

Regulatory Analysis Form		This space for use by IRRC
<p>(1) Agency</p> <p style="text-align: center;">Department of Health</p>		<p>99 APR 27 PM 4:45</p> <p style="text-align: center;">REGULATORY REVIEW COMMISSION</p> <p>IRRC Number:</p> <p style="text-align: center;"># 2034</p> <p style="text-align: right;">Bush</p>
<p>(2) I.D. Number (Governor's Office Use)</p> <p style="text-align: center;">10-129</p>		
<p>(3) Short Title</p> <p style="text-align: center;">Head Injury Program Regulations</p>		
<p>(4) PA Code Cite</p> <p style="text-align: center;">28 PA Code Chapter 4</p>	<p>(5) Agency Contacts & Telephone Numbers</p> <p>Primary Contact: Elaine Terrell, M.P.H. Division of Special Health Care Programs Room 724, Health & Welfare Harrisburg, PA 17120 (717) 772-4959</p> <p>Secondary Contact: C. Gail Stock Division of Special Health Care Programs Room 724, Health & Welfare Harrisburg, PA 17120 (717) 783-5436</p>	
<p>(6) Type of Rulemaking (Check One)</p> <p><input checked="" type="checkbox"/> Proposed Rulemaking</p> <p><input type="checkbox"/> Final Order Adopting Regulation</p> <p><input type="checkbox"/> Final Order, Proposed Rulemaking Omitted</p> <p><input type="checkbox"/></p>		<p>(7) Is a 120-Day Emergency Certification Attached?</p> <p><input checked="" type="checkbox"/> No</p> <p><input type="checkbox"/> Yes: By the Attorney General</p> <p><input type="checkbox"/> Yes: By the Governor</p>
<p>(8) Briefly explain the regulation in clear and non-technical language.</p> <p>Regulations set forth the rules governing the Head Injury Program (HIP), describe the type of services available under the program and describe eligibility criteria for applicants.</p>		

Regulatory Analysis Form

(9) State the statutory authority for the regulation and any relevant state or federal court decisions.

35 P.S. §6934(e)

Meloneyzer et al. v. Commonwealth of Pennsylvania, Department of Health, et al.
Commonwealth Court Docket No. 0135 MD 1993

(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.

35 P.S. §6934(e)

Meloneyzer et al. v. Commonwealth of Pennsylvania, Department of Health, et al.
Commonwealth Court Docket No. 0135 MD1993

(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

Orderly operation of program

(12) State the public health, safety, environmental or general welfare risks associated with non-regulation.

Program requires standards to be effective and help more citizens in need. Non-regulation will lead to abuses.

(13) Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)

All persons who qualify for HIP benefits will have a clearer understanding of the program. Each person will qualify for one year of rehabilitation services and 18 months of case management services from the Head Injury Program. Current estimate of cost per individual in rehabilitation is \$100,000.

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(14) Describe who will be adversely affected by the regulation. (Quantify the adverse effects as completely as possible and approximate the number of people who will be adversely affected.)

There are approximately 25 rehabilitation clients and 380 case management clients in the program. Time limit will cut off these long term persons after one additional year and 18 months respectively.

(15) List the persons, groups or entities that will be required to comply with the regulation. (Approximate the number of people who will be required to comply.)

1. Pennsylvania residents who sustained head trauma and wish to receive benefits (30-50 per year).
2. Providers of services including case managers and rehabilitation facilities.

(16) Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who were involved, if applicable.

The HIP shared the proposed regulations with the Pennsylvania Association of Rehabilitation Facilities (PARF) and persons involved in providing the necessary services.

(17) Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures which may be required.

Providers are currently required by contract to obtain CARF accreditation which costs \$3,000. The regulations will document this existing requirement that is now in current contracts.

(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures which may be required.

None.

(19) Provide a specific estimate of the costs and/or savings to state government associated with the implementation of the regulation, including and legal, accounting, or consulting procedures which may be required.

The state government will have some costs associated with possible appeals of Department of Health decisions on eligibility. Costs would include hearing officer, legal time and expert witnesses and usual staff and clerical support.

