

Regulatory Analysis Form		This space for use by IRRC	
(1) Agency		RECEIVED 2006 OCT 11 PM 12:31 INDEPENDENT REGULATORY REVIEW COMMISSION	
Department of Health			
(2) I.D. Number (Governor's Office Use)		IRRC Number:	
10-182		2577	
(3) Short Title			
Sexual Assault Victims Emergency Services			
(4) Pa. Code Cite		(5) Agency Contacts & Telephone Numbers	
28 Pa. Code §§ 117.51 – 117.58		Primary Contact: Gerald Radke (717) 787-8015	
		Secondary Contact: Sandra Knoble (717) 783-8980	
(6) Type of Rulemaking (Check One)		(7) Is a 120-Day Emergency Certification Attached?	
<input checked="" type="checkbox"/>	Proposed Rulemaking	<input checked="" type="checkbox"/>	No
<input type="checkbox"/>	Final Order Adopting Regulation	<input type="checkbox"/>	Yes: By the Attorney General
<input type="checkbox"/>	Final Order, Proposed Rulemaking Omitted	<input type="checkbox"/>	Yes: By the Governor
(8) Briefly explain the regulation in clear and non-technical language.			
<p>These proposed regulations would establish requirements for hospitals that provide sexual assault emergency services and for the provision of information and services relating to those services, including emergency contraception, prevention of sexually transmitted diseases and other related medical examination and testing. All hospitals that provide sexual assault emergency services to victims would be required comply with the provisions of these proposed regulations. Hospitals not providing sexual assault emergency services would be required to comply with certain notice and transport provisions.</p>			

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

Section 803(2) of the Health Care Facilities Act (Act), 35 P.S. § 448.803(2), authorizes the Department to promulgate, after consultation with the Health Policy Board, regulations necessary to carry out the purposes and provisions of the Act. *See also*, 35 P.S. § 448.601 (“The department, in the exercise of its duties under this act shall have the power to adopt such regulations as are necessary to carry out the purposes of this act.”) Section 801.1 of the Act, 35 P.S. § 448.801a, provides that a purpose of the Act is to promote the public health and welfare through the establishment of regulations setting minimum standards for the operation of health care facilities. The same section provides that the minimum standards are to assure safe, adequate and efficient facilities and services, and are also to promote the health, safety and adequate care of patients or residents of such facilities. The General Assembly has also stated that a purpose of the Act is, among other things, to assure that all citizens receive humane, courteous and dignified treatment. *See* 35 P.S. §448.102. Finally, the Act provides the Department with explicit authority to enforce its rules and regulations promulgated under the Act. *See* 35 P.S. § 449.201(12).

The Department also has the duty to protect the health of the people of the Commonwealth of Pennsylvania under section 2102(a) of the Administrative Code of 1929. *See* 71 P.S. § 532(a). The Department has general authority to promulgate regulations under the Code for this purpose. *See* 71 P.S. 532(g).

(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.

No. The proposed regulation is not mandated by any federal or state law or court order, or federal regulation.

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

According to the Pennsylvania State Police’s Uniform Crime Reporting System, there were 3,341 rapes by force reported in the Commonwealth in calendar year 2005. In addition to these forcible rapes, there were 8,636 other sexual offenses. Although some hospitals provide medical services to these sexual assault victims, there are no set minimum requirements as to which services are appropriate to provide in these circumstances. This issue is not unique to Pennsylvania and legislation has been introduced in most states as well as in at the federal level to address this problem. Although attempts to set minimum standards for these services have existed for some time, however, no standards have resulted to date. Proper physical and psychological treatment of sexual assault victims is necessary to minimize the affect of the traumatic event on the victim and to ensure the health and safety of the victim.

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

As stated above, according to the Pennsylvania State Police's Uniform Crime Reporting System, there were 3,341 rapes by force and 8,636 other sexual offenses reported in Pennsylvania in calendar year 2005. Victims of rapes and other sexual offenses may be subject to serious medical and psychological effects as a result of the crime, including sexually transmitted disease and pregnancy. It is also well accepted that in addition to the victim suffering effects as a result of the sexual assault, their families and society in general suffer from the crime long after it is committed.

(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 residents and visitors to the Commonwealth of Pennsylvania are vulnerable to sexual assault and accordingly, would all benefit from these regulations.

(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.)

All 224 hospitals in Pennsylvania may be affected by this proposed regulation. While some hospitals may have internal procedures for treating sexual assault victims, these proposed regulations would require all hospitals to review and adopt procedures that conform to the requirements of the proposed regulations. Even those hospitals that elect not to provide these services would be required to provide appropriate notification and to transport a sexual assault victim, at no cost, to a hospital that would provide the services. The Department does not expect hospitals not providing general emergency services, for example rehabilitation hospitals, would or could provide sexual assault emergency services.

In addition, many government programs providing medical insurance coverage, including Medicare and Medicaid, and third party insurers may be affected as a result of an increase in claims made to these groups through additional examination, testing or medications provided to a sexual assault victim under the proposed regulation.

(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.)

All 224 hospitals in Pennsylvania would be required to comply with the proposed regulations.

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(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.

Prior to developing the proposed regulations, the Commonwealth and the Department received requests from various organizations for the development of standards in this area. These requests came from such groups as the Pennsylvania Coalition Against Rape (PCAR), the Pennsylvania Commission on Women and the Pennsylvania Chapter of the American Civil Liberties Union (ACLU). Although no formal discussions have been held with these groups in developing these proposed regulations, much of the information which the groups provided was used to develop the language for the proposed regulations.

(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 that may be required.

