PROPOSED RULEMAKING

DEPARTMENT OF HEALTH

[4 PA. CODE CH. 255]

Confidentiality of Patient Records and Information

The Department of Health (Department) proposes to amend § 255.5 (relating to projects and coordinating bodies: disclosure of client-oriented information) by deleting the existing regulation, and replacing it with the proposed amendments in Annex A.

A. *Purpose of the Proposed Rulemaking*

The Department's regulations relating to disclosure of client-oriented information have become outdated and an impediment to service delivery and the coordination of care for individuals with substance abuse problems. The Department initially considered rescinding § 255.5(b), and amending portions of subsection (a) to conform it to those changes, but after consultation with, and upon the advice of, the Advisory Council on Drug and Alcohol Abuse, the Department decided against that course of action. Instead, after receiving comments from various stakeholders, the Department has chosen to propose amendments that would protect the interest of the patient in confidentiality of extremely sensitive and stigmatizing personal information, while at the same time providing sufficient information to persons providing treatment and benefits to those individuals, as well as allowing a client autonomy in choosing when and how to release that client's information. In general, the intent of the proposed rulemaking is to expand the amount of information treatment providers may release to other entities in accordance with the existing statute, and to clarify for treatment providers and patients what the rules relating to confidentiality and disclosure of patient-identifying information are.

B. Requirements of the Proposed Rulemaking

Subsection (a). Definitions.

The Department is proposing to add a definition subsection to clarify certain terms used in section 108 of the Pennsylvania Drug and Alcohol Abuse Control Act (Act 63) (71 P. S. § 1690.108). Section 255.5 is based on language included in section 108 of Act 63. That section contains several terms not defined in Act 63 that are integral to the understanding of the scope of confidentiality promised to the patient, for example, "medical authorities and medical personnel" and "government officials." The Department has attempted to define those terms as well as the terms, "program," "patient record" and "third-party payer" in keeping with the intent of the General Assembly contained in section 108 of Act 63, as well as the practice of the providers of drug and alcohol abuse treatment.

Subsection (b). Scope and Policy.

The Department is proposing to amend the subsection not only to set out who will be subject to the proposed amendments, and what information will be subject to it, but also to reaffirm the Department's commitment to confidentiality for persons seeking drug and alcohol abuse treatment, and to set out some basic tenets with regard to how the information should be treated by providers and persons to whom information is disclosed. (See proposed subsection (b)(2)—(5).) The Department is also clarifying to whom the record belongs (the facility), but stating that the individual has control over his record, except as limited by the proposed regulation itself. (See proposed subsection (b)(3).) Finally, this subsection would place limits on redisclosure. (See proposed subsection (b)(5) and (6).)

Subsection (c). Consensual Release of Patient Records and Information.

This proposed subsection would set out the circumstances under which a patient may consent to the release of records. This proposed subsection would expand the amount of information that treatment providers may disclose to other entities, and impose certain restrictions on the amount of information that may be disclosed to third-party payers. Subsection (c)(1) and (2) reflect the requirements of section 108 of Act 63, and would provide that a program may release a patient record to medical personnel for the purpose of diagnosis, treatment or referral for treatment, and to government officials and third-party payers to obtain benefits due the patient as the result of the patient's drug or alcohol abuse or dependence.

Proposed subsection (c)(2) would limit the information that may be released to government officials or third-party payers to information necessary to accomplish the purpose of the disclosure. Proposed subsection (c)(2) incorporates the Federal standard relating to release of confidential patient-related information. Further, in the case of disclosure to these specified groups, information that is requested for the purposes of determining medical necessity for service admission, continued stay, discharge, referral, concurrent review, and coordination of care and payment would be limited to an even greater extent. (See subsection (c)(2)(i)—(vii).) This information is in keeping with the American Society of Addiction Medicine's six dimensional criteria accepted by drug and alcohol abuse treatment providers and payers of services as the appropriate criteria by which to assess an individual seeking or in treatment. Under the proposed regulation, a provider would have protection against requests by third-party payers for information that is highly personal and has no bearing on payment for treatment services. This provision would protect a patient's privacy rights.

At the same time, the proposed amendments would provide third-party payers, including managed care plans, with sufficient information with which to make a determination of the medical necessity of the service requested. Proposed subsection (c)(2) would make it more difficult for a third-party payer to refuse coverage for services on the basis of insufficient information.

The proposed amendments would also include provisions allowing release with patient consent to probation and parole officers and to the patient's lawyer. (See proposed subsection (c)(3) and (4).) The current regulation allows for release to these individuals. (See subsection (a)(2) and (4)).

Subsection (d). Nonconsensual Release of Patient Records and Information.

This proposed subsection would be new, and would include Act 63 section 108's provisions allowing disclosure to be made without patient consent in emergency medical situations when the patient's life is in immediate jeopardy (see proposed subsection (d)(1)), and when there is a court order issued under the statute. (See proposed subsection (d)(2).)

The proposed subsection would also import from the Federal rules relating to confidentiality of alcohol and drug abuse patient records (see 42 CFR Part 2 (relating to confidentiality of alcohol and drug abuse patient record)) several provisions intended to balance the rights and protections of the patient whose information is being released against the rights and safety of the other persons present in treatment. These sections include proposed subsection (d)(3), which would allow the release of patient identifying information without a patient's consent to law enforcement when a release is directly related either to the patient's commission of a crime on the treatment premises, or the threat to commit a crime. (See proposed subsection (d)(3).) To balance the need to protect the patient in question with the need to protect other patients at the facility, the Department has included in proposed subsection (d)(3) a limitation on what information could be released under these circumstances. The proposed paragraph only allows the release to law enforcement of that information that is related to the circumstances of the incident. (*Id*.) The disclosure would include the patient's name and address, the fact that the patient was a patient of the facility, and the patient's last known whereabouts. (*Id*.)

Proposed subsection (d)(4) would allow programs to report child abuse under State law without violating patient confidentiality. The proposed language in this paragraph, too, is a provision that is included in Federal regulation (See 42 CFR 2.12(c)(6) (relating to applicability).) This provision is intended to protect a most vulnerable portion of society, children, and is particularly applicable since the Department does license facilities that serve parents and children.

Another Federal regulation that the Department has chosen to include in this proposed rulemaking is the regulation relating to the conduct of scientific research. Proposed subsection (d)(5) would allow programs to disclose information from patient records for the conduct of scientific research if that disclosure is made in accordance with 42 CFR 2.52 (relating to research activities) and if there is an agreement in writing that patient names and other identifying information will not be disclosed. (See proposed subsection (d)(5).)

The Department has also included in this proposed rulemaking language similar to the Federal regulation dealing with audit and evaluation activities. (See proposed subsection (d)(6)). This proposed regulation would allow State, Federal or local agency staff providing financial assistance or reimbursement to the program or authorized by law to regulate the program, or staff of third-party payers performing utilization or quality control review to have access to patient records on site for purposes of audit or evaluation activities. Disclosure under this proposed paragraph would be required to be in accordance with 42 CFR 2.53 (relating to audit and evaluation activities). The access and review is necessary for both fiscal and programmatic accountability on the part of the treatment provider. In actual practice, Department staff and local agency staff, along with the staff of third-party payers have reviewed patient records for these purposes; the inclusion of this language in the proposed regulation acknowledges existing practice. To protect the patient, the proposed regulation would include a prohibition on the inclusion of any patient identifying information in reports resulting from such reviews and audits.

Finally, proposed subsection (d)(7) is a general provision that makes it clear that even though patient information may be disclosed without consent in those instances enumerated in the proposed subsection, the information made available must be limited to that information that is relevant and necessary to the purpose for which the information is sought.

Subsection (e). Patient's Access to Records.

This proposed subsection contains new subject matter. The Department has included a provision that would allow a patient to have access to the patient's own records. Again, in an effort to balance the need to protect the patient, the Department has acknowledged that a program may remove portions of the record prior to the patient's inspection, if the program determines the information may be detrimental to the patient. The patient may appeal this decision, request the removal of information the patient believes to be inaccurate, irrelevant, outdated or incomplete. The patient may also submit rebuttal data or memoranda if the patient chooses to do so.

