletin*. Persons with a disability who wish to submit comments, suggestions or objections regarding the proposed regulations may do so by using V/TT (717) 783-6514 for speech and/or hearing impaired persons or the Pennsylvania AT&T Relay Service at (800) 654-5984 [TT]. Persons who require an alternative format of this document may contact Elaine Terrell so that necessary arrangements may be made.

ROBERT S. ZIMMERMAN, Jr.,
Acting Secretary

Fiscal Note: 10-129. (1) Emergency Medical Operating Services Fund; (2) Implementing Year 1998-99 is $34,000; (3) 1st Succeeding Year 1999-00 is Unknown; 2nd Succeeding Year 2000-01 is Unknown; 3rd Succeeding Year 2001-02 is Unknown; 4th Succeeding Year 2002-03 is Unknown; 5th Succeeding Year 2003-04 is Unknown; (4) 1997-98 $4.000 million; 1996-97 $3.364 million; 1995-96 $4.197 million; (7) Catastrophic Medical and Rehabilitation; (8) recommends adoption. Sufficient funds are available in this program's budget to cover the increased administrative cost of these regulations. Future year costs are unknown because they are dependent on the number of appeals that come before the Department.

Annex A

TITLE 28. HEALTH AND SAFETY

PART I. GENERAL HEALTH

CHAPTER 4. HEAD INJURY PROGRAM

Sec.

§ 4.1. Scope and purpose.

This chapter establishes standards for the Department to administer the Fund to provide rehabilitation services, facilitated through case management, to persons who incur a traumatic brain injury.

§ 4.2. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

Agency head—The Secretary or a deputy secretary designated by the Secretary.

Alternative financial resources—

(i) Income (including income from assets and public benefits).

(ii) Court awards and insurance settlements.

(iii) Funding from other State or Federal programs including Medicaid, Medicare, Social Security Disability Insurance (Title II), Supplemental Security Income (Title XVI), veterans' benefits and workers' compensation insurance.

(iv) Other funds or services which are available to the applicant or client by virtue of experiencing a traumatic brain injury.

Applicant—An individual for whom an application for enrollment in HIP is submitted to the Department.

Case management—The planning, coordination and securing of services determined by the Department to be necessary to assist the client in obtaining required services.

Case manager—The individual approved and assigned by HIP to provide case management for a client.

Client—An individual enrolled in HIP.

Day services—Nonresidential services intended to improve the cognitive, behavioral or functional abilities of the client through therapeutic intervention and supervised activities which are provided at a facility on an outpatient basis.

Department—The Department of Health of the Commonwealth.

Division—The organizational unit, within the Department, having responsibility for the administration of the HIP.

Eligibility—Determination by the Department that the applicant or client may receive services.

Exhausted—The point at which alternative financial resources for a HIP funded service required by an applicant or a client have been applied for and been denied or fully utilized.

Fund—The Catastrophic Medical and Rehabilitation Fund.

HIP—Head Injury Program—The traumatic brain injury program of the Department.

HIP Peer Review Committee—A committee, composed of professionals and organizations offering rehabilitation services in this Commonwealth to persons with traumatic brain injury, whose members are appointed by the Department to review rehabilitation plans and services offered to clients and to recommend actions to improve services.

HIP services—Rehabilitation services, facilitated through case management, for which the Department authorizes payment through HIP.

Home facilitation—A formal rehabilitation program which provides a community reentry specialist in the client's home to continue therapy learned by the client and to assist the client in the practice of techniques and strategies for living independently.

Peer review—A review of services and rehabilitation service plans for clients conducted by the HIP Peer Review Committee for the purpose of advising the Department on best practices to be followed in offering services to clients.

Provider—An individual, organization or facility delivering services to clients pursuant to contractual agreement with the Department.

Rehabilitation—Providing to a client who has progressed to a postacute phase of traumatic brain injury in a coordinated manner, services deemed appropriate to the needs of the client to improve health, welfare and

realization of the client's maximum physical, social, psychological and vocational potential for useful and productive activity:

(i) These services include case management, neuropsychological evaluation, physical therapy, occupational therapy, speech or language therapy, behavior management and psychological services which may include cognitive remediation.

(ii) These services shall be provided or their provision shall be supervised by a physician or other appropriate health professional who contracts with the Department to provide these services.

Rehabilitation service plan—The written plan, developed by the rehabilitation provider in collaboration with the client and the case manager, which outlines specific goals to be achieved and expected time frames for achievement of each goal. The primary focus of goals shall be progression toward a higher level of functioning to enable transfer of the client to a less restrictive environment.

Secretary—The Secretary of the Department.

Subrogation—The Department's right to seek reimbursement for payments made on behalf of a client from an insurer which may offer coverage to the client or from the proceeds of litigation arising out of the injury which qualified the individual for enrollment in HIP.

Traumatic brain injury—An insult to the brain, not of a degenerative or congenital nature, caused by an external physical force that may produce a diminished or altered state of consciousness, which results in impairment of cognitive abilities or physical functioning or in the disturbance of behavioral or emotional functioning. These impairments may be either temporary or permanent and cause partial or total functional disability or psychosocial maladjustment.

§ 4.3. HIP services and objectives.

(a) The Department will administer the Fund through HIP.

(b) The Department will use the Fund to pay for HIP services to assist clients in meeting the goals established in their rehabilitation service plans.

(c) Subject to the availability of moneys from the Fund, and restrictions in §§ 4.5 and 4.6 (relating to payment for services; and duration of funding), 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.

(d) Services designated by the Department to be funded through HIP are limited to postacute traumatic brain injury rehabilitation services.

§ 4.4. Eligibility for services.

(a) *Conditions.* Except as otherwise set forth in this section, the Department will deem an applicant eligible for HIP services only if the following are satisfied:

(1) The applicant sustained a traumatic brain injury on or after July 3, 1985.

(2) The applicant has been a resident in this Commonwealth for 90 consecutive days at both the time of injury and the time of application to HIP, and demonstrates the intent to maintain a permanent home in this Commonwealth for the indefinite future.

(3) The applicant exhausted all alternative financial resources to pay for services covered by HIP as determined in accordance with HIP financial eligibility criteria.

(4) The applicant is 21 years of age or older.

(b) *Eligibility.* The Department will deem an applicant eligible for HIP services only if it determines based upon the case manager's recommendation and other neuropsychological evaluations as deemed appropriate by the Department, that the applicant has the potential to benefit from the services and to live more independently as a result of the services.

(c) *Ineligibility due to impairment.* The Department will deem an applicant ineligible for HIP services if the applicant's impairment is the result of one or more of the following conditions:

(1) Cognitive or motor dysfunction related to congenital or hereditary birth defects.

(2) Putative birth trauma or asphyxia neonatorum (hypoxic-ischemic-encephalopathy).

(3) Hypoxic encephalopathy unrelated to traumatic brain injury.

(4) Significant preexisting psychiatric, organic or degenerative brain disorders.

(5) Cerebral vascular accidents.

(6) Spinal cord injuries in the absence of traumatic brain injury.