Although it is difficult to estimate the total costs to hospitals in the Commonwealth associated with compliance with the proposed regulations, the Department has estimated the costs of developing the informational materials that the proposed regulations would require hospitals providing sexual assault emergency services to distribute. The Department estimates that it would cost approximately \$7,500 to develop the written informational materials, and approximately \$2,500 to print 5,000 brochures. These costs may be shared by the hospitals if they join in developing standard information materials for all hospitals to utilize, and printing costs may be lowered significantly if a hospital explores alternative methods for printing of the written materials.

In addition to these costs, hospitals could have additional costs of reviewing current procedures and making any changes necessary to comply with the proposed regulations once they are published in final form. These costs will depend upon what procedures each of the 224 hospitals in the Commonwealth currently have in place. However, as with the costs of developing and printing written informational materials, hospitals might be able to significantly reduce their costs by coordination of these efforts.

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

Local governments are not expected to be affected by these proposed regulations and as such no costs or savings are estimated.

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

In order to effectively survey and inspect hospitals in the Department's enforcement of these proposed regulations, the Department estimates additional survey and inspection time equivalent to an additional position for one Health Facility Quality Administrator would be necessary. The total personnel and operating costs are estimated at a total of \$78,430 for the first year. This number includes salary, benefits, workstation, computer, telephone, travel, training, and other related costs.

(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	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
SAVINGS:						
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	\$10,000	\$2,500	\$2,500	\$2,500	\$2,500	\$2,500
Local Government	\$0	\$0	\$0	\$0	\$0	\$0
State Government *	\$78,430	\$73,818	\$75,814	\$77,870	\$79,987	\$82,168
TOTAL COSTS	\$88,430	\$76,318	\$78,314	\$80,370	\$82,487	\$84,668
REVENUE LOSSES:						
Regulated Community	\$10,000	\$2,500	\$2,500	\$2,500	\$2,500	\$2,500
Local Government	\$0	\$0	\$0	\$0	\$0	\$0
State Government	\$78,430	\$73,818	\$75,814	\$77,870	\$79,987	\$82,168
Total Revenue Losses	\$88,430	\$76,318	\$78,314	\$80,370	\$82,487	\$84,668

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

With regard to the costs to hospitals associated with compliance with the proposed regulations, these figures were derived using research previously conducted by the Department as part of a legislative analysis on a bill related to a similar issue.

Costs to the Department associated with enforcement of the proposed regulations were estimated based on the equivalent of an additional position for one Health Facility Quality Administrator required to survey and inspect each of the 224 Commonwealth hospitals to ensure compliance with the proposed regulations and respond to complaints relating to them. These costs would include salary, benefits, workstation, computer, telephone, travel, training, and other related costs.

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

Program	FY - 3	FY - 2	FY - 1	Current FY
Quality Assurance	\$13,330,964	\$14,157,071	\$14,529,526	\$16,057,000

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

Although the regulated community and the Department would experience some costs associated with compliance and enforcement of these proposed regulations, ensuring the health and safety of sexual assault victims must be an overriding concern. As stated above, victims of rapes and other sexual offenses may be subject to serious medical and psychological effects as a result of the crime, including sexually transmitted disease and pregnancy. It is also well accepted that in addition to the victim suffering effects as a result of the sexual assault, their families and society in general suffer from the crime long after it is committed. Reducing the effects a sexual assault may have on these individuals certainly would outweigh the estimated costs.

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

Legislation pending in the General Assembly of the Commonwealth and in the U.S. Congress includes language which provides for some of the services that would be required by these regulations. Those measures, however, have been pending at both the State and Federal level for some time. The Department is unable to estimate the costs of those alternatives at this time, although it is not expected that the costs of the requirements included in the proposed regulations would differ markedly from the requirements included in the pending legislation.

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

No alternative regulatory schemes were considered.

(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.

The Department is not aware of any 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?

The Department has not determined that these proposed regulations would put the Commonwealth in a competitive disadvantage to other states. Some states have enacted legislation dealing with some of the matters addressed by the proposed regulations, including California, Illinois, Massachusetts, New Jersey, New Mexico, New York, South Carolina and Washington. Those statutes generally require hospitals to provide emergency contraception to sexual assault victims, but most are not as comprehensive as the regulations being proposed by the Department. The proposed regulations include not only requirements relating to emergency contraception, but requirements relating to prevention and treatment of sexually transmitted diseases, provision of information relating to rape counseling and aid in accessing rape counseling centers and counselors, and evidence gathering in order to enable the successful prosecution of violent criminals that threaten individuals and the community. The proposed regulations would combine measures existing in the statutes in the states mentioned above, as well as some measures provided in legislation pending at the federal and state level and in model legislation developed by advocacy groups.

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

No existing or proposed regulations of the Department or other state agencies are expected to be affected by these proposed regulations.

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

The proposed regulations were presented to the Department's Health Policy Board on September 13, 2006. No public hearings or information meetings have been scheduled at this time, but meetings are expected to be scheduled with all interested stakeholders after the regulations are published as proposed in the *Pennsylvania Bulletin*. The Department expects to have meetings with the Pennsylvania Commission on Women, PCAR, the Hospital and Health Systems Association of Pennsylvania, the Pennsylvania Catholic Conference, third party health insurance providers, and law enforcement, among other groups. The Department will seek input on the regulations from these groups both through these stakeholder meetings as well as through the public comment period, and will also discuss these issues with other state agencies.

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

The proposed regulations would require hospitals to review their existing policies and procedures and develop new policies and procedures in order to comply with the requirements of the proposed regulations. Further, hospitals would be required to develop informational materials relating to emergency contraception for distribution.

Further, these proposed regulations would require law enforcement and ambulance and emergency medical care services to maintain lists of those hospitals able to provide sexual assault emergency services. This list would, however, be published by the Department in the *Pennsylvania Bulletin* for the assistance of both law enforcement and ambulance and emergency medical care services.