Regulatory Analysis Form

(20) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government and state government for the current year and five subsequent years.

	Current FY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
SAVINGS:	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Savings	0	0	0	0	0	0
COSTS:						
Regulated Community	\$48,000			48,000		
Local Government	0	0	0	0	0	0
State Government	\$34,000					
Total Costs	\$82,000					
REVENUE LOSSES:						
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Revenue Losses	0	0	0	0	0	

(20a) Explain how the cost estimates listed above were derived.

Costs for the regulated community are composed of the cost to obtain CARF accreditation for the 16 head injury rehabilitation contractors at \$3,000 each. This is not a new cost since their current contract requires CARF accreditation. It is a cost incurred every three (3) years. Costs for state government are the costs for the Department of Health for the hearing officer for the appeals, and other staff associated with the process. This includes the neuropsychology consultant to the Head Injury Program. The costs were estimated at \$80 per hour for the hearing officer time 8 hours per case or \$640 times 25 cases (\$16,000). The costs for the neuropsychology consultant are \$64 per hour times 200 hours (8 hours for each of the 25 cases) which equals \$12,800. The total costs were estimated at \$34,000 to include clerical staff.

Costs for state government are unknown for future years since the appeals are unknown and not anticipated.

Regulatory Analysis Form

(20b) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY - 3	FY - 2	FY - 1	Current FY
Head Injury Program	\$4,196,861	\$3,364,173	\$4 Million (estimate)	\$3.4 Million

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs.

The benefits of the regulations clearly outweigh all costs associated. This is particularly true since costs to the regulated community will not increase because of the requirements for CARF accreditation are already in their existing contracts. The only increased costs will be to state government to provide appropriate due process.

(22) Describe the nonregulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal.

The regulatory alternative is the use of administrative policy. This has been challenged and the policies of the Head Injury Program are difficult to defend without regulations.

(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

Since the regulation attempts to regulate the service and not the provider, no other regulatory scheme was considered.

Regulatory Analysis Form

(24) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulation.

There are no federal standards in this area.

(25) How does this regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?

There is no competitive disadvantage to Pennsylvania.

(26) Will the regulation affect existing or proposed regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

Possible effect on Department of Public Welfare and Office of Vocational Rehabilitation.

(27) Will any public hearings or information meetings be scheduled? Please provide the dates, times, and locations, if available.

Not planned at this time.

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(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports which will be required as a result of implementation, if available.

No.

(29) Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

N/A

(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

September 1, 1999.

(31) Provide the schedule for continual review of the regulation.

Annual.

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2034

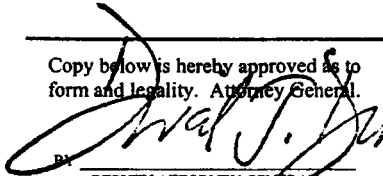
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LEGISLATIVE COUNCIL
REVIEW COMMISSION

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Copy below is hereby approved as to form and legality. Attorney General.



BY: DEPUTY ATTORNEY GENERAL
APR 14 1999.
DATE OF APPROVAL

Check if applicable. Copy not approved. Objections attached.

Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:

DEPARTMENT OF HEALTH
(AGENCY)

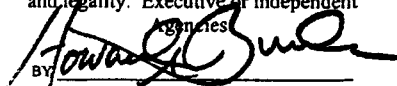
DOCUMENT/FISCAL NOTE NO. 10-129

DATE OF ADOPTION: _____


BY: Gary L. Gurian

TITLE: Acting Secretary of Health

Copy below is hereby approved as to form and legality. Executive or independent agencies



BY: _____
3/24/99
DATE OF APPROVAL

(Deputy General Counsel)
(~~Chief Counsel, Independent Agency~~)
(Strike inapplicable title)

Check if applicable. No Attorney General approval or objection within 30 days after submission.

PROPOSED RULEMAKING

DEPARTMENT OF HEALTH

Title 28. HEALTH AND SAFETY

[28 Pa. Code Ch. 4]

Head Injury Program

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The Department of Health, (Department) proposes to amend 28 Pa. Code Part I (relating to General Health) by adding Chapter 4 (relating to the 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 set forth in Annex A hereto.