(d) *Ineligibility due to symptoms.*

(1) The Department will deem an applicant ineligible for HIP services if the applicant's condition manifests one or more of the following symptoms:

(i) Comatose conditions which preclude participation in HIP services.

(ii) Symptoms of suicidal behavior, homicidal behavior, potentially harmful aggression or other behaviors which preclude an individual from participating in HIP services.

(2) An applicant may reapply to HIP at any time the applicant's condition, which makes the applicant ineligible for HIP services, changes, and a new eligibility determination will be made.

(e) *Assignment agreement.* The Department will deem an applicant ineligible if the applicant or legal guardian fails to complete an assignment agreement with the Department which, conditioned upon the applicant's enrollment in HIP, would assign to the Department rights of future or expected court awards, insurance settlements or other proceeds, which are determined by the Department to have accrued to the applicant as a result or by virtue of the applicant's traumatic brain injury, up to the amount expended by the Department for HIP services on behalf of that individual at the time the award is made.

(f) *Notification of eligibility.* The Department will notify an applicant, in writing, of eligibility for HIP services within 30 days from the date of receipt of a complete application.

§ 4.5. Payment for services.

(a) The Department will give written authorization, to the client and to the provider, as to HIP services for which the client is eligible and the maximum available funding and time limits for those services.

(b) The Department will authorize payment for HIP services for clients based on funding availability. Appli-

cants for whom moneys are not available will be placed on a waiting list maintained by HIP so they may be notified when funding becomes available, at which time they may reapply.

(c) The Department will not provide funding through HIP to pay for services to address conditions existing prior to the traumatic brain injury.

(d) The Department will not provide funding through HIP to pay for services available through other publicly funded programs.

(e) The Department will coordinate HIP with other public and private programs, to assist clients to access benefits for which they may be eligible.

(f) The Department will continue to pay for HIP services for a client until one of the following occurs:

(1) The client has reached the goals established in the client's rehabilitation service plan.

(2) The maximum funds available for allocation to the client are exhausted.

(3) The maximum duration for services has been reached in accordance with § 4.6 (relating to duration of funding).

(4) Alternative financial resources or other services become available.

(5) The client's condition deteriorates so that the client is ineligible under § 4.4(b) (relating to eligibility for services), or it is no longer feasible to implement a rehabilitation service plan for the client under § 4.8 (relating to rehabilitation service plan).

(g) The Department may seek reimbursement for payments it makes on behalf of a client from an insurer which may provide coverage to the client or from the proceeds of litigation arising out of the injury which led to eligibility for enrollment in HIP.

§ 4.6. Duration of funding.

(a) The Department will conduct evaluations to determine an applicant's initial eligibility and a client's continuing enrollment in HIP.

(b) The Department will provide funding for rehabilitation services for no more than 12 consecutive months.

(c) The Department will provide funding for case management services for no more than 18 consecutive months (during 12 months of rehabilitation and 6 months of transition out of rehabilitation) from the beginning date of the client's enrollment in HIP.

(d) The Department will notify an applicant of these maximum time limits when it accepts the applicant as a client.

§ 4.7. Services eligible for payment.

The Department will pay for the following services for clients:

(1) *Assessments.* Assessments shall include neuropsychological and functional evaluations as deemed necessary by the Department for determining eligibility for rehabilitation services.

(2) *Rehabilitation service plan.* Development of a rehabilitation service plan for each client as provided for in § 4.8 (relating to rehabilitation service plan).

(3) *Case management services.* HIP will approve the assignment of each client to a case manager who has a minimum of 2 years experience in traumatic brain injury case management. Case management services include following activities by the case manager:

(i) Collaborating with the rehabilitation provider, client and the client's family in the development of rehabilitation service plan.

(ii) Assisting the client in gaining full access tc services from which the client may benefit and for w the client may be eligible.

(iii) Monitoring the client's progress with respect tc rehabilitation service plan and making modification needed.

(iv) Providing up to 6 months of follow-up case r agement upon a client's completion of rehabilitation.

(4) *Rehabilitation services.* Residential rehabilit services shall be provided by licensed facilities accrec by an appropriate National accrediting body as appr by the Department. Outpatient, day and home-b rehabilitation services shall be provided by facilitie providers accredited by an appropriate National accr ing body as approved by the Department. Example these services include the following:

(i) Helping a client develop behaviors that enable client to take responsibility for the client's own act

(ii) Facilitating a client's successful community int tion.

(iii) Assisting the client to accomplish functional comes at home and in the community.

(iv) Teaching the client skills to live independently.

(v) Supervising a client living in a home se through the following:

(A) Home facilitation.

(B) Cognitive remediation.

(C) Life-skills coaching.

(vi) Assisting the client in maintaining independ

(vii) Providing transitional living services to assis client with community reentry skills.

§ 4.8. Rehabilitation service plan.

(a) The rehabilitation provider, the case manager client and, as appropriate, the client's parent, guardi representative, shall jointly develop a rehabilitation vice plan using forms and procedures provided by The rehabilitation provider shall submit the rehab tion service plan to HIP for approval within 30 days the date the client is enrolled in HIP.

(b) The rehabilitation service plan shall state the cific goals to be achieved and expected time frame achievement of each goal. The primary focus of goals be progression toward a higher level of functioni enable transfer of the client to a less restrictive env ment. The service plan shall also specify the follo

(1) Services determined necessary to attain the ag upon goals.

(2) Beginning and ending dates of each service.

(3) The terms and conditions for service delivery.

(4) The specific responsibilities of the client, case ager and service provider relative to implementati each service.

(5) The extent of financial responsibility of the c HIP and any third party.

(c) The service plan shall include a procedure and schedule for quarterly review and evaluation of progress towards the specified goals.

(d) Modifications to the service plan shall be made concurrent and consistent with the scheduled evaluation of progress towards the specified goals.

§ 4.9. Peer review.

(a) *Purpose.* The Department will appoint a HIP Peer Review Committee to conduct a review of services and rehabilitation service plans for HIP clients. The HIP Peer Review Committee shall advise the Department on best practices to be followed in offering services to clients.

(b) *Procedures.*

(1) Members of the HIP Peer Review Committee shall be appointed to serve terms of 3 years. Members may not serve consecutive terms.

(2) The HIP Peer Review Committee shall review client progress on a quarterly basis.

(3) Within 30 days after it completes its review, the HIP Peer Review Committee shall provide, in writing, recommendations to the Department for all ongoing services.

(4) A member of the HIP Peer Review Committee may not participate in a review conducted by the Committee which presents a conflict of interest for that member. Examples of conflicts are participating in a review conducted by the Committee for one of the following:

(i) A service provided to a client of that member or that member's employer.

(ii) A person who is in the immediate family of the member.

(5) The Department will notify the HIP Peer Review Committee of any actions taken on the recommendations of the Committee.

§ 4.10. Appeal procedures.

(a) *Administrative review.*

(1) An applicant who is dissatisfied with a HIP eligibility determination may file a request for an administrative review.

(2) The applicant or client shall file a request for an administrative review with the Division within 30 calendar days after the mailing date of the determination. The request shall state the following:

(i) Why the applicant or client disagrees with the HIP determination.