Creating and maintaining the list will, however, aid the Department, law enforcement, and ambulance and emergency medical care and transport services to ensure that sexual assault victims are being provided necessary emergency services, including emergency contraception. Maintaining this list would not cause any hardship to these entities, since the list would be developed and published by the Department, and is expected to increase the effectiveness of these entities in seeking treatment for sexual assault victims.

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(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.

Proposed section 117.55 requires that written informational materials regarding emergency contraception “[b]e in clear and concise language, readily comprehensible, in such varieties and forms as are deemed necessary to inform victims in English and languages other than English.” These requirements ensure the information is accessible to all individuals in Pennsylvania’s culturally diverse community. Furthermore, proposed section 117.53 requires that hospitals orally inform sexual assault victims of the use, risk and efficacy of emergency contraception.

(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?

The proposed regulations would become effective upon publication in the *Pennsylvania Bulletin*.

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

The Department will review the regulations as necessary.

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INDEPENDENT REGULATORY
REVIEW COMMISSION

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<p>Copy below is hereby approved as to form and legality. Attorney General.</p> <p><i>Amy W. Ehrlich</i> BY _____ DEPUTY ATTORNEY GENERAL OCT 04 2006 DATE OF APPROVAL</p> <p>9 Check if applicable. Copy not approved. Objections attached.</p>	<p>Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:</p> <p>(AGENCY)</p> <p>DOCUMENT/FISCAL NOTE NO. <u>10-182</u></p> <p>DATE OF ADOPTION: _____</p> <p>BY: <u>Calvin B. Johnson, M.D., M.P.H.</u> <i>Calvin B. Johnson</i> _____</p> <p>TITLE <u>Secretary of Health</u></p>	<p>Copy below is hereby approved as to form and legality. Executive or independent Agencies.</p> <p><i>Andrew C. Clark</i> BY _____ Andrew C. Clark SEP 22 2006 DATE OF APPROVAL</p> <p>(Deputy General Counsel) (Chief Counsel, Independent Agency) (Strike inapplicable title)</p> <p>9 Check if applicable. No Attorney General approval or objection within 30 days after submission.</p>
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DEPARTMENT OF HEALTH

NOTICE OF PROPOSED RULEMAKING

TITLE 28. HEALTH AND SAFETY

28 PA. CODE. PART IV HEALTH FACILITY

SUBPART B. GENERAL AND SPECIAL HOSPITALS

CHAPTER 101. GENERAL INFORMATION

SECTION 101.4. DEFINITIONS

CHAPTER 117. EMERGENCY SERVICES

SECTIONS 117.51 – 117.58. SEXUAL ASSAULT VICTIM EMERGENCY SERVICES

Notice is hereby given that the Department of Health (Department), proposes to amend 28 Pa. Code Part IV, Subpart B (relating to health facilities; general and special hospitals), Chapter 101 (relating to general information) and Chapter 117 (relating to emergency services). The proposed regulations are set forth in Annex A hereto.

A. PURPOSE OF THE REGULATION

The proposed regulations would amend 28 Pa. Code Chapter 117 (relating to emergency services in general and special hospitals) to add minimum requirements for the physical and psychological treatment of sexual assault victims by Pennsylvania hospitals. According to the Pennsylvania State Police's Uniform Crime Reporting System, there were 3,341 rapes by force reported in the Commonwealth in calendar year 2005. In addition to these forcible rapes, there were 8,636 other sexual offenses. Although most hospitals currently do provide medical services to sexual assault victims, there are no standard requirements for what services must be provided. It is necessary to ensure that appropriate physical and psychological services are provided to the victims of sexual assault in an effort to minimize the effects of the traumatic event on the victim and to ensure the victim's health and safety. The proposed regulations would provide minimum requirements for "sexual assault emergency services," which would include services related to assessment and prophylactic treatment of sexually transmitted diseases, counseling regarding the assault either on site or at a rape crisis center, and information and services related to emergency contraception. Further, the proposed regulations would take into consideration the needs of law enforcement in protecting the community by making evidence gathering easier, and helping in the prosecution of a violent crime.

The proposed regulations are also intended to address the physical and psychological needs of sexual assault victims, while at the same time taking into consideration issues of religious freedom. The proposed regulations include an exemption from requirements relating to the provision of emergency contraception services for those hospitals that believe provision of that particular service would create a substantial burden on the free exercise of religion by the hospital.

Finally, the proposed regulations would require hospitals choosing to provide sexual assault emergency services to also provide victims with certain written and oral information. This information would include information relating to sexually transmitted diseases, prophylactic treatment of those diseases, risks relating to that treatment, and necessary future testing. Hospitals would also be required to provide written information relating to emergency contraception in a range of languages. Hospitals not providing sexual assault emergency services would be required to comply with certain notice and transport provisions.

B. REQUIREMENTS OF THE REGULATION

In developing these proposed regulations, the Department reviewed a variety of information relating to the subject, including language from statutes in other states which currently have such requirements, such as California, Illinois, Massachusetts, New Jersey, New Mexico, New York, South Carolina and Washington. The Department also reviewed language in proposed legislation in the United States Congress and the Pennsylvania General Assembly and model legislation proposed by sexual assault victim advocacy groups.

Section 101.4. Definitions.

The Department proposes to add several definitions made necessary by the proposed regulations to Chapter 117. Because the Department's proposed regulations focus on the provision of "sexual assault emergency services," the Department proposes a definition for that term. The Department is also proposing to add definitions for "emergency contraception," "rape crisis center," "sexual assault," "sexual assault counselor," and "sexual assault victim." Although some of these terms may have a common usage in either the medical community or law enforcement community or are defined in statutes or other regulations of the Commonwealth, they are not currently defined in the Department's regulations relating to general and special hospitals. These definitions are required to ensure the purposes of the proposed regulations are properly implemented.