Subsection (f). Consent Form.

To eliminate questions over what makes a consent valid and to streamline the disclosure process, the Department has proposed minimum requirements for a valid consent form to be used by programs to obtain consent from a patient to disclose information. (See proposed subsection (f).) These elements must be present in a consent form for it to be valid. In addition to requirements such as the patient's name, the name of the program, the specific information being disclosed, the specific purpose of the disclosure and a signature, the proposed subsection would include a requirement that there be included on the form a place for a recordation of an oral consent to be made by a person physically unable to provide a signature. (See proposed subsection (f)(1)(viii).) There would also be a requirement that the consent include either a date of expiration, or an event or condition upon which expiration would be conditioned. (See proposed subsection (f)(1)(ix).) Finally, the consent would require a statement that the consent is subject to revocation at any time, except to the extent that the program or person who is to make the disclosure has already acted upon it. (See proposed subsection (f)(1)(x).)

C. *Affected Persons*

The proposed amendments to § 255.5 would benefit individuals seeking treatment for substance abuse problems. Individuals seeking treatment would benefit from the amendments because they would have greater access to services, more appropriate lengths of stay, and improved coordination between various levels and types of care. In addition, individuals seeking treatment would have the ability to control the disclosure of their confidential information by authorizing the release of specific protected information by a signed consent.

Programs would also benefit from the proposed amendments because the proposed amendments would expand the amount of drug and alcohol treatment information that may be disclosed to third-party payers, while still restricting release of personal and possibly stigmatizing information that would not aid in the determination of appropriate levels of care or the need for treatment. Further, programs would be able to coordinate care by providing specific information that would be required for utilization and review of services as requested by third-party payers.

D. *Cost and Paperwork Estimate*

The proposed amendments would have no fiscal impact on the Commonwealth, local governments that do not

operate licensed drug or alcohol abuse programs, or the general public, nor would they create any measurable additional fiscal or paperwork requirements for the regulated community or those local governments that operate licensed programs. Programs are already required to have in place policies and procedures relating to disclosure of confidential information; these proposed amendments would require some updating to those policies and procedures to address the expansion of what information may be released, but this should take minimal effort.

Further, since several of the proposed amendments closely follow existing Federal requirements, again, little effort should be required to come into compliance with the proposed amendments. For example, there should be little additional paperwork or cost stemming from the proposed amendments setting out the minimum elements for a consent form; these requirements follow existing Federal regulatory provisions relating to consent forms for release of drug and alcohol abuse patient information. (See 42 CFR 2.31 (relating to form of written consent.)

In addition, there should be no measurable additional paperwork or cost impact to the regulated community from the proposed amendments relating to patient access to records. The proposed requirements are similar to those currently contained in 28 Pa. Code § 709.30 (relating to client rights), which apply to all freestanding drug and alcohol treatment facilities. These proposed requirements are also similar to those requirements put in place by the privacy rules resulting from the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (42 CFR 164.524 (relating to access of individuals to protected health information)). Programs that are required to comply with HIPAA and to be licensed by the Department should already have in place systems allowing for patient accessibility to information, for appeals of patients whose access to that information is limited, and for allowing patients to correct that information and submit rebuttal data. These systems should be adequate for the requirements relating to patient access in these proposed amendments.

E. *Statutory Authority*

The Department is authorized to regulate drug and alcohol abuse treatment facilities under Articles IX and X of the Public Welfare Code (62 P. S. §§ 901—922 and 1001—1087) as transferred to the Department under Reorganization Plan No. 2. of 1977 (71 P. S. § 751-25) (transferring duties under the Public Welfare Code with regard to regulation, supervision and licensing of drug and alcohol abuse treatment facilities to the Governor's Council on Drug and Alcohol Abuse (Council)) and Reorganization Plan No. 4 of 1981 (71 P. S. § 751-31) (transferring the functions of the Council to the Department). The Department is also authorized to promulgate regulations under section 4 of the Pennsylvania Drug and Alcohol Abuse Control Act (71 P. S. § 1690.104).

F. *Effectiveness/Sunset Dates*

The proposed amendments would become effective upon their publication in the *Pennsylvania Bulletin* as final-form rulemaking. No sunset date has been established. The Department will continually review and monitor the effectiveness of these regulations.

G. *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (act) (71 P. S. §§ 745.5(a)), the Department submitted a copy of these proposed amendments on November 29, 2007, to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House Health and Human Services Committee and the Senate Public Health and Welfare Committee. A copy of this material is available to the public upon request.

If IRRC has any objections to any portion of the proposed amendments, it will notify the Department within 30 days of the close of the public comment period. The notifications 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.

H. *Contact Person*

Interested persons are invited to submit written comments, suggestions or objections regarding the proposed amendments to Janice Staloski, Director, Bureau of Community Program Licensure and Certification, Department of Health, 132 Kline Plaza, Suite A, Harrisburg, PA 17104-1579, (717) 783-8665, within 30 days after publication of this notice in the *Pennsylvania Bulletin*. Persons with a disability who wish to submit comments, suggestions or objections regarding the proposed rulemaking may do so by using the previous number or address. Speech or hearing impaired persons may use V/TT (717) 783-6514 or the Pennsylvania AT&T Relay Service at (800) 654-5984 (TT). Persons who require an alternative format of this document may contact Janice Staloski so that necessary arrangements may be made.

CALVIN B. JOHNSON, M. D., M.P.H.,
Secretary

Fiscal Note: 10-186. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 4. ADMINISTRATION

PART XI. GOVERNOR'S COUNCIL ON DRUG AND ALCOHOL ABUSE

CHAPTER 255. MANAGEMENT INFORMATION, RESEARCH**[,]** AND EVALUATION

§ 255.5. **[Projects and coordinating bodies: disclosure of client-oriented information] Confidentiality of patient records and information**.

[(a) *Disclosure.* Information systems and reporting systems shall not disclose or be used to disclose client oriented data which reasonably may be utilized to identify the client to any person, agency, institution, governmental unit, or law enforcement personnel. Project staff may disclose client oriented data only under the following situations:

(1) With or without the consent of the client information may be released to those judges who have imposed sentence on a particular client where such sentence is conditioned upon the client entering a project. Information released shall be limited to that provided for in subsection (b).

(2) With or without the consent of the client, information may be released to those duly authorized probation or parole officers or both who have assigned responsibility to clients in treatment if the probation or parole of the client is conditioned upon his being in treatment. Information released shall be limited to that provided for in subsection (b).

(3) With or without the consent of the client, to judges who have assigned a client to a project under a pre-sentence, conditional release program.

Presentence conditional release programs include preindictment or preconviction conditional release such as Accelerated Rehabilitative Disposition, probation without verdict or disposition in lieu of trial under sections 17 and 18 of Act 64 (35 P. S. §§ 780-117 and 780-118).

(4) With the consent of the client, in writing, to a judge in order to assist that judge in deciding whether to initiate conditional release programs including those specified in paragraph (3).

(5) Projects may disclose any information to the attorney of a client provided as follows:

(i) The client consents, in writing to the disclosure of information.

(ii) The attorney is representing the client in a criminal, civil or administrative proceeding.

(6) Projects may disclose with the consent of a client, in writing, the information to employers of a client to further the rehabilitation of a client; or, to a prospective employer who affirmatively expresses that information is sought to enable the employer to engage the client as an employe. Such information shall be limited to whether the client has or is receiving treatment with the project.

(7) Projects may disclose information as set forth in subsection (b) with the consent of a client, in writing, to an insurance company, health, or hospital plan or facsimile thereof, which has contracted with the client to provide or will provide medical, hospital, disability or similar benefits. In the event that an insurance company, health, or hospital plan remains dissatisfied with the content of the information released with regard to a client in accordance with this paragraph, such insurance company, health or hospital plan may apply to the Executive Director for additional information with the written consent of the client and, upon approval by the Executive Director, such information may be released.