(ii) The relief that the applicant or client seeks. The request shall include specific averments of fact and supporting documentation establishing that the applicant or client has cause for review. The Division will not consider requests which do not include specific averments of fact and supporting documentation.

(3) The Division will review the request for an administrative review and may reconsider HIP's determination. The Division will provide written notice to the applicant or client as to the outcome of the administrative review.

(b) *Administrative hearing.*

(1) The Division will advise the applicant or client of the right to appeal an adverse decision relating to eligibility for HIP services.

(2) The applicant or client may file the appeal with the agency head within 15 days of the mailing of that decision.

(3) If an appeal is filed an administrative hearing will be scheduled. The agency head shall designate an impartial hearing officer to preside at the administrative hearing. The hearing officer shall conduct the administrative hearing in accordance with applicable provisions of 1 Pa. Code Chapter 35, Subchapter E (relating to presiding officers).

(4) Within 10 days of the receipt of the appeal, the Division will forward to the hearing officer the file containing the eligibility determination for that applicant or client. The hearing officer shall, within 5 days of receiving the file from the Division, notify the applicant or client of the following:

(i) The time and place for the hearing.

(ii) The applicant's or client's right to:

(A) Appear in person at the hearing.

(B) Represent himself, or be represented at the hearing by an attorney, relative, friend or another person of the applicant's or client's choice.

(C) Present oral and documentary evidence, witnesses and arguments to support his position.

(D) Request a subpoena from the hearing officer for the production of evidence or appearance of witnesses at the hearing.

(E) Be provided, upon request, with the names of witnesses who will be present at the hearing.

(F) Refute testimony or other evidence, and confront and question adverse witnesses.

(G) Examine prior to and during the hearing, documents and records which are or will be presented to support the Division's decision.

(5) If the applicant or client, or that individual's representative, fails to appear at the scheduled hearing without good cause, as determined by the hearing officer, the appeal shall be dismissed with prejudice.

(6) An applicant or client may withdraw the appeal at any time before a decision is made by the hearing officer. This withdrawal shall be in writing and directed to the hearing officer.

(7) The hearing officer may order an independent medical assessment or professional evaluation of the applicant or client performed by a HIP service provider at HIP's expense.

(8) Following the receipt of evidence and testimony, or in lieu thereof, a stipulation of facts, the hearing officer shall afford the parties the opportunity to submit a written brief.

(9) The hearing officer shall, in writing, by certified mail, notify the applicant or client, or representative of that person, of the hearing officer's decision within 45 days after the record is closed.

(c) *Hearing decisions.*

(1) The hearing officer shall render a decision based exclusively on the hearing record. This decision shall be considered a proposed report as defined in 1 Pa. Code §§ 35.202—35.207

(2) The hearing officer shall submit the hearing record, which shall include a verbatim transcript or recording of testimony, exhibits submitted during the hearing and

papers and requests filed in the proceedings, to the agency head along with the hearing officer's report.

(3) A party to the administrative hearing may appeal the proposed report, within 30 days after being served with it, by filing a brief on exceptions with the agency head. Unless a party files a brief on exceptions within the time allowed, the hearing officer's decision shall become final. If a brief on exceptions is filed, the agency head will review the hearing officer's decision and the record and the agency head will issue an adjudication and order.

(4) The rules in 1 Pa. Code Part II (relating to general rules of administrative practice and procedure) apply to appeal procedures under this chapter except when inconsistent with this chapter.

[Pa.B. Doc. No. 99-818. Filed for public inspection May 21, 1999, 9:00 a.m.]

FISH AND BOAT COMMISSION

[58 PA. CODE CH. 117]

Boat Rental Business

The Fish and Boat Commission (Commission) proposes to amend Chapter 117 (relating to boat rental businesses). The Commission is publishing these amendments as a notice of proposed rulemaking under the authority of 30 Pa.C.S. (relating to the Fish and Boat Code) (code). The proposed amendments relate to livery operators.

A. *Effective Date*

The proposed amendments, if approved on final rulemaking, will go into effect on January 1, 2000, or upon publication of an order adopting the amendments in the *Pennsylvania Bulletin*, whichever occurs later.

B. *Contact Person*

For further information on the proposed changes, contact John F. Simmons, Director, Bureau of Boating and Education (717) 657-4538 or Laurie E. Shepler, Assistant Counsel, (717) 657-4546, P. O. Box 67000, Harrisburg, PA 17106-7000. This proposal is available electronically through the Commission's Web site (http://www.fish.state.pa.us).

C. *Statutory Authority*

The proposed amendments are published under the statutory authority of section 5122 of the code (relating to registration, licenses, permits, plates and statistics).

D. *Purpose and Background*

The proposed amendments are designed to update, modify and improve Commission regulations relating to boat rental businesses. The specific purpose of the proposed amendments is described in more detail under the summary of proposal. Prior to consideration by the Commission, the Commission's Boating Advisory Board reviewed the proposal and recommended that the Commission approve the publication of a notice of proposed rulemaking containing these changes.

E. *Summary of Proposal*

At its July 1998 meeting, the Commission adopted a regulation that requires operators of personal watercraft to obtain and carry a Boating Safety Education Certificate when operating their craft. The regulation al authorized and directed staff to prepare guidelines th would provide for the issuance of temporary certificates operators of rental boats and purchasers of new boat

Currently, the Commission's regulations require rent businesses to keep records, provide equipment and ma a safety presentation prior to a rental. To proper manage the issuance of temporary certificates by liveri the Commission must identify these businesses and pr vide an enforceable mechanism to provide terms a conditions for the operators of the liveries. The co authorizes the Commission to promulgate special pro sions applicable to operators of boat liveries, and t Commission proposes to exercise this authority by requ ing that most active liveries receive an annual live operator's permit.

The Commission proposes to amend Chapter 117 replacing it in its entirety to read as set forth in Annex

F. *Paperwork*

The proposed amendments will slightly increase pap work in that boat liveries will be required to apply f and the Commission will provide, annual livery operato permits. The recordkeeping requirements for boat liver have not changed.

G. *Fiscal Impact*

The proposed amendments will have a slight fis impact on the Commonwealth in that the Commissi will incur relatively modest costs associated with printi the livery operator's permits as well as posters and oth written educational materials. There are currently o about 100 boat liveries in this Commonwealth. T Commission estimates that its annual printing/post costs will be less than $1,000. Educational materials to supplied to the liveries will cost the Commission additional $1,000 per year. The proposed amendme also will have a minimal fiscal impact on the priv sector in that livery operators will incur modest costs applying for the permits. There is, however, no permit f The proposed amendments will impose no new costs political subdivisions or the general public.

H. *Public Comments*

Interested persons are invited to submit written c ments, objections or suggestions about the propo amendments to the Executive Director, Pennsylvania F and Boat Commission, P. O. Box 67000, Harrisburg, 17106-7000, within 30 days after publication of this no in the *Pennsylvania Bulletin*. Comments submitted facsimile will not be accepted.

Comments also may be submitted electronically "regulations@fish.state.pa.us." A subject heading of proposal and a return name and address must be cluded in each transmission. If an acknowledgment electronic comments is not received by the sender wit 2 working days, the comments should be retransmitte ensure receipt.