A. PURPOSE OF THE REGULATIONS

1. Statutory Background

In 1985, the General Assembly passed legislation which created a statewide emergency medical services system. This legislation, the Act of July 3, 1985 (P.L. 164, No. 45) (35 P.S. §§6921-6938), known as the Emergency Medical Services Act (EMS Act), provided for an Emergency Medical Services Operating Fund to be funded by a ten dollar fine to be levied on all moving traffic violations. The EMS Act further directed that 25 percent 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

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when all alternative financial resources were exhausted. (35 P.S. §6934(e)). 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 EMS Act by the Act of October 21, 1988 (P.L. 1055, No. 121). This amendment modified the type of traffic violations for which a ten dollar 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 EMS Act, the Department recognized that the size of the Fund would be insufficient to meet the needs of all victims of trauma in Pennsylvania. 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

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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 to review the interim policies and advise the Department on the development of program regulations. This advisory 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 REGULATIONS

The proposed regulations propose to 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 EMS Act. A brief description of the proposals follows.

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Sections 4.1 and 4.2 Authority; Scope and purpose.

These sections would identify the statutory authority for the chapter and describe its scope and purpose.

Section 4.3. Definitions.

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

Section 4.4. HIP services and objectives.

This section, along with section 4.2 (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 4.5. Eligibility for services.

This 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 Pennsylvania 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 Pennsylvania for the indefinite

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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 14(e) of the EMS Act 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 monies 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.

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This section would also exclude from HIP any 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 monies will enable the Department to stretch further the monies available to it for this program and to provide services to more eligible persons.

Section 4.6. Payment for services.

This 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 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, such provisions

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will enable the Department to prioritize need, and to provide services to more individuals.

This 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 4.7. Duration of funding.

This section would set forth strict time limitations for HIP funding. No client would receive more than one 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 two years for rehabilitation services and a maximum of three years for case management (also referred to as case coordination). The Department, however, believes that the limitations set forth 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

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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 post-acute traumatic brain injury rehabilitation program in one to three years. Thus, the one 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.

The proposed regulations also provide that the Department will give prior notification to all clients of HIP of the date that their funding for HIP services will terminate.

Section 4.8. Services eligible for payment.

This section would describe the specific services covered by the categories of services set forth in section 4.4 (relating to services and objectives) and as those categories are defined in section 4.3 (relating to definitions). This section would also emphasize case management as an important service to be provided immediately upon a determination of eligibility for HIP. Case management requirements would emphasize, but not be limited to, the development of a rehabilitation service plan for each eligible client.

Rehabilitation services are designed to be part of the continuum of treatment with the goal of transitioning an individual to independent living in the individual's home or

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community; transitioning an individual to meaningful activity or vocational training; and transitioning an individual to appropriate living and service arrangements once he or she has met the goals established in the rehabilitation service plan.

The case manager is required to have certain qualifications under this section: a minimum of two years of experience in traumatic head injury case management; at least a bachelor's degree in nursing, education, social work, psychology, or a rehabilitation field; and a knowledge of services and facilities available in the geographic area of practice.

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Section 4.9. Rehabilitation service plan.

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

Section 4.10. Peer review.

This section would describe the establishment of a peer review committee to conduct a review of services and rehabilitation plans for HIP clients. The members of the HIP Peer Review Committee would be appointed to serve three year terms. Members could not serve

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consecutive terms. The HIP Peer Review Committee would review cases on a quarterly basis and, within 30 days of its review, provide recommendations for all ongoing services. Members of the Committee who would have a conflict of interest if they would participate in the review of a particular case would not be permitted to participate in that review. The Department would notify the Committee of all actions taken on the recommendations of the Committee.

Section 4.11. Appeal procedures.

