

Report To

The Mississippi Legislature



A Review of the Mississippi State Department of Health's Enforcement of the Informed Consent Laws

September 12, 1995

State law does not give any state agency explicit authority for enforcing informed consent laws relative to abortion. After the Legislature passed informed consent laws in 1991, the State Department of Health appropriately assumed enforcement responsibility as an extension of the department's authority to license abortion clinics.

The department lacks internal written procedures to guide facilities in compliance requirements and to aid its own personnel performing informed consent inspections.

Although in 1991 the department satisfied its statutory responsibility to produce written materials on informed consent, the department did not update counseling and referral agency addresses and telephone numbers within these materials until 1995.

The PEER Committee

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The Mississippi Legislature created the Joint Legislative Committee on Performance Evaluation and Expenditure Review (PEER Committee) by statute in 1973. A standing joint committee, the PEER Committee is composed of five members of the House of Representatives appointed by the Speaker and five members of the Senate appointed by the Lieutenant Governor. Appointments are made for four-year terms with one Senator and one Representative appointed from each of the U. S. Congressional Districts. Committee officers are elected by the membership with officers alternating annually between the two houses. All Committee actions by statute require a majority vote of three Representatives and three Senators voting in the affirmative.

Mississippi's constitution gives the Legislature broad power to conduct examinations and investigations. PEER is authorized by law to review any public entity, including contractors supported in whole or in part by public funds, and to address any issues which may require legislative action. PEER has statutory access to all state and local records and has subpoena power to compel testimony or the production of documents.

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The Committee assigns top priority to written requests from individual legislators and legislative committees. The Committee also considers PEER staff proposals and written requests from state officials and others.

**A Review of the Mississippi State Department of Health's
Enforcement of the Informed Consent Laws**

September 12, 1995

**The PEER Committee
Mississippi Legislature**

The Mississippi Legislature

Joint Committee on Performance Evaluation and Expenditure Review

PEER Committee

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September 12, 1995

Honorable Kirk Fordice, Governor
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At its meeting of September 12, 1995, the PEER Committee authorized release of the report entitled **A Review of the Mississippi State Department of Health's Enforcement of the Informed Consent Laws.**



Representative Alyce Clarke, Chairman

**This report does not recommend increased
funding or additional staff.**

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A Review of the Mississippi State Department of Health's Enforcement of the Informed Consent Laws

Executive Summary

September 12, 1995

Introduction

The PEER Committee received complaints regarding the state's enforcement of informed consent laws for abortion. These complaints alleged improper counseling at abortion facilities and the Department of Health's toleration of these practices. In response, the PEER Committee authorized a review of the Department of Health's overall enforcement efforts, including the scope of the department's statutory authority to enforce informed consent laws, its obligation to produce printed materials on informed consent, and an evaluation of its policies and procedures for informed consent.

The Department of Health's statutory authority to regulate abortions directly in one form or another in the state of Mississippi is limited. The department's licensing authority for abortion extends only to abortion facilities themselves, as defined by state law. The Department of Health is without statutory authority to regulate any physician's office or other type of medical facility performing abortions that is not "primarily" organized or used for such procedures.

The informed consent statute imposes requirements for compliance on all physicians, whether practicing at an abortion facility or not. However, the department's licensing authority does not extend either to physicians themselves, or to facilities that were not established primarily as abortion facilities, but where abortions are nonetheless performed.

Overview

At present, state law does not place responsibility for the enforcement of Mississippi's informed consent laws within any state agency. While the Board of Medical Licensure and Department of Health have statutory authority to regulate the conduct of physicians and health care facilities, respectively, state law provides neither agency with explicit statutory authority to enforce informed consent laws.

In the absence of specific statutory authority, the Department of Health's assumption of responsibility for enforcement of the state's informed consent laws is an appropriate extension of the department's explicit statutory authority. The Department of Health has incorporated informed consent enforcement within its annual licensure inspections of abortion facilities. Since 1991, the department has identified four instances in which abortion facilities did not comply with informed consent statutes. In each of these instances, the facility took corrective action in accordance with a written plan submitted to the department. To date, the Department of Health has not sanctioned any abortion facility through license suspension or revocation for failing to comply with informed consent laws.