PETER A. COLANGEL
Executive Dire

Fiscal Note: 48A-90.(1) Boat Fund; (2) Implemen Year 1999-00 is $2,000; (3) 1st Succeeding Year 200 os $2,000; 2nd Succeeding Year 2001-02 is $2,000; Succeeding Year 2002-03 is $2,000; 4th Succeeding Y 2003-04 is $2,000; 5th Succeeding Year 2004-05 is $2,((4) Fiscal Year 1998-99 $n/a; Fiscal Year 1997-98 $ Fiscal Year 1996-97 $n/a; (7) General Government Op tions; (8) recommends adoption.

Original: 2034
Bush
cc: Harris, Smith, Jewett
Markham, Sandusky, Legal

Leshko, Tanya

Regulation 10-129 No. 2034 Head Injury Program, DOH

The definition of "neuropsychologist," as found in the glossary of the Commission on Accreditation of Rehabilitation Facilities (CARF) 1999 Medical Rehabilitation and Standards Manual reads as follows:

"A professional psychologist who applies principles of assessment and intervention based on the scientific study of human behavior as it relates to the normal and abnormal functioning of the central nervous system. A neuropsychologist is a doctoral-level psychology provider of diagnostic and intervention services who has demonstrated competence in the application of such principles and meets applicable legal requirements for the practice of psychology."

DEPARTMENT OF HEALTH
...in pursuit of good health

OFFICE OF LEGAL COUNSEL

FAX

TO: John Jewett, Regulatory Analyst
Independent Regulatory Review Commission

Phone Number: (717) 783 -5475
Fax Number: (717) 783 -2664

FROM: Tanya Leshko
Assistant Counsel
Office of Legal Counsel

Phone Number: (717) 783-2500
Fax Number: (717) 705-6042

DATE and TIME: July 20, 1999 10:10 a.m.

NUMBER OF PAGES (including this page): 2 **pages**

If you do not receive entire document, please contact my secretary, Karen. Thank You.
MESSAGE:

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HEAD INJURY PROGRAM REGULATION COMMENTS:

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Gene Bianco, President/CEO
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Telephone: (717) 657-7608

PENNSYLVANIA PSYCHOLOGICAL ASSOCIATION

416 Forster Street • Harrisburg, Pennsylvania 17102-1714 • Telephone 717-232-3817 • Fax 717-232-7294

An affiliate of the American Psychological Association

June 22, 1999

Original: 2034
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Elaine Terrell, M.P.H.
Director Head Injury Program
Division of Special Health Care Programs
Room 724, Health and Welfare Building
Harrisburg, PA 17120

Dear Ms. Terrell:

On behalf of the Pennsylvania Psychological Association (PPA), I am responding to the draft regulations which were published in the May 22 issues of the Pennsylvania Bulletin.

PPA commends the Department of Health for the work it has done in this area. Under the definition of "rehabilitation" section (ii) we suggest that the Department of Health can enumerate the professionals who can supervise these services so that it specifically includes psychologists.

Our major comment, however, is that there does not appear to be any provision in the regulations to give incentives to rehabilitation centers for cost-efficient outpatient services. It may be more prudent to establish a monetary limit, as opposed to a time limit, for these services.

Thank you for you consideration of our views.

Sincerely,

Samuel Knapp, Ed.D.
Professional Affairs Officer

HEAD INJURY PROGRAM REGULATION COMMENTS:

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DEPARTMENT OF HEALTH
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June 29, 1999

Mr. Robert E. Nyce
Executive Director
Independence Regulatory Review Commission
14th Floor, Harristown II
333 Market Street
Harrisburg, Pennsylvania 17101

RE: Proposed Regulations
Head Injury Program
No. 10-129

Dear Mr. Nyce:

The Pennsylvania Department of Health has recently received the enclosed public comments to the above-referenced regulations.

Sincerely,

Elaine M. Terrell, MPH

Elaine M. Terrell, MPH
Director, Head Injury Program
Division of Special Health Care Programs

EMT:cas

Enclosures

Pennsylvania Association of
P • A • R • F
Rehabilitation Facilities

Original: 2034
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Jewett, Markham, Sandusky
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Enhancing the quality of life for persons with disabilities

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June 21, 1999

Elaine M. Terrell, MPH
Director
Head Injury Program
Division of Special Health Care Programs
Room 724, Health & Welfare Building
Harrisburg, PA 17120

Dear Ms. Terrell:

The Pennsylvania Association of Rehabilitation Facilities (PARF) has solicited comments and conducted a review of proposed regulations for the Department of Health Head Injury Program.

The proposed regulations have received an endorsement by the PARF Head Injury Committee subject to review of member comments. Attached are comments on the proposed regulations published in the *Pennsylvania Bulletin* on May 22, 1999.

We look forward to working with the department in developing final form regulations. Thanks again for your invitation to participate.

Sincerely,

Gene Bianco
President/CEO
Attachment

PARF
Pennsylvania Association of Rehabilitation Facilities
2400 Park Drive, Harrisburg, PA 17110
Phone: 717/657-7608 * Fax: 717/657-8265

PARF Comments
PHIP/DOH Proposed Regulations
June 18, 1999

PREAMBLE

A. *Summary of the Proposed Regulations*
Section 4.4 Eligibility for services
It is proposed that the Fund be used to pay only for services to individuals who are 21 years of age and older, as individuals under 21 years of age are currently eligible to receive coverage for appropriate services from Medical Assistance and the Department of Education.
There is concern that those who graduate from high school and are under the age of 21 would not be eligible for services through Department of Education.

Section 4.6 Duration of funding.
Data pertaining to treatment of victims of head trauma reflect that the average client completes a post-acute traumatic brain injury rehabilitation program in 1 to 3 years. Thus, the 1-year funding limit is established to coincide with the needs of both existing and new clients while operating within budgetary limitations. This time restriction should ensure that moneys will be available from the Fund so new victims of head trauma will be afforded an opportunity to receive services from which they may benefit.
There is concern that the chronic needs of patients are not addressed. The program should indicate how the needs of clients who receive rehabilitation may be sustained and how they may secure services beyond one year. Plans should indicate how transition from the rehabilitation programs would be managed.

Section 4.10 Appeal procedures.
DOH should indicate how it will make accommodations in communicating this information on appeals and the rights to individuals who may be unable or face difficulty in comprehending formal legal letters.

D. *Fiscal Impact*
4. *General Public*
That portion of the general public suffering from traumatic head injuries, and their families, will be affected by the adoption of these proposed regulations. The restructuring of priorities under these proposed regulations will undoubtedly remove funds from some clients currently receiving moneys but who are not making rehabilitative progress with services provided with those moneys. These individuals will be required to find other funding sources for

maintenance. The limited funds available for HIP necessitate some realignment of funding, and section 14(e) of the act provides the Department with the discretion to make that realignment.

DOH should indicate the process and criteria for deciding on the progress of clients in the rehabilitation program.

REGULATIONS

4.2 Definitions

(iv) Other funds or services which are available to the applicant or client by virtue of experiencing a traumatic brain injury.