This section would contain a two-tiered appeal mechanism which protects the interests of both applicants 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 he or she 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 the HIP's final determination, but not necessarily the final decision of the Department. An individual could appeal the Division's

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final determination to the agency head by seeking a formal administrative hearing. The hearing would be conducted in accordance with the General Rules of Administrative Practice and Procedure (1 Pa. Code Chapters 33-35), 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 or her representative would be required to appear at the hearing unless the hearing officer finds he or she 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 a brief or 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 such individuals may have a

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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 Pennsylvania 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 Pennsylvania 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 such 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

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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 monies but who are not making rehabilitative progress with services provided with those monies. 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 EMS Act provides the Department with the discretion to make that realignment.

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E. PAPERWORK REQUIREMENTS

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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 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 EMS Act (35 P.S. §6934(e)) 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 (Act), the Act of June 30, 1989 (P.L. 73, No. 19) (71 P.S. §§745.1-745.15), the Department submitted a copy of this proposed regulation on April 27, 1999, to the Independent Regulatory Review Commission and to the Chairpersons of the House Committee on Health and Human Services and the

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Senate Committee on Public Health and Welfare. In addition to submitting the proposed regulations, the Department has provided the Commission 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 the Commission has any objections to any portion of the proposed regulations, it will notify the Department by July 8, 1999. Such notification shall specify the regulatory review criteria which have not been met by that portion. The Act specifies detailed procedures for review prior to final publication of the regulation, 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, Pennsylvania, 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

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persons or the Pennsylvania AT&T Relay Service at (800-654-5984)[TT]). Persons who require an alternative format of this document may contact Ms. Terrell so that necessary arrangements may be made.

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ANNEX A

TITLE 28 - HEALTH AND SAFETY

PART I - GENERAL HEALTH

CHAPTER 4 - HEAD INJURY PROGRAM

§4.1. Authority.

This chapter is authorized by section 14(e) of the Emergency Medical Services Act, 35 P.S. Section 6934(e).

§4.2. Scope and purpose.

The purpose of this chapter is to establish standards for the Department to administer the Fund to provide rehabilitation services, facilitated through case management, to persons who incur a traumatic brain injury.

§4.3. Definitions.

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

Alternative financial resources - Income (including income from assets and public benefits); court awards and insurance settlements; funding from other state or federal programs including but not limited to: Medicaid, Medicare, social security disability insurance (Title II), supplemental security income (Title XVI), veterans' benefits and workers' compensation insurance; and any 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 - Non-residential 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 out-patient basis.

Department - Department of Health, Commonwealth of Pennsylvania.

Division - The organizational unit, within the Department of Health, having responsibility for the administration of the Head Injury Program.

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.

Head Injury Program (HIP) - The traumatic brain injury program of the Department.

HIP Peer Review Committee - A committee, composed of professionals and organizations offering rehabilitation services in Pennsylvania 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 re-entry 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 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 the realization of the client's maximum physical, social, psychological, and vocational potential for useful and productive activity. Such services include case management, neuropsychological evaluation, physical therapy, occupational therapy, speech or language therapy, behavior management, and psychological services which may include cognitive remediation. 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 any payments made on behalf of a client from any insurer which may offer coverage to the client or from the proceeds of any 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.

§4.4. 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 monies from the Fund, and restrictions set forth in §§4.6 (relating to payment for services) and 4.7 (relating to 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 shall be limited to

post-acute traumatic brain injury rehabilitation services.

§4.5. Eligibility for services.

(a) Except as otherwise set forth in this section, the Department will deem an applicant eligible for HIP services only if all of 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 Pennsylvania 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 Pennsylvania 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 has reached 21 years of age.

(b) 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) The Department will deem an applicant ineligible for HIP services if the applicant's impairment is the result of any 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 pre-existing psychiatric, organic, or degenerative brain disorders.

(5) Cerebral vascular accidents.

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

(d) The Department will deem an applicant ineligible for HIP services if the applicant's condition manifests any of the following symptoms:

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

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

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) 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 any 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) 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.

§4.6. 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. Applicants for whom monies 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 §4.7

(relating to duration of funding).

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

(5) The client's condition deteriorates such that the client would be ineligible under § 4.5(b) (relating to eligibility for services), or it is no longer feasible to implement a rehabilitation service plan for the client pursuant to § 4.9 (relating to rehabilitation service plan).