Despite acting as the enforcement authority for informed consent laws since 1991, the Department of Health has not promulgated written policies and procedures to govern informed consent compliance and inspections. The department relies on the facility inspector's personal knowledge of state informed consent laws to guide the inspection process and reach a conclusion regarding an abortion facility's compliance with informed consent laws.

The Department of Health has satisfied its statutory obligations to compile and make available written materials on informed consent. However, until March 1995, the department had not updated the information contained in the printed materials since the booklet was first published in 1991. The department's failure to update these materials has led to the continued use and distribution of potentially unreliable and inaccurate information.

Recommendations

1. If the Legislature intends for the Department of Health to enforce compliance with the state's informed consent laws, the Legislature should amend § 41-41-33, MISS. CODE ANN. (1972), to make the department's authority and responsibility in this area of abortion regulation explicit. (See Appendix C, page 20, for proposed legislation.)

2. By December 31, 1995, the Department of Health should promulgate written policies and procedures concerning informed consent for abortion. These policies and procedures should be used to inform facilities of elements of compliance and guide inspectors in enforcement efforts. (See Appendix D, page 23, for PEER's list of criteria that should be satisfied for these policies and procedures.)
3. The Legislature should amend § 41-41-35 of the MISS. CODE ANN. to require the Department of Health to review the printed materials required by that statute on an annual basis to assess whether the materials should be revised or updated.
4. The Department of Health should immediately establish written guidelines for reviewing annually, and if needed, revising and updating the printed materials mandated by § 41-41-35.

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Printed Materials

Section 41-41-35 of the informed consent provisions addresses the provision of printed materials on abortions and abortion alternatives by the State Department of Health. The statute requires the following elements to be present in the printed materials: a geographically indexed (by regions of the state) listing of public and private agencies that assist women through the pregnancy and childbirth process, including a description of services and telephone numbers, or a toll-free telephone number for patients to call to obtain a listing of these services and their telephone numbers. The printed materials must inform the woman of probable anatomical and physiological characteristics of the unborn child, at two week increments, from the time a woman can be known to be pregnant to full term, including any relevant information on the possibility of the unborn child's survival. Finally, the information must be clearly legible and "must be available, at no cost, upon request, to any person, facility or hospital." For a full copy of the text of § 41-41-35, see Appendix B, page 19.

Criminal Penalties

The informed consent laws also contain explicit criminal sanctions for violations of the law. Under the provisions of § 41-41-39, anyone who performs an abortion without complying with the requirements of §§ 41-41-31 through -37 is subject to prosecution for the failure to comply. The penalty upon conviction is a \$1,000 fine or imprisonment in the county jail for a period not to exceed six months, or both.

Licensing of Abortion Facilities (Chapter 75)

The Department of Health is responsible for licensing abortion facilities, as defined under § 41-75-1, MISS. CODE ANN. (1972):

"Abortion facility" means a facility primarily organized or established for the purpose of performing abortions for outpatients and is a separate identifiable legal entity from any other health care facility. This term includes physicians' offices which are used primarily to perform elective abortions.

Pursuant to its authority to license abortion facilities, the Department of Health is charged under § 41-75-13 with the responsibility of adopting rules, regulations and standards for abortion facilities "to further the accomplishment of the purpose of this chapter in protecting and promoting the health, safety and welfare of the public by ensuring adequate care of individuals receiving services from such facilities." The Department of Health has promulgated these statutorily mandated rules and regulations

in the form of a document entitled "Minimum Standards of Operation for Abortion Facilities."

Scope of the Department of Health's General Statutory Authority to Regulate Abortions

The Department of Health's authority to regulate abortions directly in one form or another in the state of Mississippi is limited by statute. The department's licensing authority for abortion extends only to abortion facilities themselves, as defined by § 41-75-1 of the MISS. CODE ANN. The Department of Health is without statutory authority to regulate any physician's office or other type of medical facility performing abortions that is not "primarily" organized or used for such procedures.