Day Services –

Revise to read: Non-residential services intended to improve the physical, **cognitive,** behavioral or functional abilities of the client through therapeutic intervention and supervised activities which are provided at the facility on an outpatient basis.

Rehabilitation –

Revise to read:

Providing to a client who has progressed to a post-acute phase of traumatic brain injury, in a coordinated manner, services deemed appropriate to the needs of the client to improve health, welfare and realization of a client's maximum physical, social, **cognitive,** psychological and vocational potential for useful and productive activity:

(i) These services include case management, neuropsychological evaluation, physical therapy, occupational therapy, speech or language therapy, behavior management, **home facilitation,** and psychological services which may include cognitive remediation.

Rehabilitation service plan:

Revise the initial phrase to read:

The written plan, developed by the rehabilitation provider in collaboration with the client, case manager, **and the client's parent, guardian, or representative**, which outlines the specific goals to be achieved

4.3 Eligibility for services.

(4) The applicant is 21 years of age or older.

There is a concern with this criteria element. Services may not be available to individuals who are under 21 and hold a high school diploma.

(b) Eligibility. The Department will deem an applicant eligible for HIP services only if it determines based upon the case manager's recommendation and other neuropsychological evaluations as deemed appropriate by the Department, that the applicant has the potential to benefit from the services and to live more independently as a result of the services.

DOH should clarify the role of the consultant in providing neuropsychological evaluations.

Duration of funding.

(a) The Department will conduct evaluations to determine an applicant's initial eligibility and client's continuing enrollment in HIP.

The process for conducting such evaluations should be described.

(b) The Department will provide funding for rehabilitation services for no more than 12 consecutive months.

DOH should clarify whether or not services can be continued for any term if they are interrupted within a twelve-month period.

4.5 Services eligible for payment.

(1) Case management services. HIP will approve the assignment of each client to a case manager who has a minimum of 2 years experience in traumatic brain injury case management. Case management services include the following activities by the case manager:

Provisions should be made to allow for exceptional circumstances to allow that services/funding may be put on hold and the 1-year limit extended. Criteria should be established to qualify for an exemption to the one-year limit on funding.

Rehabilitation services.

(A) Home facilitation.

(B) Cognitive remediation.

(C) Life-skills coaching.

DOH should indicate that PT, OT, ST, and Psychology services may be provided in a home setting.

4.6 Rehabilitation service plan.

Revise to read:

(b) The rehabilitation service plan shall state the specific goals **and outcomes** to be achieved **in objective and measurable terms** and shall indicate the expected time frames for achievement of each goal **and anticipated outcome**. The primary focus of goals and outcomes shall be progression toward a higher level of functioning to enable transfer of the client to a less restrictive environment. **Desirable goals shall be stated in the rehabilitation plan.**

4.7 Peer review.

(c) Procedures

More information should be provided on the Peer Review Committee, its membership and the DOH process for selection of Committee members.

4.8 Appeal procedures.

(b) Administrative hearing.

(1) The Division will advise the applicant or client of the right to appeal an adverse decision relating to eligibility for HIP services.

DOH should indicate whether or not services continue during an appeal.

General Comments

<u>One Year Limit:</u> Some commentators acknowledged that not all HIP clients will meet their full potential but indicated that the one year term on rehabilitation services was satisfactory to provide an opportunity for individuals to make significant progress.

On the other hand, some commentators indicated that given the data presented in Section 4.6, regarding the average length of time an individual with TBI is in post-acute rehabilitation (i.e., one to three years), it would seem more logical to provide a one and one-half to two year funding limit. Although the idea of providing funding to as many individuals as possible is supported, they indicated that the one-year limit suggests that many people will be served, but many of them may not be able to reach their full potential.

<u>Consultant Role:</u> Commentators indicated that DOH should provide information about the role and term of the consultant.

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DEPARTMENT OF HEALTH
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(717) 772-4959

June 23, 1999

Mr. Robert E. Nyce
Executive Director
Independence Regulatory Review Commission
14th Floor, Harristown II
333 Market Street
Harrisburg, Pennsylvania 17101

RE: Proposed Regulations
Head Injury Program
No. 10-129

Dear Mr. Nyce:

The Pennsylvania Department of Health has recently received the enclosed public comments to the above-referenced regulations.

Sincerely,

Elaine M. Terrell, MPH
Director, Head Injury Program
Division of Special Health Care Programs

EMT:cas

Enclosures

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June 21, 1999

Elaine M. Terrell, M.P.H., Director
Head Injury Program
Division of Special Health Care Programs
Room 724, Health & Welfare Building
Harrisburg, PA 17120

RE: Comments to Head Injury Program Regulations

Dear Ms. Terrell:

This firm represents one of the individuals that is currently enrolled as a recipient of the Head Injury Program (the "HIP"). On behalf of that individual, this letter provides you with comments on the proposed regulations of the Department of Health ("DOH") that were published in the May 22, 1999 *Pennsylvania Bulletin.*

Our comments are directed to: (1) the propriety of promulgating regulations at a time when the Commonwealth is evaluating whether the HIP should remain in DOH or be transferred to the Department of Public Welfare ("DPW"), and (2) the statutory authority for the regulations.

Timing of the Regulations

It is our understanding that there are a number of activities currently under way that would suggest a policy direction by the Commonwealth which would transfer the HIP program from DOH to DPW. In furtherance of this objective, we understand the following steps have or will be taken:

1. The Office of Social Programs, DPW is applying for a waiver from the Health Care Financing Administration that will permit the use of Medicaid funding for home and community-based head injury rehabilitation services;

2. Approximately $450,000 of state funds from the Emergency Medical Services Operating Fund ("EMSOF") will be transferred from DOH to DPW in the 1999-2000 fiscal year;

3. H.B.1467, which creates a head injury program in the Office of Social Programs of DPW, was introduced in the House by Representative Roy Cornell on May 6, 1999, and was referred to the House Health and Human Services Committee, also on May 6, 1999.

We have been told that the Medicaid waiver program is expected to begin in the 1999-2000 fiscal year. We understand that the EMSOF funds will be transferred from the Department to DPW to provide the State share for the Medicaid waiver program.

Because the Commonwealth appears to be moving in the direction of transferring responsibility for the HIP from DOH to DPW, the promulgation of the regulations by DOH at this time is particularly inopportune. DOH makes no mention of these other activities in the preamble to the regulations or how these activities might effect the proposed regulations.

Under the Regulatory Review Act, the Independent Regulatory Review Commission (the "IRRC") is charged with reviewing proposed regulations of the Commonwealth agencies and providing comments or objections to the agency. *See* Act of June 25, 1982, P.L. 633, No. 181, *as amended*, 71 P.S. § 745.1 *et seq.* The IRRC is required to consider a number of factors in deciding whether to approve or disapprove a final-form regulation, but it may not disapprove a final-form regulation or portion thereof if it does not raise its objection to the relevant portion of the regulation when it is initially proposed. *See* 71 P.S. 745.5(g). Thus, the criteria for disapproving a final-form regulation become relevant in the review of a proposed regulation.