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

§4.7. 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 six 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.

§4.8. Services eligible for payment.

The Department will pay for the following services for clients:

(a) Assessments. Assessments shall include neuropsychological and functional

evaluations as deemed necessary by the Department for determining eligibility for rehabilitation services.

(b) Rehabilitation service plan. Development of a rehabilitation service plan for each client as provided for in §4.9 (relating to rehabilitation service plan).

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

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

(2) Assisting the client in gaining full access to all services from which the client may benefit and for which the client may be eligible.

(3) Monitoring the client's progress with respect to the rehabilitation service plan and making modifications as needed.

(4) Providing up to six months of follow-up case management upon a client's completion of rehabilitation.

(d) Rehabilitation services. Residential rehabilitation services shall be provided by licensed facilities accredited by an appropriate national accrediting body as approved by the Department. Outpatient, day, and home-based rehabilitation services shall be provided by facilities or providers accredited by an appropriate national accrediting body as approved by the Department. Examples of these services include the following:

(1) Helping a client develop behaviors that enable the client to take

responsibility for his or her own actions.

(2) Facilitating a client's successful community integration.

(3) Assisting the client to accomplish functional outcomes at home and in the community.

(4) Teaching the client skills to live independently.

(5) Supervising a client living in a home setting through the following:

(i) Home facilitation.

(ii) Cognitive remediation.

(iii) Life-skills coaching.

(6) Assisting the client in maintaining independence.

(7) Providing transitional living services to assist the client with community re-entry skills.

§4.9. Rehabilitation service plan.

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

(b) The rehabilitation service plan shall state the 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. The service plan shall also specify the following:

- (1) Services determined necessary to attain the agreed-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 manager, and service provider relative to implementation of each service.
 - (5) The extent of financial responsibility of the client, 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.

§4.10. 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 three 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 shall not participate in a review conducted by the Committee which presents a conflict of interest for that member.

Examples of such conflicts are participating in a review conducted by the Committee for either 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.

§4.11. 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 Chapter 1 of the Pennsylvania Code, relating to presiding officers.

(4) Within ten 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 five 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 herself, or be represented at the hearing by an attorney, relative, friend or any other person of the applicant's or client's choice.

(C) Present oral and documentary evidence, witnesses and arguments to support his or her 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 any testimony or other evidence, and confront and question any adverse witnesses.

(G) Examine prior to and during the hearing any 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 all 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) General Rules of Administrative Practice and Procedure, 1 Pa. Code, Chapter 31-35, shall be applicable to appeal procedures under this chapter except where inconsistent with this chapter.

Department of Health - Proposed Regulation (No. 10-129)
28 Pa. Code Part I, Chapter 4, Head Injury Program

Section 4.5. -- Eligibility for Services

- Sustained Traumatic Brain Injury (TBI) on or after July 3, 1985
- Pennsylvania resident 90 days at time injury and application to Head Injury Program (HIP), intent to maintain permanent home in Pennsylvania
- Exhausted alternative financial resources
- Reached 21 years of age
- Specific conditions exclude applicant
- Excludes applicants who fail to complete assignment agreement

Section 4.6. -- Payment for services

- Establishes maximum funding for rehabilitation and case management
- HIP payment of client services until:
 - Exhausts maximum funds available during client's benefit year
 - Reaches maximum duration for HIP services
 - Gains access to alternative financial resource
 - Undergoes change affecting client's clinical condition which affect eligibility or execution service plan
- DOH subrogation rights

Section 4.7. -- Duration of funding

- Duration limit for rehabilitation 1 benefit year (12 consecutive months beginning on date HIP services initially purchased)
- Duration limit for case management 18 consecutive months
- Limits protect fiscal integrity of Fund, service maximum eligible individuals
- Data reflect average client completes post-acute TBI rehabilitation in one to three years
- 1 year limit coincides with needs of existing and new clients
- DOH to provide HIP clients prior notification of funding termination