(8) Projects may disclose information as set forth in subsection (b) with the consent of a client, in writing, to governmental officials for the purpose of obtaining governmental benefits due the client as a result of his drug or alcohol abuse or dependence.

(9) In emergency medical situations where the life of the client is in immediate jeopardy, projects may release client records without the consent of the client to proper medical authorities solely for the purpose of providing medical treatment to the client.

(10) Projects shall keep and maintain a written record of all information and data which are disclosed under this section.

(b) *Restrictions.* Information released to judges, probation or parole officers, insurance company health or hospital plan or governmental officials, under subsection (a)(1), (2), (4), (7) and (8), is for the purpose of determining the advisability of continuing the client with the assigned project and shall be restricted to the following:

(1) Whether the client is or is not in treatment.

(2) The prognosis of the client.

(3) The nature of the project.

(4) A brief description of the progress of the client.

(5) A short statement as to whether the client has relapsed into drug, or alcohol abuse and the frequency of such relapse.

(c) *Record transfer.* The Client Admission Forms, the Treatment/Discharge Forms, and Discharge Summary Records are the only client records which may be transferred for treatment purposes. The transfer may be initiated upon the request of a client or by the present project of a client. In any case, the client shall fully understand the nature of the information, the purpose of the record transfer, and the identity of the recipient of the information. Only after these conditions are met, may the client authorize the transfer by signing a Release Form provided by the UDCS.

(d) *Coordinating bodies.* Coordinating bodies can gather and retain client oriented data provided they will receive or send only those forms as listed in subsection (c) in assigning or transferring clients and those bodies will not disclose such data, except to the Council, in manner that is consistent with this chapter and Act 63.]

(a) *Definitions.* The following words and terms, when used in this section, have the following meanings, unless the context clearly indicates otherwise:

Government officials—Officials or employees of Federal, State or local government agencies responsible for assisting a patient to obtain benefits or services due to the patient as a result of the patient's drug or alcohol abuse or dependence.

Medical authorities and medical personnel—A physician, nurse, emergency medical technician or other person employed, licensed, certified, or otherwise authorized by law to provide medical, mental health or addiction treatment to a patient.

Patient information—A patient record.

Patient record—A record, document or other information, whether written, electronic, or in any other form or format, relating to a patient's treatment for drug or alcohol abuse or dependence that is prepared or obtained by a program. A patient record may include medical, psychological, social, occupational, financial and other data prepared or obtained as part of the diagnosis, classification and treatment of a patient.

Program—A medical facility, clinic, rehabilitation or treatment program, institution, practitioner, project or other entity licensed or holding itself out to provide treatment for drug or alcohol abuse or dependence or any government agency authorized to provide treatment for drug or alcohol abuse or dependence.

Third-party payer—An entity, such as an insurance company, that pays for diagnosis, treatment, or referral for treatment services provided to a patient as a result of the patient's drug or alcohol abuse or dependence.

(b) *Scope and policy.*

(1) This section applies to the record of a patient seeking, receiving or having received addiction treatment services from any program.

(2) A patient seeking or receiving services from an addiction treatment program is entitled to do so with the expectation that information about the patient will be treated with respect and confidentiality by those providing services. Confidentiality between a provider of addiction treatment services and the provider's patient is necessary to develop the trust and confidence that is important for therapeutic intervention.

(3) The patient record of a patient receiving addiction treatment services is the property of the program providing services. The patient shall exercise control over the release of information contained in the patient record except as limited by subsections (c) and (d), and shall be provided with access to the patient record except as limited by subsection (e).

(4) Program staff shall respect the patient's privacy and confidentiality when using or discussing patient information.

(5) Unless otherwise noted, redisclosure of patient information is prohibited unless specifically reauthorized by the patient.

(6) The disclosure of a patient record or information from the patient record may not be used to initiate or substantiate criminal charges against the patient.

(c) *Consensual release of patient records and information.*

(1) With the patient's written consent, a program may release a patient record to medical personnel, as defined in subsection (a), for the purpose of diagnosis, treatment or referral for treatment.

(2) With the patient's written consent, a program may release a patient record to government officials and third-party payers to obtain benefits due the patient as a result of his drug or alcohol abuse or dependence.

(i) A program shall limit the patient information released to government officials and third-party payers to the information necessary to accomplish the specific purpose for the disclosure.

(ii) If the patient information requested by a government official or third-party payer is necessary to determine medical necessity for service admission, continued stay, discharge, referral, concurrent review, coordination of care and payment for entitled service benefits, a program shall limit the patient information released to the government official or third-party payer to the following:

(A) A statement of whether or not the patient is in treatment for drug or alcohol abuse or dependence.

(B) The patient's level of intoxication from alcohol, illicit drugs or medication, including the quantity, frequency and duration of use, and any specific withdrawal symptoms exhibited by the patient currently or in the past.

(C) The patient's vital signs, specific medical conditions to include pregnancy, specific medications taken and laboratory test results.

(D) The patient's specific diagnosis, mental status, level of functioning and treatment history.

(E) A brief description of the patient's progress in treatment related to the impact of substance use, abuse or dependence on life problems, participation in program activities and motivation to change.

(F) The patient's risk level for resuming substance use, abuse or dependence based on patterns of use, relapse history, existing relapse triggers and coping skills to maintain recovery.

(G) The patient's social support system, environmental supports and stressors that may impact ongoing recovery.

(3) With the patient's written consent that includes confirmation of legal representation, a program may disclose patient information to any lawyers representing the patient as a client.

(4) With the patient's written consent, a program may disclose patient information to the patient's probation or parole office if the following occur:

(i) Participation in the program is a condition of the patient's probation or parole.

(ii) The probation or parole office has a need for the information in connection with its duty to monitor the patient's progress. The probation or parole office that receives patient information under this section may only use or redisclose the information to carry out its official duties with regard to the patient's conditional release from custody.

(d) *Nonconsensual release of patient records and information.*

(1) A program may disclose a patient record, without the patient's consent, to proper medical authorities in emergency medical situations when the patient's life is in immediate jeopardy.

(2) A program may disclose a patient record, without the patient's consent, under an order of a court of competent jurisdiction issued after an application showing good cause for the disclosure.

(3) A program may disclose the following communications from programs to law enforcement personnel:

(i) Communications that are directly related to a patient's commission of a crime on the premises of the program or against program personnel or a threat to commit a crime.

(ii) Communications that are limited to the circumstances of the incident, including the patient status of the individual committing or threatening to commit the crime, that individual's name and address and that individual's last known whereabouts.

(4) A program may disclose information from patient records when reporting incidents of suspected child abuse in accordance with the 23 Pa.C.S. Chapter 63 (relating to child protective services) to the appropriate State or local authorities, except that restrictions on redisclosure of patient records in this section and in Federal law and regulations relating to confidentiality of drug and alcohol abuse client information, including the prohibition against redisclosure and use in civil or criminal proceedings that may arise out of the report of suspected child abuse and neglect continue to apply.

(5) A program may disclose information from patient records for the purpose of conducting scientific research if the disclosure is made in accordance with 42 CFR 2.52 (relating to research activities) and upon agreement in writing that patient names and other patient identifying information will not be disclosed.

(6) A program may disclose information from patient records to persons reviewing records on program premises in the course of performing audits or evaluations on behalf of any Federal, State or local agency which provides financial assistance to the program or is authorized by law to regulate its activities, or on behalf of any third-party payer providing financial assistance or reimbursement to the program or performing utilization or quality control reviews of the program.

(i) A disclosure made in the course of audit or evaluation activities shall be made in accordance with 42 CFR 2.53 (relating to audit and evaluation activities).

(ii) A report produced as a result of an audit or evaluation may not disclose patient names or other patient identifying information.

(7) Patient information made available under this section shall be limited to that information relevant and necessary to the purpose for which the information is sought.

(e) *Patient's access to records.*

(1) A patient has the right to inspect the patient's own records.

(i) The program may temporarily remove portions of the records prior to inspection by the patient if the program determines that the information may be detrimental if presented to the patient.

(ii) The program shall document reasons for removing portions of the records keep them on file.

(2) The patient has the right to appeal a decision limiting access to his own records to the program.