One of the factors to be considered by the IRRC in approving or disapproving a regulation is whether the regulation "represents a policy decision of such a substantial nature that it requires legislative review." 71 P.S. § 745.5a(i)(4). Transfer of the HIP from DOH to DPW does present a substantial policy decision which deserves legislative review. In fact, that legislative review has begun through the introduction of H.B.1467 and its referral to the House Health and Human Services Committee. The publication of these regulations at this time ignores that overriding policy issue.

If the transfer of the HIP to DPW occurs, these regulations would be obsolete. On that basis alone, these regulations, as a whole, should be questioned by the IRRC, the House Committee on Health and Human Services and the Senate Committee on Public Health and Welfare. To be proposing regulations at this time, more than ten years after the passage of

legislation upon which DOH relies to promulgate these regulations and simultaneous with Representative Cornell's proposal to transfer the HIP to DPW, defies logic.

Statutory Authority for the Regulations

When reviewing regulations, the IRRC "shall, first and foremost, determine whether the agency has the statutory authority to promulgate the ....regulation and whether that regulation conforms to the intention of the General Assembly in the enactment of the statute upon which the regulation is based." 71 P.S. § 745.5a(h).

We question the Department's authority to promulgate the regulations as proposed. The regulatory authority that flows from the statutory language is very limited. In fact the entire subsection that relates to this funding provides as follows:

> Twenty-five percent of the [EMSOF] fund shall be allocated to a Catastrophic Medical and Rehabilitation Fund for victims of trauma. The catastrophic fund shall be available to trauma victims to purchase medical, rehabilitation and attendant care services when all alternative financial resources have been exhausted. The Department may by regulation, prioritize the distribution of funds *by classification of traumatic injury.*

35 P.S. § 6934(e)(Emphasis supplied). The plain meaning of the legislation gives the Department only the ability to decide which *class or type* of traumatic injury it will fund, in order of priority. It does not provide the Department with the authority to develop detailed administrative regulations relating to operation of the HIP.

Clearly, when the General Assembly intends to delegate comprehensive authority to an agency to develop regulations, it does so through broad statutory language. *See, e.g.*, 35 P.S. § 448.803 (With respect to health care facility licensure, DOH "shall have the power and its duty shall be...to promulgate, after consultation with the policy board, the rules and regulations necessary to carry out the purposes and provisions of this chapter."); 35 P.S. § 449.5(b) (With respect to the collection of health care data, the Health Care Cost Containment Council "may, in a manner provided by law, promulgate rules and regulations necessary to carry out the purposes of this act."). In contrast, the General Assembly in this instance delegated a specific task to the DOH. DOH is permitted, but not mandated, to carry out this task through regulation. The General Assembly established a portion of the EMSOF to be used for victims of "trauma" generally. It then gave DOH the limited ability to decide through regulation what classes of traumatic injury should be funded.

DOH made the decision long ago to fund head injuries. The proposed regulations surpass that decision, however, and thus, DOH has exceeded its statutory authority. The level of detail present in these proposed regulations relating to administration of the HIP is not necessary or authorized. "When the words of a statute are clear and free from all ambiguity, the letter of it is not to be disregarded under the pretext of pursuing its spirit." 1 Pa.C.S.A. § 1921(b). In this instance, DOH has abandoned the clear meaning of the statute. Furthermore, it has taken this step when it is both unnecessary and untimely to do so.

Thank you for your consideration of these comments.

Respectfully,

Ruth E. Granfors

cc: The Honorable Senator Harold F. Mowery
The Honorable Senator Vincent J. Hughes
The Honorable Representative Dennis M. O'Brien
The Honorable Representative Frank L. Oliver
Robert E. Nyce, Executive Director,
Independent Regulatory Review Commission
Lori McLaughlin, Esq.

HAP

THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

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cc: Harris
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June 21, 1999

Elaine M. Terrell, M.P.H.
Director, Head Injury Program
Division of Special Health Care Programs
Room 724
Health and Welfare Building
Harrisburg, PA 17120

Subject: Head Injury Program

Dear Ms. Terrell:

The Hospital & Healthsystem Association of Pennsylvania (HAP), on behalf of the over 220 hospitals and health systems it represents, offers comments on the proposed rules and regulations for the commonwealth's Head Injury Program (HIP). HAP, in general, is supportive of the regulations and their emphasis on rehabilitation and rehabilitative potential. The proposed regulations should make HIP services available to more eligible applicants and result in HIP resources being spent on those who can most benefit from them.

We do have some questions and areas of concern:

- § 4.2. **Definitions**

  Questions/comments: Therapeutic recreation and pre-vocational services are not included in rehabilitation services. These services are often critical to community reentry and integration.

- § 4.4. **Eligibility for services.**

  Questions/comments: How are pre-existing and co-morbid conditions going to be addressed in the determination of eligibility? Will they exclude a patient from eligibility?

- § 4.5. **Payment for services.**

  Questions/comments: Will HIP reimburse under a fee schedule? If not, how will the disparity in charges between facilities be addressed?

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HAP

- § 4.6. **Duration of funding.**

  Questions/comments: Should an exception process for the 12-month eligibility time frame be developed for those patients who have not achieved their rehabilitation goal within 12 months, but continue to make measurable progress?

- § 4.7. **Services eligible for payment.**

  Questions/comments: The regulations propose to limit eligibility for providing services to "licensed facilities accredited by an appropriate National accrediting body as approved by the Department." This proposal would essentially make voluntary accreditation mandatory. The Department has avoided relying on accreditation in any of its other regulatory chapters, and has instead outlined within the chapters themselves the minimum standards. In addition, our understanding is that at the current time the only accreditor of head injury programs is the Commission on Accreditation of Rehabilitation Facilities (CARF). A requirement of specific accreditation of head injury programs could result in lack of access to HIP and necessary head injury services for patients in some regions of the commonwealth.

  Recommendation: We recommend that the minimum standards for head injury programs be defined in the regulations and not deferred to accreditation.

Thank you for the opportunity to comment. Access to appropriate and necessary quality head injury services is obviously a critical need for those with traumatic brain injury. If you have any questions on our comments, please feel free to contact me at (717) 561-5325, or by e-mail at crinehart@hap2000.org.

Sincerely,

Cheri L. Rinehart

CHERI L. RINEHART
Vice President
Integrated Delivery Systems

Original: 2034
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HEAD INJURY PROGRAM REGULATION COMMENTS:

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James G. Williams, Jr., M.Ed.
MECA Case Manager
MECA United Cerebral Palsy
3745 West 12th St
Erie, Pennsylvania 16505
Telephone: (814) 836-9113

Ms. Ruth E. Granfors
Kirkpatrick & Lockhart LLP
Payne-Shoemaker Building
240 North Third St
Harrisburg, Pennsylvania 17101-1507
Telephone: (717) 231-5835

The Hospital & Healthsystem
Association of Pennsylvania
4750 Lindle Rd
P. O. Box 8600
Harrisburg, PA 17105-8600
(Late arrival received 6/24/99)

Donald W. Marion, M.D.
Professor of Neurological Surgery
Director, Brain Trauma Research Center
UPMC Health System
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Gene Bianco, President/CEO
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DEPARTMENT OF HEALTH
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(717) 772-4959

June 24, 1999

Mr. Robert E. Nyce
Executive Director
Independence Regulatory Review Commission
14th Floor, Harristown II
333 Market Street
Harrisburg, Pennsylvania 17101

RE: Proposed Regulations
Head Injury Program
No. 10-129

Dear Mr. Nyce:

The Pennsylvania Department of Health has recently received the enclosed public comments to the above-referenced regulations.