SEXUAL ASSAULT VICTIMS EMERGENCY SERVICES

Section 117.51. Principle.

This proposed section would be new. This section would explain the scope of the proposed regulations, and clarify that any hospital that chose to provide sexual assault emergency services would be required to comply with the minimum standards set out in the proposed regulations. This proposed section would also provide, however, that any hospital choosing to seek a religious or moral exemption under provisions existing elsewhere in the proposed regulations would not be required to provide certain services relating to emergency contraception. Further, this proposed section would provide that hospitals not providing sexual assault emergency services would be required to comply with certain notice and transport provisions.

Section 117.52. Minimum requirements for sexual assault emergency services.

This proposed section would be new. Proposed subsection (a) would set out the minimum standards for sexual assault emergency services, which would be provided only with the consent of the sexual assault victim. Those services would include services to treat both the physical and the psychological health of the victim. The amendments would require testing to ensure the health, safety and welfare of the victim, the presence or absence of a sexually transmitted disease, the provision of information on sexually transmitted diseases and pregnancy and on medical procedures, medication and accepted contraindications of medication available for prevention or treatment of infection or disease resulting from the assault, the provision of prophylactic treatment against the transmission of sexually transmitted diseases and HIV, and provision of information regarding the need for additional testing and treatment. A comprehensive approach to the treatment of the victim would maximize the benefits to the victim of seeking proper treatment for a sexual assault in a hospital.

Proposed subsection (a) would also require that a hospital choosing to provide sexual assault emergency services provide the victim with information on the availability of a rape crisis center or sexual assault counselor, provide the victim with the telephone number and contact a rape crisis center or sexual assault counselor at the victim's request. The proposed subsection would also require that the hospital provide the victim with the opportunity to consult with the rape crisis center or sexual assault counselor in person and in private while at the hospital.

Finally, this proposed section would take into account the needs of law enforcement, since prosecution of a violent crime remains important to the well-being of the victim and the

community. Proposed subsection (a) includes tests that may be used in evidence at a criminal proceeding in its list of minimum requirements that hospitals providing sexual assault emergency services are to provide. Currently, these tests may be conducted with the assistance of law enforcement and such procedures would not be impeded by these regulations. The Department intends that hospitals coordinate with law enforcement to ensure that all appropriate tests are conducted to maintain the integrity of evidence collection and analysis. However, the proposed regulations would not require a hospital to contact law enforcement prior to conducting the tests, as on certain occasion a victim does not desire to report the crime to law enforcement. The examinations and tests conducted by the hospital would provide for some evidence to be collected in the event the victim later decides to report the crime to law enforcement and seek apprehension and prosecution of the offender. Further, proposed subsection (b) would require that hospitals maintain records of all examinations, tests and services provided to a sexual assault victim and make the records available to law enforcement at the victim's request, and with the victim's consent.

Section 117.53. Emergency contraception.

This proposed section would be new. Proposed subsection (a) would require that a hospital inform a female sexual assault victim of the availability, use, risks and efficacy of emergency contraception and offer and provide her emergency contraception on site at her request, unless the medication is contraindicated. These services must be provided by any hospital that provides sexual assault emergency services, unless that hospital claims an exemption under proposed § 117.57 (relating to religious and moral exemptions).

All hospitals providing sexual assault emergency services, including those claiming a religious or moral exemption under proposed section 117.57, must provide the victim with medically and factually accurate and objective written informational materials regarding emergency contraception. The Department is also proposing guidelines for the preparation of that material in proposed section 117.55 (relating to informational materials).

Proposed subsection (b) would allow a hospital to require a sexual assault victim to undergo a pregnancy test before providing her with emergency contraception. Subsection (b) would also allow the hospital to refuse emergency contraception to the victim if she were pregnant.

Emergency contraception is intended to prevent a pregnancy and will not have an effect on eliminating an already existing pregnancy.

The Department also proposes the provisions regarding pregnancy in order to address some of the concerns of Catholic hospitals and the U.S. Conference of Catholic Bishops, as well as the Pennsylvania Catholic Conference. See *Ethical and Religious Directives for Catholic Health Care Services*, 4th Edition, June 15, 2001 (<http://www.usccb.org/bishops/directives.shtml>) and *Guidelines for Catholic Hospitals Treating Victims of Sexual Assault*, September 23, 1998 (<http://www.pacatholic.org/pcha/statements/sexgdlines.htm>). These guidelines include conducting a pregnancy test on the victim and prohibit Catholic hospitals from giving emergency contraception to a pregnant sexual assault victim.

Section 117.54. Prevention of sexually transmitted diseases.

This proposed section would be new, and would require hospitals to perform sexually transmitted disease risk assessments on sexual assault victims according to recommendations from the United States Centers for Disease Control and Prevention (CDC), to advise victims of the risk of transmission of sexually transmitted diseases and the availability of post-exposure prophylaxis treatment for sexually transmitted diseases, the risks of deferral of the treatment, and to provide post-exposure prophylaxis treatment for sexually transmitted diseases with the consent of the victim. These requirements are proposed for the health of the victim, and are intended to prevent and control the spread of sexually transmitted disease not only to the victim, but to the victim's future consensual sexual partners if the victim is untreated or unaware that a sexually transmitted disease may have been transmitted. In some cases, sexually transmitted diseases such as syphilis, chlamydia and gonorrhea can lead to infertility and even death.

Section 117.55. Emergency contraception informational materials.

This proposed section would be new, and would set minimum standards for the development of medically and factually accurate and objective written informational materials relating to emergency contraception to be provided to sexual assault victims in accordance with the requirements of proposed section 117.53(a)(1). Further the informational materials would be required to be prepared and produced in clear and concise, readily comprehensible language, and in such varieties and forms as necessary to inform victims in English and languages other than English. The Department expects individual hospitals will determine which languages are appropriate based on the needs of the community the hospital serves.