(3) The patient has the right to request the correction of inaccurate, irrelevant, outdated or incomplete information from his records.

(4) The patient has the right to submit rebuttal data or memoranda to his own records.

(f) *Consent form.* A patient's consent to disclose information must be in writing and include the following:

(1) The name of the patient.

(2) The name of the program or person making the disclosure.

(3) The name and title of the person to whom disclosure is being made or the name of the organization to which disclosure is being made, or both.

(4) The specific information being disclosed.

(5) The specific purpose of the disclosure.

(6) The dated signature of the patient, following a statement that the patient understands the nature of the release.

(7) The dated signature of the person obtaining the consent from the patient.

(8) A place to record an oral consent to release of information given by a person physically unable to provide a signature and a place for the signatures of two responsible persons who witnessed that the person understood the nature of the release and freely gave oral consent.

(9) The expiration date of the consent, or the event or condition the occurrence of which will cause the consent to expire.

(10) A statement that the consent is subject to revocation at any time except to the extent that the program or person who is to make the disclosure has already acted in reliance on it.

[Pa.B. Doc. No. 07-2307. Filed for public inspection December 14, 2007, 9:00 a.m.]

DEPARTMENT OF PUBLIC WELFARE

[55 PA. CODE CHS. 283, 285 AND 1251]
Payment for Burial and Cremation

Statutory Authority

The Department of Public Welfare (Department), under the authority of sections 201(2) and 403(b) of the Public Welfare Code (62 P. S. §§ 201(2) and 403(b)) proposes to adopt the proposed rulemaking as set forth in Annex A.

Purpose of Rulemaking

The purpose of this proposed rulemaking is to add a new Chapter 283 (relating to payment for burial and cremation) to replace the existing burial regulations in Chapter 285 (relating to payment for burial). Further, this rulemaking proposes to codify policies that have been in effect since a notice of rule change (NORC) was published at 30 Pa.B. 2957 (June 10, 2000). This proposed rulemaking increases the maximum payment to funeral directors for burial or cremation services to a standard $750 for all eligible individuals. This proposed rulemaking also increases the maximum level of contributions that may be made by another agency or individual towards burial expenses without reducing the Department payment. This amount is increased from $180 to $750. Additionally, this proposed rulemaking eliminates several restrictive requirements for burial, thus allowing families and funeral directors more flexibility and choice in planning and selecting burial goods and services. Finally, this proposed rulemaking amends cross-references in Chapter 1251 (relating to funeral directors' services) that reference Chapter 285 to conform to the addition of Chapter 283.

Background

Regulations governing maximum payment amounts for burial were adopted at 7 Pa.B. 2180 (August 5, 1977). The maximum allowance for burial services in Chapter 285 is inadequate and does not reflect the prevailing costs to provide burial and cremation services. The costs for transportation and preparation of the body, memorial services, gratuities to clergy and cemetery procedures have increased considerably since the adoption of the current regulations governing maximum payment. This proposed rulemaking is necessary to update the regulations to provide for a payment that more adequately covers the actual costs of burial and cremation goods and services.

The Department published prior proposed rulemaking to amend Chapter 285 at 34 Pa.B. 1774 (April 3, 2004). This prior proposed rulemaking proposed to amend only those sections of Chapter 285 related to the increase in the maximum payment and maximum level of contributions that reduce Department payment. Public comments received primarily from individuals in the funeral industry pointed out that the proposed amendments were still too restrictive and limited consumer choice. Based on these public comments and internal review, the Department concluded that Chapter 285 needed major revision and that a new chapter should be added to replace Chapter 285. This proposed rulemaking codifies not only requirements of the NORC but also incorporates new requirements in response to the public comments.

Requirements

The following is a summary of the specific provisions in the proposed rulemaking:

Chapter 283 (relating to payment for burial and cremation)

Cremation was always considered a compensable service under Chapter 285. To clarify that cremation is a compensable service, the Department proposes to add cremation to the title of the chapter.

§ 283.1 (relating to policy)

The Department proposes to establish the requirement that only a funeral director who is enrolled with the Department may be eligible for a payment for burial or cremation, or both, and includes a reference to the definition of a funeral director. This policy is consistent with § 1251.1 (relating to policy) under which the Department makes payment to enrolled funeral directors. Restricting payment to enrolled funeral directors is intended to protect the rights and dignity of both the deceased and individuals representing the deceased. The Department understands that other providers, such as cemeteries and crematoriums, may provide services for which payment is required. The Department expects the funeral director and the individual representing the deceased to reach an agreement regarding how the payment should be allocated.

§§ 283.3—283.7

The Department describes eligibility requirements for the request for payment, including who may make the request, when a request must be submitted and exceptions to this time frame. A request for payment of burial or cremation, or both, may be made by a family member, friend, fraternal organization representing the deceased or a funeral director on behalf of an individual. A request may also be made by another source if a certificate issued by the Anatomical Board of the Department of Health accompanies the request. A request for payment must be submitted on a form approved by the Department within 30 days of the date of death unless valid, unusual circumstances for the delay are provided. Additionally, this section describes the assistance status of the deceased who may be eligible for burial or cremation payment.

§ 283.11 (relating to standards for providing burial or cremation, or both)

The Department describes the standards to which funeral directors shall adhere when providing services for burial or cremation, or both. These standards include abiding by legal requirements, commonly accepted practices of the funeral industry and a written agreement between the funeral director and the individual handling the funeral arrangements. This written agreement will include provisions for payment, including payment for interment if services for interment are selected. This agreement should protect families by assuring that payment will be made for certain items or services specified in the agreement.

The Department did not include specific minimum requirements for goods and services in Chapter 283. This allows greater flexibility and freedom of choice between the funeral director and the individual handling the funeral arrangements.

§§ 283.21 and 283.22 (relating to Department payment; and resources that do not reduce Department payment)

The Department describes the maximum payment for burial or cremation, or both, and the maximum value of contributions that may be made by friends, family or other agencies without reducing the Department payment.

§ 283.23 (relating to resources from which the Department will seek to collect)

The Department describes resources that do not reduce the Department payment, but from which the Department will seek recovery.

§ 283.24 (relating to resources reducing Department payment)

The Department describes resources that reduce the Department payment.

§ 283.31 (relating to funeral director violations)

The Department describes that it can take action against a funeral director if a funeral director has or appears to have violated a regulation under Chapters 1101 and 1251 (relating to general provisions; and funeral directors' services). The Department believes that the written agreement included in § 283.11 will protect consumers and allow for allocation of resources to ensure the complete burial process, cremation process, or both. The Department does not penalize funeral directors for failure to apportion payments, unless a funeral director fails to pay another service provider in accordance with the written agreement between the funeral director and the individual handling the funeral arrangements for the deceased.

§§ 1251.1, 1251.21, 1251.23, 1251.42, 1251.51, 1251.71 and 1251.81

The Department proposes to amend the cross-references that reference Chapter 285 in these sections since Chapter 283 will be replacing Chapter 285.

Affected Individuals and Organizations

This proposed rulemaking affects individuals acting on behalf of deceased individuals who were eligible and authorized for or receiving cash assistance at the time of death. This proposed rulemaking affords individuals responsible for making funeral arrangements more flexibility and choice in planning and selecting burial and cremation goods and services.

Funeral directors who are enrolled with the Department are the beneficiaries of increased payments that more adequately cover the actual cost of burial and cremation goods and services. In addition, other individuals in the funeral industry may receive increased compensation for services rendered if these services are a part of the agreement between the funeral director and the individual handling the funeral arrangements.

Accomplishments and Benefits

This proposed rulemaking benefits individuals acting on behalf of a deceased individual by allowing more flexibility and choice in planning and selecting burial and cremation goods and services.

This proposed rulemaking also benefits funeral directors and may benefit other members of the funeral industry by providing increased payments that more adequately cover the actual costs of burial and cremation goods and services. Increased payments reduce uncompensated costs that are incurred by funeral directors and may reduce costs incurred by other service providers.