Sincerely,

Elaine M. Terrell, MPH

Elaine M. Terrell, MPH
Director, Head Injury Program
Division of Special Health Care Programs

EMT:cas

Enclosures

Original: 2034
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Ms. Elayne Klein
671 River Road
Yardley, Pa. 19067

June 21, 1999

Elaine M. Terrell, M.P.H., Director
Head Injury Program
Division of Special Health Care Programs
Room 724, Health & Welfare Building
Harrisburg, PA 17120

RE: Comments to Head Injury Program Regulations

Dear Ms. Terrell:

This letter provides you with comments on the proposed regulations for the Head Injury Program ("HIP") that were published in the May 22, 1999 Pennsylvania Bulletin. As you know, my son Scott Sarubin is currently a client of the HIP.

Initially, I want to convey how grateful we are for the HIP and the difference it has made in Scott's life. Scott suffered his severe traumatic injury in March, 1991. He became eligible for HIP rehabilitation funding in September 1992. Scott suffers from a number of problems due to his head injury that diminished his cognitive abilities. Scott's participation in the head injury rehabilitation program at Beechwood has transformed him. When he entered the program, Scott was disoriented, unable to walk independently, control emotional outbursts and panic attacks, stay focused on a task, follow a schedule, initiate tasks of daily living, focus his attention or write. Since being in the structured, therapeutic environment at Beechwood, he continues to learn compensatory strategies which have had a significant impact on his ever-improving growth and capabilities. Although Scott is still significantly impaired, he has learned to overcome many obstacles. He was able to walk down the aisle with a cane at his sister's wedding, recite a poem at his cousin's wedding, improve in his social interactions, begin relearning rudimentary computer skills, complete activities of daily living, work in a sheltered workshop, participate in a community learning workshop and become a valued member of his community skills group.

In light of our experience, we have the following comments regarding the HIP regulations. Our comments fall into primarily two categories: (1) comments on how the regulations can be improved; and (2) comments on whether any Department regulations are appropriate, given the significant and fundamental policy decisions being considered at the State level that may change the face of the HIP in the near future.

Our greatest concern is the inflexible one-year limit on rehabilitation services proposed at section 4.6 of the regulations. If there ever was an example of why the HIP

should consider some exception to this rigid proposal, Scott is that example. If Scott's services had ended after his first year, he would have developed to the point of requiring assistance in areas of ambulating, activities of daily living, all areas of cognitive functioning, socialization and vocational skills. We understand the desire of the Department of Health (the "Department") to provide benefits to as many individuals as possible, but we cannot see the benefit of operating the HIP in such a rigid manner that it would not take into account individual characteristics and progress of the clients beyond one year. For that reason, we suggest a modification of section 4.6 that would allow for an exception to the one year requirement if the client is continuing to make tangible concrete progress in rehabilitation.

Our second concern is related to the first. We are pleased to see that there is a two step appeal process for individuals who are denied or terminated from HIP participation. However, given the strict one year limit for benefits that is proposed in section 4.6, what sort of appeal is really available to an individual who is terminated after one year of rehabilitation services? The regulation is not clear in this respect. We suggest that section 4.10 explicitly indicate that an appellant may raise through the appeal proceedings reasons why an exception to the one year rehabilitation rule would be appropriate in that case. We suggest that this basis for appeal be specifically recognized in the regulation at both levels of the appeal, i.e., the administrative review process and the administrative hearing.

Our third concern relates to the lack of available alternatives for an individual that is required to transition from the HIP. Based on the Department's current one year rehabilitation requirement, many individuals who will be removed from HIP-funded rehabilitation will be facing inappropriate placement in a nursing home or back in the family home, neither of which generally provide the requisite combination of skills and socialization necessary for a young adult who requires significant assistance and continued rehabilitation and therapy in order to achieve his or her fullest potential. For example, to date, there has been no appropriate facility available to which Scott could be transferred if HIP rehabilitation benefits were no longer available to him.

We understand that the Pennsylvania Department of Public Welfare ("DPW") is seeking a waiver from the Health Care Financing Administration in order to use Title IXX Medicaid funding for head injured individuals, so that appropriate services and a proper placement may be available for individuals such as Scott. We applaud these efforts by the Commonwealth. However, we believe that these proposed regulations should not go into effect until the waiver program is in place.

Sincerely yours,

Elayne Klein

Elayne Klein

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(717) 772-4959

June 24, 1999

Mr. Robert E. Nyce
Executive Director
Independence Regulatory Review Commission
14th Floor, Harristown II
333 Market Street
Harrisburg, Pennsylvania 17101

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Head Injury Program
No. 10-129

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Sincerely,

Elaine M. Terrell, MPH

Elaine M. Terrell, MPH
Director, Head Injury Program
Division of Special Health Care Programs

EMT:cas

Enclosures

SAINT VINCENT HEALTH CENTER
232 West 25 Street
Erie, Pennsylvania 16544
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SAINT VINCENT

June 18, 1999

Elaine M. Terrelim, M.P.H
Director, Head Injury Program
Division of Special Health Care Programs
Room 724
Health and Welfare Building
Harrisburg, PA, 17120

Dear Ms. Terrelim,

I have reviewed the proposed Rules and Regulations of the Head Injury Program. Thank you for your consideration of my comments below.

B. Summary of Proposed regulations
Section 4.5 Payment for Services

1. Will HIP have a Fee Schedule for reimbursement? Ie:What if one facility charges $100/session and another charges $80/session?

D. **Fiscal Impact**
3. Private Sector:what are the **National accrediting bodies** approved by DOH for each level of care?

E. **Paper work Requirements**
1. Will HIP have a specific form with timeline guidelines for submission of **periodic patient status reports?**
2. Is there a specific **application** form and how do patients get a copy? What **verifying documentation** need to accompany the application?

4.2 **Definitions**
HIP Peer Review Committee:what specific criteria/form will they use to **review rehab service plans and services and recommend actions**?

Rehabilitation-Therapeutic Recreation and pre-voc services aren't listed as services. They are the services that often work on community integration, community reentry skills.

4.4 **Eligibility for services**
c) ineligibility due to impairment
   4. preexisting...:what if pt sustains TBI and has h/o emotional illness?
   5. CVA:what if pt has TBI then sustains CVA as result of the brain injury?
d) ineligibility due to symptoms
   ii) ...aggression:what if pt is transitioning thru an agitated phase of Ranchos Level IV? Is there a duration level?

4.8 **Rehab Service Plan**
   b. 2) beginning and ending dates:this is often unknown. It depends on the pts progress. The duration may say 6 months but it may take a shorter or longer time for the pt to reach the goal.