The informed consent statute imposes requirements for compliance on all physicians, whether practicing at an abortion facility or not. However, the department's licensing authority does not extend either to physicians themselves, or to facilities that were not established primarily as abortion facilities, but where abortions are nonetheless performed. Because the department is not authorized to regulate such physicians or facilities, the department cannot regulate all abortions performed in the state. Thus, any Department of Health authority over informed consent, whether explicit or implicit, does not directly affect physicians themselves, or non-abortion facilities, as defined by statute.

Complaints Regarding the Department of Health's Enforcement of Informed Consent

PEER received citizen complaints regarding the Department of Health's enforcement of the state's informed consent laws. The complaints centered on allegations of improper counseling at abortion facilities and the department's toleration of these practices.

Specifically, the complainants alleged that the Department of Health allowed an abortion facility to conduct the counseling required by MISS. CODE ANN. § 41-41-33 by use of a videotaped presentation. Because the complainants considered the state's informed consent laws to be weak already, they alleged that the department was further impairing informed consent enforcement by not requiring in-person counseling, as the complainants believed was required by the law. The complaints also alleged that some facilities did not allow patients to speak with a doctor during the counseling phase of the procedure.

In response to these complaints and a request from a legislator, the PEER Committee authorized a review of the Department of Health's overall enforcement efforts, including the scope of its statutory authority to enforce informed consent laws, its obligation to produce printed materials on

informed consent, and an evaluation of its policies and procedures for informed consent.

Findings

While Mississippi's informed consent laws require that women be given specified information prior to an abortion, state law does not provide specific authority to any state agency to ensure compliance with such laws.

MISS. CODE ANN. § 41-41-33 clearly states legislative intent that abortions not be performed or induced without the voluntary and informed consent of the woman upon whom the abortion is to be performed or induced. The section requires the physician who is to perform or induce the abortion, the referring physician, or the physician's agent to provide the prospective patient with medical and other related information specified by informed consent laws.

While § 41-41-33 mandates the voluntary and informed nature of an abortion, the section does not provide authority or responsibility to any state agency to ensure physicians' or clinics' strict adherence to state informed consent law. Although the state Board of Medical Licensure and Department of Health have statutory authority to regulate the conduct of physicians and health care facilities, respectively, state law provides neither agency with enforcement responsibilities for informed consent laws.

In the absence of specific statutory authority, the Department of Health's assumption of responsibility for enforcement of the state's informed consent laws is an appropriate extension of the department's explicit statutory authority.

In the absence of explicit statutory authority, the Department of Health has assumed responsibility for enforcing compliance with the state's informed consent laws since the laws were enacted by the Legislature in 1991. Pursuant to the authority given the department by § 41-75-1, et. seq., the Department of Health developed the "Minimum Standards of Operation for Abortion Facilities" to guide abortion facilities on the requirements for licensing compliance. The department's Division of Licensure and Regulation, which is responsible for conducting annual licensure inspections of abortion facilities and other health care facilities, employs a registered nurse to inspect abortion clinics in accordance with the department's Minimum Standards. Rule 102.6 of the Minimum Standards states that "[p]rior to terminating a pregnancy, the physician shall obtain the written informed consent of the pregnant woman or, in the case of a mental incompetent, the written consent of her court-appointed guardian." (See the finding beginning on page 8 for a discussion of the department's inspection procedures.)

Based on the following, PEER concludes that the Department of Health is acting within the scope of the authority intended by the

Legislature in regulating informed consent compliance and that this regulatory role is appropriate for the Department of Health:

- *Consistency with the department's general statutory authority--* Under general provisions of state law outlining the State Board of Health and Department of Health's scope of authority, the Department of Health is authorized to establish programs "to promote the public health," including, but not limited to, "maternal and child health" and "family planning." [See § 41-3-15 (5)(a)(i) and (ii).] Enforcement of informed consent provisions can reasonably be classified as a program covered under either or both of these designations. Because the Department of Health already has explicit and direct authority for conducting health care facility inspections, it is reasonable for the department to conduct informed consent inspections as well. In addition, state law gives the Department of Health specific authority for dissemination of printed materials (§ 41-41-35) on abortion and other related information and for conducting licensure inspections of abortion facilities (§ 41-75-1, et. seq.).
- *Potential harm if the department does not enforce informed consent--* According to Department of Health data, approximately 93% of all reported abortions performed in the state of Mississippi in 1994 were performed at abortion facilities. If no agency performed the enforcement function, the majority of abortions performed annually in Mississippi would be unregulated relative to informed consent.