Fiscal Impact

From Fiscal Year (FY) 2000-2001 through FY 2006-2007, the Department incurred an average annual increase in expenditures of $360,000 since the maximum payment was raised from $350 to $750 in Fiscal Year (FY) 2000-2001. Of this overall increase, $140,400 is due to the increased payment amount and $219,600 is due to an increase in the number of claims paid. The estimated increase in annual expenditures for FY 2007-2008 is $433,000.

The proposed rulemaking reduces the uncompensated costs for services that are incurred by funeral directors and may reduce uncompensated costs for other individuals in the funeral industry.

Paperwork Requirements

This proposed rulemaking does not increase paperwork requirements.

Effective Date

This proposed rulemaking will be effective upon final publication in the *Pennsylvania Bulletin*, with two exceptions. The proposed amendment to §§ 283.21 and 283.22(2) are effective retroactive to July 3, 2000, to coincide with the effective date of the NORC.

Public Comment

Interested persons are invited to submit written comments, suggestions or objections regarding the proposed rulemaking to the Department at the following address: Edward J. Zogby, Director, Bureau of Policy, Room 431, Health and Welfare Building, Harrisburg, PA 17120, (717) 787-4081 within 30 calendar days after the date of publication of this proposed rulemaking in the *Pennsylvania Bulletin*. Reference Regulation No. 14-510 when submitting comments.

Persons with a disability who require an auxiliary aid or service may submit comments by using the AT&T Relay Service at (800) 654-5984 (TDD users) or (800) 654-5988 (voice users).

Regulatory Review Act

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on November 29, 2007, the Department submitted a copy of this proposed rulemaking 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 rulemaking, the Department has provided IRRC and the Committees with a copy of a Regulatory Analysis Form prepared by the Department. A copy of this form is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, if IRRC has any comments, recommendations or objections to any portion of the proposed rulemaking, it may notify the Department and the Committees within 30 days after the close of the public comment period. The notification shall specify the regulatory review criteria that have not been met. The Regulatory Review Act specifies detailed procedures for review by the Department, the General Assembly and the Governor, of any comments, recommendations or objections raised, prior to final publication of the regulation.

ESTELLE B. RICHMAN,
Secretary

Fiscal Note: 14-510. (1) General Fund; (2) Implementing Year 2007-08 is $433,000; (3) 1st Succeeding Year 2008-09 is $438,000; 2nd Succeeding Year 2009-10 is $442,000; 3rd Succeeding Year 2010-11 is $445,000; 4th Succeeding Year 2011-12 is $448,000; 5th Succeeding Year 2012-13 is $451,000; (4) 2006-07 Program—$671,472,000; 2005-06 Program—$945,950,000; 2004-05 Program—$842,991,000; (7) Medical Assistance Outpatient; (8) recommends adoption. Funds have been included in the budget to cover these increases.

Annex A

TITLE 55. PUBLIC WELFARE

PART II. PUBLIC ASSISTANCE MANUAL

Subpart I. OTHER INCOME MAINTENANCE PROGRAMS

CHAPTER 283. PAYMENT FOR BURIAL AND CREMATION

GENERAL PROVISIONS

REQUIREMENTS

STANDARDS

PAYMENTS

VIOLATIONS

GENERAL PROVISIONS

§ 283.1. Policy.

(a) The Department will pay for expenses related to burial or cremation, or both.

(b) The Department will pay a funeral director, or anyone acting for him, if the funeral director is the following:

(1) A funeral director as defined in section 2(1) of the Funeral Director Law (63 P. S. § 479.2(1)).

(2) Enrolled with the Department.

REQUIREMENTS

§ 283.3. Requirements for payment.

The requirements of §§ 283.4—283.7 shall be met for the Department to pay expenses related to burial or cremation, or both. These requirements apply regardless of where death occurs.

§ 283.4. Assistance status of deceased.

The deceased individual shall have been a recipient of Cash Assistance—Temporary Assistance for Needy Families (TANF), General Assistance (GA), State Blind Pension (SBP), Supplemental Security Income (SSI) or State Supplementary Payment (SSP)—at the time of death. This includes:

(1) An individual who was determined eligible for cash assistance, including SBP, regardless of whether the individual had received a cash assistance benefit.

(i) Eligibility for payment begins with the date on which eligibility for cash assistance begins.

(ii) Eligibility for payment extends through the period covered by the last cash assistance benefit for which the individual was eligible.

(2) A former assistance recipient whose assistance had been discontinued due to hospitalization and who died while hospitalized within 3 months from the date of his admission.

(3) A child born dead to an assistance recipient.

(4) A child of an assistance recipient who died so soon after birth that assistance could not be authorized.

(5) A member of a recipient's family who formerly received assistance with the family, returned to the residence, was planning to apply for assistance and died before assistance could be authorized.

§ 283.5. Source of request for payment.

(a) The Department will accept a request for payment for burial or cremation, or both, if the request is made by one of the following:

(1) A relative.

(2) A friend.

(3) The representative of a fraternal society of which the deceased was a member.

(4) The representative of a charitable or religious organization.

(5) A funeral director acting on behalf of an individual described in paragraphs (1)—(4).

(b) If the request for payment comes from another source, the request must be accompanied by a certificate issued by the Anatomical Board, Department of Health, declaring the body unfit for anatomical purposes.

§ 283.6. Submission of form for payment.

The individual requesting payment or the funeral director on behalf of the individual requesting payment shall submit the request on a form approved by the Department in accordance with § 283.7 (relating to date of request for payment). This form shall be completed by the individual requesting payment and the funeral director.

§ 283.7. Date of request for payment.

This form to request payment shall be submitted to the Department within 30 days of the date of death with the following exceptions:

(1) When there are unusual circumstances and the individual requesting payment or the funeral director submits valid reasons for the delay. In this case, the individual requesting payment or the funeral director shall submit the form to the Department within 30 days from the date of the request for payment.

(2) When the funeral director is waiting for notification regarding a resource that may reduce the Department payment according to § 283.24 (relating to resources reducing Department payment). Under these circumstances, the individual requesting payment or the funeral director shall submit the form to the Department within 15 days from the date the funeral director receives payment from the resource or a notification regarding payment from the resource, whichever is sooner.

STANDARDS

§ 283.11. Standards for providing burial or cremation, or both.

The funeral director shall provide services for burial or cremation, or both, in accordance with the following:

(1) Commonly accepted funeral industry practices established under the Funeral Director Law (63 P. S. §§ 479.1—479.20).

(2) Requirements for professional and vocational standards for funeral directors under 49 Pa. Code Chapter 13 (relating to state board of funeral directors).

(3) Federal standards required by the Federal Trade Commission as specified at 16 CFR Part 453 (relating to funeral industry practices).

(4) A written agreement between the funeral director and the individual handling the funeral arrangements for the deceased. The agreement will include provisions for funeral directors to provide payment for other services, including payment for interment, if services for interment are requested.

PAYMENT

§ 283.21. Department payment.

The Department's total payment for burial or cremation, or both, is $750 for goods and services and interment charges. The Department will make a total payment not to exceed $750 for a deceased individual who was eligible and authorized for cash assistance at the time of death.

§ 283.22. Resources that do not reduce Department payment.

Resources that are not considered in determining the Department payment include:

(1) Small contributions, such as articles of clothing, the use of cars to carry the funeral party, newspaper obituary, flowers and religious services.

(2) Contributions in money, goods or services by an agency or individual, including legally responsible relatives, up to a total of $750.

§ 283.23. Resources from which the Department will seek to collect.

Under the following circumstances, the Department payment is not reduced by the value of the resources described in § 283.24 (relating to resources reducing Department payment), but instead the Department will seek recovery if resources:

(1) Are reported to the funeral director after the deadline date as set forth in § 283.7 (relating to date of request for payment), and the funeral director does not collect from these resources.

(2) Become available only after the Department pays for burial or cremation, or both.

§ 283.24. Resources reducing Department payment.

(a) When an individual submits a payment form to the Department, the Department will determine the resources available to meet expenses.

(b) Resources may be in the estate of the deceased, payable on behalf of the deceased to the estate or to another individual, or contributed on behalf of the deceased.