The materials would explain what emergency contraception is, and describe its use, risks and efficacy as well as informing victims of locations where emergency contraception may be obtained in the event it is not obtained at the hospital. These requirements would ensure victims are fully aware of the use of emergency contraception in order to make an informed decision on whether taking the medication is desired. Further, providing information on alternate locations for obtaining emergency contraception would allow the victim to consider the information before taking the medication as well as reducing the strain in finding emergency contraception for those victims treated at hospitals that do not offer or provide emergency contraception to the victim pursuant to the proposed religious and moral exemption in section-117.57.

Section 117.56. Payment for sexual assault emergency services.

This proposed section would be new. This proposed section would require hospitals to inform the sexual assault victim of the availability of known financial resources for services provided to the victim, including the victim's medical insurance provider, the Pennsylvania Crime Victim's Compensation Program and any programs administered by the hospital. Informing the victim of these resources for payment for the services received at the hospital would further diminish the concern to the victim resulting from the criminal assault, and hopefully encourage victims to report the crimes to law enforcement to secure resources for payment of the services provided. The hospital would also provide the victim with any information required to obtain these services, including copies of itemized bills and medical records.

Section 117.57. Religious and moral exemptions.

This section would be new. This proposed section would clearly provide that a hospital would not be required to comply with section 117.53(a)(2) and (3) if doing so would be contrary to the stated religious or moral beliefs of the hospital. Offering and providing emergency contraception is well established to be a sensitive matter for certain religious groups, and the requirements of the § 902 of the Health Care Facilities Act, 35 P.S. § 448.902, may mandate that the requirements of offering and providing emergency contraception would be unenforceable against hospitals able to establish that such requirements are contrary to the hospital's stated religious or moral beliefs.

Although a hospital may be exempt from offering and providing emergency contraception under this section, it would still be required to provide all the other services required in the proposed regulations, including providing the victim with written and oral information about emergency contraception under the requirements established in section 117.55, and informing the victim of locations where emergency contraception may be obtained. Furthermore, the proposed section would require a hospital that is exempt from offering and providing emergency contraception to a sexual assault victim under this proposed section, to inform the victim of this fact and to arrange for transportation of the victim, at no cost, to a Pennsylvania hospital that does provide the service. Including this proposed section furthers the Department's goal of ensuring the appropriate treatment is provided to the sexual assault victim while attempting to avoid having hospitals decide against providing other sexual assault emergency services based on objections under § 902 of the Health Care Facilities Act, 35 P.S. § 448.902.

Section 117.58. Hospitals not providing sexual assault emergency services.

This proposed section would also be new. Recognizing that some of the hospitals in the Commonwealth are specialty hospitals with limited services and are not staffed and equipped to provide the services, this proposed section allows a hospital to self-evaluate its facilities to determine if providing sexual assault emergency services at the hospital would be appropriate. Although ideally it would be of greater benefit to the Commonwealth to have sexual assault emergency services provided in as many locations as possible throughout the state, there is a greater risk to the victim and the integrity of future criminal prosecution if a sexual assault victim is treated at a hospital without the appropriate staff and equipment. For example, the Department does not expect that hospitals not providing general emergency services, such as rehabilitation hospitals, would or could provide sexual assault emergency services.

Proposed subsection (a) would require hospitals electing not to provide sexual assault emergency services to provide notification to the Department, law enforcement, and ambulance and emergency medical care and transport services that these services will not be provided by the hospital. This notification must be in writing and provided within 30 days of the hospital's decision not to provide the services. Further, the Department will publish this notice in the *Pennsylvania Bulletin* to inform other facilities, local government and the general public that sexual assault emergency services are not provided at that facility. The notice published by the Department will differentiate between hospitals which elect not to provide emergency contraception pursuant to the religious and moral exemption in section 117.57, from those which do not provide any sexual assault emergency services under the provisions of section 117.58.

Proposed subsection (b) would require a hospital that elects not to provide sexual assault emergency services to inform the victim of this fact and to arrange for transportation of the victim, at no cost, to a Pennsylvania hospital that does provide the service. This proposed subsection would ensure that a victim that presents at a hospital receives treatment at a facility that is properly staffed and equipped.

C. AFFECTED PERSONS

The proposed regulations would affect all Commonwealth hospitals, which would be required to consider whether or not they will provide sexual assault emergency services. Those hospitals that choose not to perform these services would be required to inform the Department, ambulance and emergency medical care and transport services, and law enforcement agencies of this decision within a specified time frame. Further, those hospitals choosing not to provide these services, including those that choose to take an exemption under section 117.57 (relating to religious and moral exemptions), would be required to develop policies and procedures for informing sexual assault victims who present at those hospitals of the hospital's position on these issues, and for transporting victims who request a transfer to hospitals that would provide the services.

Hospitals that choose to provide emergency sexual assault services would need to develop policies and procedures to comply with the provisions of the proposed regulations, including those relating to provision of informational materials relating to emergency contraception, sexually transmitted diseases, and pregnancy.

The proposed regulations would also affect sexual assault victims, who would be offered the same information and care at all Commonwealth hospitals providing sexual assault services.

Victims would also be offered the opportunity to be transported to hospitals that did offer these services, if they present at a hospital that does not do so.

Lastly, these proposed regulations would affect law enforcement agencies and ambulance and emergency medical care and transport services, since those services would be required to be aware of the list of hospitals that have chosen to provide emergency sexual assault services, so that victims may be taken to these hospitals to ensure they receive sexual assault emergency services and information relating to those services.