Section 4.8. -- Services eligible for payment

- Describes specific services covered
- Emphasizes case management important service provided upon eligibility
- Case management must develop rehabilitation service plan
- Rehabilitation goal of transitioning individual to independent living, activity or vocational training, to appropriate living and service arrangement
- Case manager qualifications: minimum 2 years experience in TBI case management; bachelor's degree in nursing, education, social work, psychology, or rehabilitation field; and knowledge of services, facilities in geographic area

Section 4.9. -- Rehabilitation service plan

- Describes development required rehabilitation service plan and elements
- Rehabilitation service plan identifies specific rehabilitation goals, time to achieve

Section 4.10. -- Peer review

- Conducts review client's services, rehabilitation plans on quarterly basis, recommendations to DOH
- Appointed for 3 year term, not consecutive

Section 4.11. -- Appeal procedures

- Internal administrative review and formal hearing procedure for appeals

Commonwealth of Pennsylvania



DEPARTMENT OF HEALTH

HARRISBURG

THE SECRETARY

April 27, 1999

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

Re: Department of Health Regulations Relating to the Head Injury Program
No. 10-129

Dear Mr. Nyce:

Enclosed is a copy of proposed regulations for review by the Commission pursuant to the Regulatory Review Act (Act) (P.L. 73, No. 19) (71 P.S. §§745.1-745.15). The proposed regulations would establish the Department's initial regulations promulgated under the Emergency Medical Services Act (EMS Act) (P.L. 164, No. 45) (35 P.S. §§6921-6938), specifically section 14(e) of the EMS Act (35 P.S. §6934(e)), to aid the Department in administering the Catastrophic Medical and Rehabilitation Fund to assist head trauma victims in securing medical, rehabilitation and attendant care services when their alternative financial resources have been exhausted.

Section 5(g) of the Act, 71 P.S. §745.5(g), provides that the Commission, within 10 days after expiration of the Standing Committee review period, shall notify the proposing agency of any objection to the proposed regulations. The Department expects the proposed regulations to be published on May 8, 1999. A 30-day comment period is provided.

Pursuant to section 5.1(a) of the Act, 71 P.S. §745.5a(a), upon completion of the Department's review of comments, the Department shall submit to the Commission a copy of the Department's response to the comments received, the text of the final-form regulations which the Department intends to adopt, and a list of the names and addresses of the commentators who requested a copy of the final-form regulations.

The Department will provide the Commission within 5 days of receipt, a copy of any comment received pertaining to the proposed regulations. The Department will also provide the Commission with any assistance it requires to facilitate a through review of the proposed

Robert E. Nyce
April 27, 1999
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regulations. If you have any questions, please contact Kim Sokoloski, Director of the Office of Legislative Affairs, at (717) 783-8770.

Sincerely,

A handwritten signature in black ink, appearing to read "Gary L. Gurian", with a stylized flourish extending to the right.

Gary L. Gurian
Acting Secretary of Health

Enclosures

**TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE
REGULATORY REVIEW ACT**

RECEIVED

I.D. NUMBER: 10-129
 SUBJECT: Head Injury Program
 AGENCY: DEPARTMENT OF HEALTH

99 APR 27 PM 4:45

INDEPENDENT REGULATORY
REVIEW COMMISSION

TYPE OF REGULATION

- X Proposed Regulation
- Final Regulation
- Final Regulation with Notice of Proposed Rulemaking Omitted
- 120-day Emergency Certification of the Attorney General
- 120-day Emergency Certification of the Governor
- Delivery of Tolled Regulation
 - a. With Revisions
 - b. Without Revisions

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
4/27/99	<i>D. H. [Signature]</i> 4:28 pm	HOUSE COMMITTEE ON HEALTH & HUMAN SERVICES
4-27-99	<i>Margaret Belliter</i>	
4/27/99	<i>Debi [Signature]</i> 4:17 pm	SENATE COMMITTEE ON PUBLIC HEALTH & WELFARE
4/27/99	<i>Kruti Krueger</i> 4:21 pm	
4/27/99	<i>Ken C. [Signature]</i>	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL
4/27/99	<i>Mayra Garcia</i> 4:15 pm	LEGISLATIVE REFERENCE BUREAU

April 21, 1999