(c) The combined value of the following contributions in money, goods or services by an agency or individual, except as specified in § 283.22 (relating to resources that do not reduce Department payment), reduces the Department payment:

(1) The contributions and resources made by an agency or individual.

(2) Burial reserve in the estate of the deceased, and the value of a burial reserve and burial space as set forth in § 177.2 (relating to definitions).

(3) Cash on hand in the estate of the deceased.

(4) Other personal property in the estate of the deceased that may be readily converted into cash, and is not needed to meet a living requirement for the survivors.

(5) Life insurance death benefits payable to legally responsible relatives or individuals or organizations that paid insurance premiums by agreement with the insured that the benefits are used for burial.

(6) Burial benefits from a lodge or fraternal organization.

(7) A lump-sum death benefit from the Social Security Administration (SSA) as defined in 20 CFR 401.25 (relating to terms defined) payable to a surviving spouse or to a funeral director.

(i) The individual who assumed responsibility for payment of the funeral expenses may authorize that the lump-sum payment be paid to the funeral director.

(ii) The Department, at the request of the funeral director, may authorize that the lump-sum payment be paid to the funeral director if:

(A) The individual who assumed responsibility for payment of the funeral expenses does not authorize the payment to the funeral director.

(B) The SSA determines that the individual who arranged burial did not assume responsibility.

(iii) The Department will not pay costs for burial or cremation, or both, until definite information about payment of the lump-sum death benefit is provided by the funeral director.

(8) The lump-sum death benefit from railroad retirement payable to a surviving spouse or a funeral director.

(9) Benefits available from county commissioners on behalf of deceased widows of deceased veterans.

(10) Benefits available for burial in a National cemetery.

(11) Workers compensation benefits designated for burial or cremation, or both, if death results from an accident or injuries sustained in connection with the employment of the deceased.

(12) Awards resulting from accidental death not connected with the employment of the deceased. Pending awards do not reduce the Department payment. When an award is pending, the Department will pay for burial or cremation, or both, and seek recovery when the award is made.

(13) Department of Veterans Affairs death benefits.

(14) Death benefits from United Mine Workers of America welfare and retirement or health and retirement funds.

VIOLATIONS

§ 283.31. Funeral director violations.

If the Department learns that a funeral director has or appears to have violated a regulation, the Department will determine whether further action is needed in accordance with Chapters 1101 and 1251 (relating to general provisions; and funeral directors' services).

CHAPTER 285. (Reserved)

(*Editor's Note:* The following sections are proposed to be deleted: §§ 285.1, 285.3 and 285.4 which appear in pages 285-1 to 285-13, serial pages (291137) to (291138), (278375) to (278378), (310007) to (310008) and (278381) to (278385).)

PART III. MEDICAL ASSISTANCE MANUAL

CHAPTER 1251. FUNERAL DIRECTORS' SERVICES

GENERAL PROVISIONS

§ 1251.1. Policy.

The Department provides payment for funeral directors' services rendered to eligible deceased recipients by funeral directors who are enrolled as providers under the program. Payment shall be subject to this chapter and Chapters **[285] 283** and 1101 (relating to payment for burial **and cremation**; and general provisions).

SCOPE OF BENEFITS

§ 1251.21. Scope of benefits for the categorically needy.

Categorically needy recipients who were receiving a money payment at the time of their death as set forth in § **[285.3] 283.4** (relating to **[requirements] assistance status of deceased**) are eligible for funeral directors' services listed in Chapter 1150 (relating to MA Program payment policies) and the MA Program fee schedule hereto subject to the conditions and limitations of this chapter and Chapter **[285] 283** (relating to payment for burial **and cremation**).

§ 1251.23. Scope of benefits for State Blind Pension recipients.

State Blind Pension recipients are eligible for funeral directors' services subject to the conditions and limitations of this chapter and Chapter **[285] 283** (relating to payment for burial **and cremation**).

PROVIDER PARTICIPATION

§ 1251.42. Ongoing responsibilities of providers.

In addition to the applicable responsibilities of providers established in § 1101.51 (relating to ongoing responsibilities of providers), funeral directors shall, as a condition of participation comply fully with §§ **[285.4(a)—(c)(relating to procedures)] 283.1, 283.3, 283.11, 283.21 and 283.22**.

PAYMENT FOR FUNERAL DIRECTORS' SERVICES

§ 1251.51. General payment policy.

Payment shall be made for funeral directors' services subject to the conditions and limitations established in Chapter **[285] 283** (relating to payment for burial **and cremation)**.

UTILIZATION CONTROL

§ 1251.71. Scope of claims review procedures.

Claims submitted for payment under the MA Program are subject to the utilization control procedures established in Chapters **[285] 283** and 1101 (relating to payment for burial **and cremation**; and general provisions).

ADMINISTRATIVE SANCTIONS

§ 1251.81. Provider misutilization.

Providers determined to have billed for services inconsistent with MA Program regulations or to have otherwise violated the standards set forth in the provider agreement, are subject to the sanctions described in Chapter 1101 (relating to general provisions) and § **[285.4(e)] 283.31** (relating to **[procedures] funeral director violations)**.

[Pa.B. Doc. No. 07-2308. Filed for public inspection December 14, 2007, 9:00 a.m.]

STATE BOARD OF MEDICINE

[49 PA. CODE CHS. 16 AND 18]

Nurse Midwife Prescriptive Authority

The State Board of Medicine (Board) proposes to amend §§ 16.11, 16.13, 18.1, 18.2, 18.3, 18.5 and 18.6 and to add §§ 18.6a and 18.9 (relating to prescribing, dispensing and administering drugs; and notification of changes in collaboration), to read as set forth in Annex A.

A. *Effective Date*

The amendments will be effective upon publication as final-form rulemaking in the *Pennsylvania Bulletin*.

B. *Statutory Authority*

The amendments implement the act of July 20, 2007, (P. L. 324, No. 50) (Act 50) which directs the Board to adopt, promulgate and enforce regulations that establish requirements for prescriptive authority for midwives to be met by individuals so licensed who elect to obtain prescriptive authority in this Commonwealth.

C. *Background and Purpose*

Act 50, which became effective September 18, 2007, amended the Medical Practice Act of 1985 (act) (63 P. S. §§ 422.1—422.51.1) by amending section 2 of the act (63 P. S. § 422.2) to define "legend drug," by adding section 35(c) of the act (63 P. S. § 422.35(3)) authorizing prescriptive authority and by adding section 35(d) of the act providing for collaborative agreements with physicians. Section 8 of the act (63 P. S. § 422.8) and section 35(a) of the act authorize the Board to promulgate regulations as necessary to carry out the purposes of the act. In addition, section 3 of the act (63 P. S. § 422.3) requires the Board to promulgate regulations within 12 months of its effective date.

D. *Description of Proposed Amendments*

Section 16.11 (relating to licenses, certificates and registrations) is proposed to be amended by adding the issuance of a certificate of prescriptive authority for nurse midwives.

Section 16.13 (relating to licensure, certification, examination and registration fees) is proposed to be amended by adding fees relating to licensure and prescriptive authority for nurse midwives.

Section 18.1 (relating to definitions) is proposed to be amended by revising the name of the National certifying organization recognized by the Board. The definition of "midwife" is proposed to be amended to reflect that the midwife would practice in collaboration with a Board-licensed physician. The definitions of "midwife examination" and "midwife program" are proposed to by amended to reflect the name change of the National certifying organization. A definition of "midwife colleague" is proposed to be amended to refer to another midwife who is available to substitute for the midwife who has primary responsibility for a pregnant woman under that midwife's care. The definition of "legend drug" is proposed to be added as delineated by statute. Section 18.2 (relating to licensure requirements) is also proposed to be amended to reflect the recent name change of the National certifying organization.

Subsection 18.3(b) (relating to biennial registration requirements) is proposed to be amended to reflect that a midwife shall complete the continuing education requirements required under section 12.1 of the Professional Nursing Law (63 P. S. § 222). This section also requires that in the case of a midwife who has prescriptive authority, 16 of those continuing education hours must include at least 16 hours in pharmacology.