D. COST AND PAPERWORK ESTIMATE

1. Cost

a. Commonwealth

There would be additional costs to the Commonwealth resulting from this regulation associated with the Department's need to enforce the proposed regulations. The Department estimates that an additional position for a Health Facility Quality Administrator would be required to survey and inspect hospitals to ensure compliance with the proposed regulations and respond to complaints relating to the manner in which these proposed regulations would be implemented by those hospitals. These costs would include salary, benefits, workstation, computer, telephone, travel, training, and other related costs. Reducing the effects a sexual assault would have on victims through implementation of the proposed regulations and the services offered through them, however, would outweigh the estimated costs.

b. Local Government

There would be no additional cost to local government. Although the proposed regulations would require that hospitals not providing sexual assault emergency services send notice to law enforcement agencies of their decision not to provide those services, and law enforcement agencies should be aware of this list to the extent that they transmit sexual assault victims to hospitals, this requires no additional work on the part of law enforcement agencies. The Department will publish a compiled list of those hospitals in the *Pennsylvania Bulletin*.

c. Regulated Community

There would be additional cost to hospitals in the Commonwealth. The Department has estimated the costs of developing the informational materials that the proposed regulations would require hospitals providing sexual assault emergency services to distribute. The Department estimates that it would cost approximately \$7,500 to develop the written informational materials, and approximately \$2,500 to print 5,000 brochures. These costs may be shared by the hospitals, however, if they join in developing standard information materials for all hospitals to utilize, and printing costs may be lowered significantly if a hospital explores alternative methods for printing of the written materials.

In addition to these costs, hospitals could have additional costs of reviewing current procedures and making any changes necessary to comply with the proposed regulations once they are published in final form. These costs will depend upon what procedures individual hospitals in the Commonwealth currently have in place. However, as with the costs of developing and printing

written informational materials, hospitals might be able to significantly reduce their costs by coordination of these efforts.

d. General Public

There is no additional cost for the general public. In fact, since victims of rapes and other sexual offenses and their families are members of the general public, and may be subject to serious medical and psychological effects as a result of the crime, including sexually transmitted disease and pregnancy, there would be a benefit to the general public from the implementation of these proposed regulations. Because the proposed regulations would also aid in gathering information necessary for investigation and successful prosecution of a violent crime, society as a whole would benefit from the implementation of the proposed regulation

2. Paperwork Estimates

a. Commonwealth

In order to effectively survey and inspect hospitals for the purpose of enforcing the proposed regulations, the Department estimates additional survey and inspection time equivalent to an additional position for one Health Facility Quality Administrator would be necessary. There would be the need to review complaints in this additional area of regulation; the Department, however, already has a process in place for the review and investigation of complaints against hospitals.

Further, the Department would be required to obtain and compile a list of hospitals that have decided not to provide sexual assault emergency services, and to publish that list in the *Pennsylvania Bulletin*.

b. The Regulated Community

Hospitals would be required to either develop or obtain informational material on sexually transmitted diseases, pregnancy, emergency contraception, and the need for additional testing.

With respect to information relating to emergency contraception, the proposed regulations would require that this written information be available in languages other than English. It is possible that this written information may be available in part from the CDC; it is also possible that hospitals may be able to join in developing standard information materials for all hospitals to utilize.

Hospitals would be required to review current policies and procedures and make any changes necessary to comply with the proposed regulations once they are published in final form.

Whether additional or revised policies or procedures are necessary would depend upon what policies and procedures each hospital currently has in place. However, as with the costs of developing and printing written informational materials, hospitals might be able to significantly reduce their costs by coordination of these efforts.

b. Local Government

There is no additional paperwork requirement for local government. Although the proposed regulations would require that hospitals providing sexual assault emergency services send notice

to law enforcement agencies of their decision not to provide sexual assault emergency services, and law enforcement agencies should be aware of this list to the extent that they transmit sexual assault victims to hospitals, this requires no additional work on the part of law enforcement agencies. The Department will publish a compiled list in the *Pennsylvania Bulletin*.

c. General Public

There is no additional paperwork requirement for the general public.

E. STATUTORY AUTHORITY

Section 803(2) of the Health Care Facilities Act (Act) (35 P.S. § 448.803(2)) authorizes the Department to promulgate, after consultation with the Health Policy Board, regulations necessary to carry out the purposes and provisions of the Act. (*See also*, 35 P.S. § 448.601 (“The department, in the exercise of its duties under this act shall have the power to adopt such regulations as are necessary to carry out the purposes of this act.”)) Section 801.1 of the Act (35 P.S. § 448.801a) provides that a purpose of the Act is to promote the public health and welfare through the establishment of regulations setting minimum standards for the operation of health care facilities. The same section provides that the minimum standards are to assure safe, adequate and efficient facilities and services, and are also to promote the health, safety and adequate care of patients or residents of such facilities. The General Assembly has also stated that a purpose of the Act is, among other things, to assure that all citizens receive humane, courteous and dignified treatment. (35 P.S. §448.102). Finally, the Act provides the Department with explicit authority to enforce its rules and regulations promulgated under the Act. (35 P.S. § 449.201(12)).

The Department also has the duty to protect the health of the people of the Commonwealth of Pennsylvania under section 2102(a) of the Administrative Code of 1929. (*See* 71 P.S. § 532(a)). The Department has general authority to promulgate regulations under the Code for this purpose. (71 P.S. 532(g)).

F. EFFECTIVENESS/SUNSET DATES

The proposed regulations would become effective upon their publication in the *Pennsylvania Bulletin* as final 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 (71 P.S. §§ 745.1 – 745.15), the Department submitted a copy of this proposed regulation on October 11, 2006, 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. In addition to submitting the proposed regulations, the Department has provided IRRC and the Committees with a copy of a Regulatory Analysis Form prepared by the Department in compliance with Executive Order 1996-1, “Regulatory Review and Promulgation.” A copy of this material is available to the public upon request.