Sincerely,

SAINT VINCENT HEALTH CENTER

Jeanne Downey

Jeanne Downey, M.S.
Team Leader of Rehabilitation

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June 24, 1999

Mr. Robert E. Nyce
Executive Director
Independence Regulatory Review Commission
14th Floor, Harristown II
333 Market Street
Harrisburg, Pennsylvania 17101

RE: Proposed Regulations
Head Injury Program
No. 10-129

Dear Mr. Nyce:

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Sincerely,

Elaine M. Terrell, MPH

Elaine M. Terrell, MPH
Director, Head Injury Program
Division of Special Health Care Programs

EMT:cas

Enclosures

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UPMC Rehabilitation Hospital
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June 18, 1999

Elaine M. Terrell, M.Ph.
Director, Head Injury Program
Division of Special Health Care Programs
Room 724
Health and Welfare Building
Harrisburg, PA 17120

RE: Proposed Rule Making: DOH: (28 PA.CODE CH, 4)
Head Injury Program (as published in the Pennsylvania Bulletin 5/22/99); 29:(21); 2671-8, 1999

Dear Ms. Terrell:

I have received and reviewed the proposed rulemaking to the Head Injury Program. I have several areas of concern regarding the proposed rules and greatly appreciate your taking the time to consider these.

1. Section 4.4 Eligibility for Services

The proposed rule states that the Department "would deem a client ineligible if that client lacks the potential to *benefit and to live more independently* as a result of the services sought. This determination would be based upon the recommendation of the *client's case manager and other neuropsychological evaluations."* Apparently, the logic for this is that the Department is attempting to "prioritize funds for those persons who have the ability to progress in rehabilitation." The Department's position is that the monies used should be aimed at rehabilitation of "as many individuals as possible... rather than to maintain a static number of persons...past the point where progress in rehabilitation can be made by those persons".

First, it is inappropriate to have determination of achievement of maximum medical improvement accomplished by a case manager and/or neuropsychologist. The opinion of physician experts more qualified to look at the whole picture rather than just at resource allocation or cognitive and neuropsychological function would seem more appropriate. Pennsylvania enjoys

a wealth of board certified physiatrists specializing in brain injury as well as a large complement of neurosurgeons and neurologists with experience in brain injury rehabilitation. The involvement of these resources would seem most appropriate to judicious use of obviously limited funds.

Secondly, the determination of benefit and the determination of living more independently should be accomplished through the use of generally accepted performance measures such as the Functional Independence Measure. Specific outcome measures can show improvement when more global outcome measures show no change. In the case of the FIM, there is a direct correlation between a person's FIM score and caregiver burden, so that while a person may remain at the same less-than-independent level of living, they may in fact impose a lower caregiver burden on family and support services thus making their rehabilitation effective and justifying use of funds. It is my hope that a more systemized and careful determination of a patient's benefit from rehabilitation services will be mandatory under your program.

Thirdly, recovery from brain injury, unlike many other neurologic injuries, can present in varied ways. Some patients may languish for several months before showing significant improvement, some patients may show significant improvement initially then plateau for some period of time and then show yet another period of improvement. It is critical that the opinion of experts with clinical experience in brain injury rehabilitation be sought in determining that a person might or might not benefit from further services.

2. Section 4.6 Duration of Funding

The proposed rule states that "no client would receive more than one benefit year of rehabilitation." A benefit year would be defined as "twelve consecutive months beginning on the date that the HIP services are initially purchased". This would seem particularly short sighted despite the defending paragraphs in the proposal. Particularly in the case of younger brain injury victims, it is critical that funding be intermittently available as persons with brain injury undergo life changes. There is a high rate of family distress, divorce among parents, divorce from spouse, and other changes in support patterns that affect the course of a person's recovery from brain injury. Separate from the neurologic time course of recovery, these sorts of support system changes, along with normal developmental changes, such as graduating from college or vocational programs can impose a need for increased services at unpredictable times. Since this program aims to use its funds more judiciously, I would recommend that services be scrutinized at 3-6 month intervals. It would seem preferable if volume necessitates decreasing the availability of funds to 12 months, that they at least not be 12 *consecutive* months, but rather that they be able to be used at points in time when clients are most in need of the particular services in question. The emphasis on case management and goal setting would seem to speak to an

understanding of the variable nature of rehabilitation service needs in brain injury patients and, makes the 12 consecutive months rule even less appropriate.

Finally, I urge you to include on your peer review panel, sufficient physician representation such that the more global and holistic needs of brain injury patients are adequately addressed. Board certified physiatrists with significant clinical experience in brain injury, neurosurgeons with clinical experience in brain injury and neurologists with experience and training in brain injury rehabilitation would be appropriate for inclusion on this committee.

I greatly appreciate your attention to these concerns. The science of brain injury rehabilitation is changing rapidly as we study outcomes as a result of pharmacologic and therapeutic interventions in this population. It is my hope that the Head Injury Program of the State of Pennsylvania will allow itself sufficient flexibility to be responsive to these changes in state of the art rehabilitation.

Sincerely,

Margaret E. Reidy, M.D.
Director, Brain Injury Services
Medical Director, UPMC Rehabilitation Hospital

MER/bd

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(717) 772-4959

June 25, 1999

Mr. Robert E. Nyce
Executive Director
Independence Regulatory Review Commission
14th Floor, Harristown II
333 Market Street
Harrisburg, Pennsylvania 17101

RE: Proposed Regulations
Head Injury Program
No. 10-129

Dear Mr. Nyce:

The Pennsylvania Department of Health has recently received the enclosed public comments to the above-referenced regulations.

Sincerely,

Elaine M. Terrell, MPH
Director, Head Injury Program
Division of Special Health Care Programs

EMT:cas

Enclosures

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6/15/99

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Original: 2034
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Dear Mrs Cerilli,

I have before me "Proposed Rulemaking" Dept of Health [28 PA. CODE CH. 4] MAY 22 1999.

Since this is the third year since enactment of the T.B.I Act when 24.5 million dollars were provided for services for people with brain injuries, and to conduct research, it is our hope you will put forth a request for monies for "Case Managers", they need to have full time employment + are need to have access to them full time. Their task is huge.

Our case manager Jim Williams has only 12 hours weekly to work with and for fifteen clients, he needs to be re-embursed for all the incidentals that are required to do a good job.

PAGE 2675

We agree with 'Rehabilitation Service Plan' Our concerns are that residents in care facilities get very little rehabilitation, other than their daily living skills. We feel these be monitored more closely.

Thank you for your time

Very truely yours

Joan M Gehrlein Mother of
Christopher J Gehrlein
(MRS. D.J GEHRLEIN)

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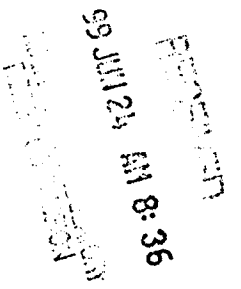

June 18, 1999

Mr. Robert E. Nyce
Executive Director
Independence Regulatory Review Commission
14th Floor, Harristown II
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Harrisburg, Pennsylvania 17101

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Head Injury Program
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