Section 18.5 (relating to collaborative agreements) is proposed to be amended by adding subsection (f) to require that a physician with whom a midwife has a collaborative agreement must have hospital clinical privileges in the same specialty area of care. The Board also proposes to add subsection (g) to require review of the collaborative agreement by the Board, and subsection (h) to require that the midwife or collaborating physician provide immediate access to the collaborative agreement to anyone seeking to confirm the scope of the midwife's authority.

Section 18.6 (relating to practice of midwifery) is proposed to be amended by adding in paragraph (5) the authority to prescribe, dispense, order and administer medical devices, immunizing agents, laboratory tests and therapeutic, diagnostic and preventative measures, so long as those activities are in accordance with the midwife's collaborative agreement and consistent with the midwife's education and National certification. Paragraph (6) is proposed to be added to set forth the criteria for qualifications of the midwife to obtain prescriptive authority from the Board. This section would permit the prescribing, dispensing, ordering and administration of legend drugs, and Schedule II through Schedule V controlled substances by a midwife who possesses a master's degree or its substantial equivalent, and National certification. Paragraph (6)(i) would require that the midwife demonstrate to the Board that the midwife has successfully completed at least 45 hours of course-work specific to advanced pharmacology at a level above that required by as professional nursing education program. In paragraph (6)(ii), the proposed requirement is that the midwife act in accordance with a collaborative agreement with a physician that at a minimum identifies the categories of drugs the midwife may prescribe or dispense, as well as the drugs that require referral, consultation or co-management. Paragraph (7) would be amended to delete the prohibition against prescribing or dispensing of drugs.

Section 18.6a sets forth the parameters of the prescriptive authority of the midwife. Subsection (a) prohibits the prescribing or dispensing of Schedule I controlled substances and restricts the prescribing, dispensing, ordering or administration of a controlled substance except for a woman's acute pain. The proposal also includes a provision in subsection (a)(2)(ii) which would limit the prescribing, dispensing, ordering or administration of a Schedule II drug to 72 hours, and would prohibit the extension of that time limit except with the approval of the collaborating physician.

Subsection (a)(1)(iii) also sets forth the requirement that prescribing, dispensing, ordering or administration of psychotropic drugs only be undertaken after consulting with the collaborating physician. The proposal also includes a provision in subsection (a)(1)(iv) to prohibit the prescribing or dispensing of a drug unless it is in accordance with the collaborative agreement. Subsection (a)(3) specifically requires that a midwife who is authorized to prescribe or dispense, or both, controlled substances be registered with the United States Drug Enforcement Administration (DEA).

Section 18.6a(b) sets forth the requirements for prescription blanks. It would require that the name and license number of the midwife in addition to a designation that the signer is a midwife be included on the prescription blank. As appropriate, space on prescription blanks must be provided for the midwife to record the midwife's DEA number, when appropriate. This reminds the midwife of the requirement to register with the DEA and serves to bring the midwife's practice into conformance with Federal law. Subsection (b)(3) would permit a midwife to use a prescription blank generated by a hospital provided that the name and license number of the midwife is on the blank.

Subsection 18.6a(c) sets forth the process that a collaborating physician shall follow in the event the midwife prescribes or dispenses a drug inappropriately. The collaborating physician is required to advise the patient, notify the midwife or midwife colleague, if any, and in the case of a written prescription, advise the pharmacy of the inappropriate prescribing. The midwife, midwife colleague or collaborating physician would also be required under this proposed rulemaking to advise both the patient and the midwife to discontinue the drug use, and advise the pharmacy if there was a written prescription. The order discontinuing use of the drug would be required to be noted in the patient's medical record.

In § 18.6a(d), the Board proposes to establish recordkeeping requirements which detail the maintenance of information on any drug prescribed by the midwife and number of refills, if any. If a midwife dispenses a drug, the midwife's name and the name, amount, dose and date dispensed of the medication are to be a part of the patient's medical record.

Section 18.6a(e) mandates compliance by the midwife with other sections of Chapter 16 (relating to State Board of Medicine—general provisions), as well as with Department of Health regulations in 28 Pa. Code (relating to health and safety) relating to prescribing, administering, dispensing, packaging and labeling of drugs.

Section 18.9 (relating to notification of changes in collaboration) proposes a requirement that the midwife notify the Board in writing of any change regarding the midwife's collaborative agreement, as well as notifying the Board of a change in address. A change in collaboration requires inclusion of the name of the new registered collaborating physician. Subsection (b) requires the collaborating physician to notify the Board in writing within 30 days of a change or termination of collaboration with a midwife. The midwife's failure to notify the Board of changes in employment would subject the midwife's license to discipline. Finally, subsection (d) would require that a midwife with prescriptive authority notify the Board within 30 days if the midwife cannot continue to fulfill the requirements for prescriptive authority.

E. *Fiscal Impact and Paperwork Requirements*

The proposed rulemaking will have no quantifiable adverse fiscal impact on the Commonwealth or its political subdivisions.

F. *Sunset Date*

The Board continuously monitors the effectiveness of its regulations. Therefore, no sunset date has been assigned.

G. *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on December 5, 2007, the Board submitted a copy of this proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the Senate Consumer Protection and Professional Licensure Committee and the House Professional Licensure Committee. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey any comments, recommendations or objections to the proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections must specify the regulatory review criteria that have not been met. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the rulemaking, by the Board, the General Assembly and the Governor of comments, recommendations or objections raised.

H. *Public Comment*

Interested persons are invited to submit written comments, recommendations or objections regarding the proposed rulemaking to Sabina I. Howell, Board Counsel, P. O. Box 2649, Harrisburg, PA 17105-2649 within 30 days following publication for the proposed rulemaking in the *Pennsylvania Bulletin*.

CHARLES D. HUMMER, Jr., M. D.,
Chairperson

Fiscal Note: 16A-4926. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 16. STATE BOARD OF MEDICINE—GENERAL PROVISIONS

Subchapter B. GENERAL LICENSE, CERTIFICATION AND REGISTRATION PROVISIONS

§ 16.11. Licenses, certificates and registrations.

* * * * *

(b) The following nonmedical doctor licenses **and certificates** are issued by the Board:

(1) Midwife license.

(2) **Midwife certificate of prescriptive authority.**

(3) Physician assistant license.

* * * * *

§ 16.13. Licensure, certification, examination and registration fees.

* * * * *

(b) *Midwife License:*

[Application ..... $ 30

Biennial renewal ..... $ 40]

Application for midwife license without prescriptive authority ..... $ 50

Application for additional collaborative agreement without prescriptive authority ..... $ 30

Application for midwife license with prescriptive authority ..... $ 70

Application for additional collaborative agreement with prescriptive authority ..... $ 50

Biennial renewal of midwife license ..... $ 40

Biennial renewal of each prescriptive authority ..... $ 25

Verification of licensure ..... $ 15

* * * * *

CHAPTER 18. STATE BOARD OF MEDICINE—PRACTITIONERS OTHER THAN MEDICAL DOCTORS

Subchapter A. LICENSURE AND REGULATION OF MIDWIFE ACTIVITIES

§ 18.1. Definitions.

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

[*ACNM*—The American College of Nurse-Midwives.]

***AMCB*—The American Midwifery Certification Board.**

* * * * *

***Legend drug*—A drug:**

(i) Limited by the Federal Food, Drug and Cosmetic Act (21 U.S.C.A. §§ 301—399) to being dispensed by prescription.

(ii) The product label of which is required to contain the following statement: "Caution: Federal law prohibits dispensing without a prescription."

Midwife—A person licensed by the Board to practice midwifery **in collaboration with a physician licensed by the Board to practice medicine**.

***Midwife colleague*—A midwife who is available to substitute for the midwife who has primary responsibility in the management of a pregnant woman under the midwife's care.**

Midwife examination—An examination offered or recognized by the Board to test whether an individual has accumulated sufficient academic knowledge with respect to the practice of midwifery to qualify for a midwife license. The Board recognizes the certifying examination of the **[ACNM] AMCB** as a midwife examination.