If IRRC has any objections to any portion of the proposed regulations, it will notify the Department by _____. 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 regulation to Gerald Radke, Director, Bureau of Facility Licensure and Certification, Department of Health, Room 932, Health and Welfare Building, 7th and Forster Streets, Harrisburg, PA 17120, Telephone (717) 787-8015, 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 regulation may do so by using the above number or address, or for speech and/or hearing impaired persons by using 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 Mr. Radke at the above address or telephone numbers so that necessary arrangements may be made.

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REVIEW COMMISSION

Annex A

TITLE 28: HEALTH AND SAFETY

* * *

PART IV. HEALTH FACILITIES

* * *

SUBPART B. GENERAL AND SPECIAL HOSPITALS

CHAPTER 101. GENERAL INFORMATION

* * *

§101.4. Definitions.

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

* * *

Emergency contraception – A drug, drug regime or device approved by the Food and Drug Administration that is used after sexual intercourse to inhibit or prevent ovulation, fertilization or the implantation of a fertilized ovum within the uterus.

* * *

Rape crisis center – An office, institution or center that offers assistance to a sexual assault victim or the victim's family through crisis intervention, medical and legal accompaniment and follow-up counseling.

* * *

Sexual assault – An offense specified in 18 Pa.C.S. Ch. 31 Subch. B (relating to definition of offenses).

Sexual assault counselor – A person who is engaged or employed by a rape crisis center that arranges for the provision of services to a sexual assault victim, who has undergone at least 40 hours of sexual assault training and is under the control of a direct services supervisor of a rape crisis center, whose primary purpose is the rendering of advice, counseling or assistance to victims of sexual assault.

Sexual assault emergency services – A medical examination, forensic examination, or other procedure or service provided by a hospital to a sexual assault victim because of a sexual assault.

Sexual assault victim or victim – A person who has been sexually assaulted.

* * *

CHAPTER 117. EMERGENCY SERVICES.

* * *

SEXUAL ASSAULT VICTIMS EMERGENCY SERVICES

§ 117.51. Principle.

These sections establish requirements for a hospital that provides sexual assault emergency services and for the provision of information and services relating to emergency contraception and prevention of sexually transmitted diseases to sexual assault victims. A hospital that provides sexual assault emergency services to sexual assault victims shall comply with the provisions of these sections, except that a hospital may be excluded from providing the services required by § 117.53(a)(2) and (3) pursuant to § 117.57. All hospitals electing not to provide sexual assault emergency services pursuant to § 117.58 shall comply with the notification and transfer provisions therein.

§ 117.52. Minimum requirements for sexual assault emergency services.

- (a) Promptly upon a sexual assault victim's presenting to a hospital that provides sexual assault emergency services, the hospital shall, at a minimum, provide, with the consent of the sexual assault victim, the following:
- (1) Medical examinations and laboratory or diagnostic tests required to ensure the health, safety, and welfare of the sexual assault victim, or which may be used as evidence in a criminal proceeding against a person accused of the sexual assault, or both.
 - (2) Oral and written information concerning the possibility of sexually transmitted disease and pregnancy resulting from the sexual assault.

- (3) Oral and written information concerning accepted medical procedures, medication, and possible contraindications of such medication available for the prevention or treatment of infection or disease resulting from the sexual assault.
- (4) Such medication as is deemed appropriate by the attending physician, including HIV and sexually transmitted disease prophylaxis.
- (5) A blood test to determine the presence or absence of sexually transmitted disease.
- (6) Oral and written instructions indicating the need for a additional blood tests at such time periods after the sexual assault as medically indicated to determine the presence or absence of sexually transmitted disease.
- (7) Information on the availability of a rape crisis center or sexual assault counselor and the telephone number of a local rape crisis center or sexual assault counselor. The hospital shall contact the local rape crisis center or sexual assault counselor at the request of the victim.
- (8) The opportunity for the victim to consult with the rape crisis center or sexual assault counselor in person and in private while at the hospital.

- (b) A hospital shall maintain records of the results of all examinations, tests and services provided to a sexual assault victim and make those records available to law enforcement officials upon the request and with the consent of the sexual assault victim.

§ 117.53. Emergency contraception.

- (a) The hospital shall provide the following services to a female sexual assault victim in addition to the minimum requirements set forth in § 117.52:

- (1) Provide the victim with medically and factually accurate written informational materials regarding emergency contraception prepared under § 117.55 (relating to informational materials).
- (2) Orally inform the victim of the availability of emergency contraception, its use, risks and efficacy unless the hospital claims an exception in accordance with § 117.57 (relating to religious and moral exemptions).
- (3) Offer emergency contraception to the victim and provide emergency contraception onsite upon the victim's request, unless contraindicated or unless the hospital claims an exception in accordance with § 117.57 (relating to religious and moral exemptions).

- (b) Prior to providing emergency contraception to a sexual assault victim as required in subsection (a)(3), a hospital may require the victim to submit to a pregnancy test. A hospital is not required to provide emergency contraception to a pregnant sexual assault victim, but shall provide the victim with information regarding the pregnancy and information relating to appropriate medical care for the pregnancy.

§ 117.54. Prevention of sexually transmitted diseases.

- (a) A hospital shall promptly provide a sexual assault victim with an assessment of the victim's risk for contracting a significantly prevalent sexually transmitted disease.
- (b) The hospital shall base the risk assessment upon the following considerations:
- (1) Available information regarding the assault as well as the subsequent findings from medical examination and test that may be conducted.
 - (2) Established standards of risk assessment, including consideration of any recommendations established by the United States Department of Health and Human Services Centers for Disease Control and Prevention.
- (c) In addition to the assessment required in subsection (a), a hospital shall advise a sexual assault victim of significantly prevalent sexually transmissible diseases for which post-exposure prophylaxis exists, and for which deferral of treatment would either

significantly reduce treatment efficacy or would pose a substantial risk to the individual's health.

- (d) Upon the victim's consent, the hospital shall provide the victim with post-exposure prophylactic treatment for sexually transmissible diseases, except that a hospital shall not be required to comply with this subsection when risk evaluation, adopted by the United States Department of Health and Human Services Centers for Disease Control and Prevention, clearly recommends against the application of post-exposure prophylaxis.

§ 117.55. Emergency contraception informational materials.

- (a) A hospital that provides sexual assault emergency services shall ensure that each member of the hospital personnel that provides the services is furnished with medically and factually accurate and objective written informational materials about emergency contraception developed by the hospital under this section.
- (b) The hospital shall prepare, produce and distribute the written informational materials. The informational material shall meet the following standards:
- (1) Be in clear and concise language, readily comprehensible, in such varieties and forms as are deemed necessary to inform victims in English and languages other than English.

- (2) Explain the nature of emergency contraception, including its use, risks and efficacy.
- (3) Provide sexual assault victims with information on finding locations where emergency contraception may be obtained in the event it is not obtained at the hospital.

§ 117.56. Information regarding payment for sexual assault emergency services.

A hospital shall inform a sexual assault victim receiving sexual assault emergency services at the hospital of the availability of known financial resources for services provided to the victim due to the sexual assault, including payments by the victim's medical insurer, if applicable, the Crime Victim's Compensation Program administered by the Pennsylvania Commission on Crime and Delinquency, and any programs administered by the hospital. The hospital shall provide the victim any information required to secure such services, including copies of itemized bills and medical records.

§ 117.57. Religious and moral exemptions.

In accordance with 35 P.S. § 448.902(a) (relating to the administration of the Health Care Facilities Act), a hospital is not required to comply with § 117.53(a)(2) and (3) if providing those services would be contrary to the stated religious or moral beliefs of the hospital. If the hospital

does not provide services under this religious and moral exemption, the hospital shall provide the following services:

- (1) Provide individual oral and written notice to the sexual assault victim that those services are not provided at the hospital due to the services being contrary to the stated religious or moral beliefs of the hospital.
- (2) Upon request of the victim, arrange for the immediate transfer of the victim, at no cost, to a Pennsylvania hospital in close proximity that does provide those services.

§ 117.58. Hospitals not providing sexual assault emergency services.

- (a) If a hospital otherwise governed by the provisions of this subpart elects not to provide sexual assault emergency services to victims, including a hospital not providing certain emergency contraception services under the provisions of § 117.57, the hospital shall provide the following notifications:

- (1) The hospital shall notify the Department within 30 days of the hospital's decision not to provide sexual assault emergency services. The hospital shall address and send the written notice to the Division of Acute and Ambulatory Care. The Department will publish a list of hospitals in the *Pennsylvania Bulletin* that have chosen not to provide sexual assault emergency services.

Commonwealth of Pennsylvania



DEPARTMENT OF HEALTH

HARRISBURG

THE SECRETARY

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INDEPENDENT REGULATORY
REVIEW COMMISSION

October 11, 2006

Mr. Kim Kaufman
Executive Director
Independent Regulatory Review Commission
333 Market Street, 14th Floor
Harrisburg, PA 17101

Re: Department of Health – Proposed Regulations No. 10-182
Sexual Assault Victim Emergency Services

Dear Mr. Kaufman:

Enclosed are proposed regulations for review by the Commission in accordance with the Regulatory Review Act (71 P.S. §§ 745.1-745.15). The proposed regulations establish requirements for hospitals that provide sexual assault emergency services and for the provision of information and services relating to those services, including emergency contraception, prevention of sexually transmitted diseases and other related medical examination and testing. All hospitals that provide sexual assault emergency services to victims would be required to comply with the provisions of these proposed regulations. Hospitals not providing sexual assault emergency services would be required to comply with certain notice and transport provisions.

Section 5(g) of the Regulatory Review Act, 71 P.S. § 745.5(g), provides that the Commission may, within 30 days after the close of the public comment period, convey to the proposing agency and the Standing Committees any comments, recommendations and objections to the proposed regulations. The Department expects the regulations to be published on October 21, 2006. A 30-day comment period is provided.

Section 5.1(a) of the Regulatory Review Act, 71 P.S. § 745.5a(a), provides that upon completion of the agency's review of comments, the agency shall submit to the Commission a copy of the agency's response to the comments received, the names and addresses of the commentators who have requested additional information relating to the final-form regulations, and the text of the final-form regulations which the agency intends to adopt.

The Department will provide the Commission within 5 business 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 thorough review of the proposed

regulations. If you have any questions, please contact Mike Yantis, Director of the Office of Legislative Affairs, at (717) 783-3985.

Sincerely,

A handwritten signature in black ink, appearing to read 'C. Johnson', written in a cursive style.

Calvin B. Johnson, M.D., M.P.H.
Secretary of Health

Enclosures

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

I.D. NUMBER: 10-182
 SUBJECT: SEXUAL ASSAULT VICTIM EMERGENCY SERVICES
 AGENCY: Department of Health

TYPE OF REGULATION

- 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

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FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
10/11	<i>[Signature]</i> ^{10/11/06} <i>W. Thompson</i>	HOUSE COMMITTEE ON HEALTH & HUMAN SERVICES
	<i>Matt Franchile</i>	
10/11/06	<i>Nickel Bros</i> #1	SENATE COMMITTEE ON PUBLIC HEALTH & WELFARE
10/11/06	<i>Kristina M. Hayes</i>	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
10/11/06	<i>C. La. B.</i>	LEGISLATIVE REFERENCE BUREAU (for Proposed only)