Midwifery practice—**[anagement] Management** of the care of essentially normal women and their normal neonates—initial 28-day period. This includes antepartum, intrapartum, postpartum and nonsurgically related gynecological care.

Midwife program—An academic and clinical program of study in midwifery which has been approved by the Board or by an accrediting body recognized by the Board. The Board recognizes the **[ACNM] AMCB** as an accrediting body of programs of study in midwifery.

* * * * *

§ 18.2. Licensure requirements.

The Board will grant a midwife license to an applicant who meets the following requirements. The applicant shall:

* * * * *

(4) Have obtained one of the following:

(i) A passing grade on a midwife examination. The Board accepts the passing grade on the certifying examination of the **[ACNM] AMCB** as determined by the **[ACNM] AMCB**.

(ii) **[ANCM certification] Certification** as a midwife **by the American College of Nurse-Midwives (ACNM)** before the **[ACNM]** certification examination was first administered in 1971.

* * * * *

§ 18.3. Biennial registration requirements.

* * * * *

(b) **As a condition of biennial license renewal, a midwife shall complete the continuing education requirement in section 12.1 of the Professional Nursing Law (63 P. S. § 222). In the case of a midwife who has prescriptive authority under the act, the continuing education required by the Professional Nursing Law must include at least 16 hours in pharmacology completed each biennium.**

(c) The **[fee] fees** for the biennial **[registration] renewal** of a midwife license **[is] and prescriptive authority are** set forth in § 16.13 (relating to licensure, certification, examination and registration fees).

§ 18.5. Collaborative agreements.

* * * * *

(f) The physician with whom a midwife has a collaborative agreement shall have hospital clinical privileges in the specialty area of the care for which the physician is providing collaborative services.

(g) The collaborative agreement must satisfy the substantive requirements set forth in subsections (a)—(e) and as being consistent with relevant provisions of the act and this subchapter, and shall be submitted to the Board for review.

(h) A midwife or collaborating physician shall provide immediate access to the collaborative agreement to anyone seeking to confirm the scope of the midwife's authority, and the midwife's ability to prescribe or dispense a drug.

§ 18.6. Practice of midwifery.

The midwife is authorized and required to do the following:

* * * * *

(5) **A midwife may, in accordance with a collaborative agreement with a physician, and consistent with the midwife's academic educational preparation and National certification by the AMCB or its successor organizations, prescribe, dispense, order and administer medical devices, immunizing agents, laboratory tests and therapeutic, diagnostic and preventative measures.**

(6) A midwife who possesses a master's degree or its substantial equivalent, and National certification, may be eligible to receive a certificate from the Board which will authorize the midwife to prescribe, dispense, order and administer drugs, including legend drugs and Schedule II through Schedule V controlled substances, as defined in The Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. §§ 780-101—780-144), in accordance with § 18.6a (relating to prescribing, dispensing and administering drugs) provided that the midwife demonstrates to the Board that:

(i) The midwife has successfully completed at least 45 hours of course-work specific to advanced pharmacology at a level above that required by a professional nursing education program.

(ii) The midwife acts in accordance with a collaborative agreement with a physician which must at a minimum identify:

(A) The categories of drugs from which the midwife may prescribe or dispense.

(B) The drugs which require referral, consultation or co-management.

(7) Perform medical services in the care of women and newborns that may go beyond the scope of midwifery, if the authority to perform those services is delegated by the collaborating physician in the collaborative agreement, **and** the delegation is consistent with standards of practice embraced by the midwife and the relevant physician communities in this Commonwealth**[, and the delegated medical services do not involve the prescribing or dispensing of drugs]**.

[(6)] (8) Refer and transfer to the care of a physician, as provided for in the midwife protocol or a collaborative agreement, or both, those women and newborns whose medical problems are outside the scope of midwifery practice and who require medical services which have not been delegated to the midwife in a collaborative agreement.

[(7)] (9) Review and revise the midwife protocol and collaborative agreements as needed.

[(8)] (10) Carry out responsibilities placed by law or regulation upon a person performing the functions that are performed by the midwife.

§ 18.6a. Prescribing, dispensing and administering drugs.

(a) *Prescribing, dispensing and administering drugs.* A midwife who has prescriptive authority may prescribe, administer and dispense drugs as follows:

(1) A midwife may not prescribe or dispense Schedule I controlled substances as defined by section 4 of The Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. § 780-104).

(2) A midwife may prescribe, dispense or administer Schedule II through V controlled substances and legend drugs in accordance with the following restrictions:

(i) A midwife may not prescribe, dispense, order or administer a controlled substance except for a woman's acute pain.

(ii) In the case of a Schedule II controlled substance, the dose must be limited to 72 hours and may not be extended except with the approval of the collaborating physician.

(iii) A midwife shall prescribe, dispense, order or administer psychotropic drugs only after consulting with the collaborating physician.

(iv) A midwife shall only prescribe or dispense a drug for a patient in accordance with the collaborative agreement.

(3) A midwife authorized to prescribe or dispense, or both, controlled substances, shall register with the United States Drug Enforcement Administration (DEA).

(b) *Prescription blanks.* The requirements for prescription blanks are as follows:

(1) Prescription blanks must bear the license number of the midwife and the name of the midwife in a printed format at the heading of the blank.

(2) The signature of the midwife must be followed by the initials "C.N.M." or similar designation to identify the signer as a midwife. When prescribing controlled substances, the midwife's DEA registration number must appear on the prescription.

(3) A midwife may use a prescription blank generated by a hospital provided the information in paragraph (1) appears on the blank.

(c) *Inappropriate prescribing.* The collaborating physician shall immediately advise the patient, notify the midwife or midwife colleague and, in the case of a written prescription, advise the pharmacy if the midwife is prescribing or dispensing a drug inappropriately. The midwife, midwife colleague or collaborating physician shall advise the patient to discontinue use of the drug and the midwife shall cease prescribing that drug for the patient. In the case of a written prescription, the midwife, midwife colleague or collaborating physician shall notify the pharmacy to discontinue the prescription. The order to discontinue the use of the drug or prescription must be noted in the patient's medical record.

(d) *Recordkeeping requirements.* Recordkeeping requirements are as follows:

(1) When prescribing a drug, the midwife shall do one of the following:

(i) Keep a copy of the prescription, including the number of refills, in a ready reference file.

(ii) Record the name, amount, directions for use and doses of the drug prescribed, the number of refills, the date of the prescription and the midwife's name in the patient's medical records.

(2) When dispensing a drug, the midwife shall record the following:

(i) The midwife's name.

(ii) The name of the medication dispensed.

(iii) The amount of medication dispensed.

(iv) The dose of the medication dispensed.

(v) The date dispensed in the patient's medical records.

(e) *Compliance with regulations relating to prescribing, administering, dispensing, packaging and labeling of drugs.* A midwife shall comply with §§ 16.92—16.94 (relating to prescribing, administering and dispensing controlled substances; packaging; and labeling of dispensed drugs) and Department of Health regulations in 28 Pa. Code §§ 25.51—25.58 (relating to prescriptions) and regulations regarding packaging and labeling dispensed drugs. See § 16.94 and 28 Pa. Code §§ 25.91—25.95 (relating to labeling of drugs, devices and cosmetics).

§ 18.9. Notification of changes in collaboration.

(a) A midwife shall notify the Board, in writing, of a change in or termination of a collaborative agreement or a change in mailing address within 30 days. Failure to notify the Board, in writing, of a change in mailing address may result in failure to receive pertinent material distributed by the Board. The midwife shall provide the Board with the new address of residence, address of employment and name of registered collaborating physician.

(b) A collaborating physician shall notify the Board, in writing, of a change or termination of collaboration with a midwife within 30 days.

(c) Failure to notify the Board of changes in, or a termination in the collaborating physician/midwife relationship is a basis for disciplinary action against the midwife's license.

(d) A midwife with prescriptive authority who cannot continue to fulfill the requirements for prescriptive authority shall notify the Board within 30 days of the midwife's request to place the midwife's prescriptive authority on inactive status.

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