By assuming responsibility for informed consent compliance as part of its duty to license abortion facilities, the Department of Health has taken affirmative steps to ensure that abortion facilities will be held accountable for violations of state informed consent laws. Moreover, because the Department of Health combined its explicit statutory responsibilities with others that were implicit, the responsibility for enforcing all laws governing abortion in the state of Mississippi has been undertaken by the agency best suited for the role.

Although the Department of Health has assumed responsibility for enforcing the state's informed consent laws and has identified four instances of non-compliance with such laws, the department has no written policies and procedures to govern the enforcement process.

MISS. CODE ANN. § 41-75-1 provides the Department of Health with its most explicit authority to exercise control over abortion facilities. The section requires the Department of Health to license abortion facilities (and other ambulatory surgical facilities) and promulgate and enforce rules, regulations and standards to protect and promote the health, safety and welfare of the public by ensuring adequate care of individuals receiving services from such facilities. With regard to abortion facilities, the Department of Health has developed "Minimum Standards of Operation for

Abortion Facilities.” These rules address major subject areas such as administration, patient care, and working environment. Rule 102.6 requires that the informed consent of the patient be obtained prior to the performance of an abortion. Rule 212.4 requires that documentation of each patient’s informed consent to an abortion be maintained by the abortion facility as part of the patient’s records.

The Department of Health monitors abortion facilities’ compliance with the minimum standards by conducting annual facility inspections. The inspection process involves an inspector’s completion of a fifty-three-page survey document. The survey document is designed to allow an inspector to monitor a facility’s compliance with a wide variety of standards, such as staffing, personnel policies, and patient care. The survey document addresses informed consent compliance through a ten-item examination of the facility’s preservation of medical records. Specifically, the form states the following regarding informed consent:

Each patient’s medical record shall include at least the following information: . . . [item] I. Informed consent.

The form contains a box to be marked showing the presence or absence of informed consent compliance with additional space for comments of the inspector.

Presently, the Department of Health’s facility licensing inspector for abortion clinics is a registered nurse who has personally conducted such inspections since the Legislature enacted informed consent laws in 1991. If the inspector notes any non-compliance with the state’s informed consent laws, based on the inspector’s personal interpretation of such laws, the department notifies the facility of the deficiency. The facility must create a plan for correcting the shortcomings and submit the plan to the Department of Health for approval, with a target date for correction of the deficiencies. The department then conducts an unannounced re-inspection of the facility (initial inspections are also unannounced) to assess the facility’s corrective actions. A failure to correct deficiencies may subject the facility to suspension or revocation of its license, although the department has never resorted to this sanction for an informed consent violation. As detailed in Exhibit 1, page 10, the nurse has conducted sixteen facility inspections at the state’s four abortion clinics since 1991, identifying four instances of non-compliance with informed consent laws. (Because two of the four clinics have closed, Mississippi currently has only two licensed abortion facilities.)

Despite Rules 102.6 and 212.4 and minimum standards for operation of abortion facilities, the Department of Health has not promulgated detailed written policies and procedures that outline the required elements of informed consent compliance. The department relies on the facility inspector’s personal knowledge of state informed consent laws to guide the inspection process and reach a conclusion regarding an abortion

Exhibit 1

Results of Department of Health Informed Consent Inspections By Abortion Facility, 1991 through August 1, 1995

Facility	City	Date of Inspection	Type of Inspection*	In compliance?	Type of Violation
Jackson Women's Health Organization	Jackson	January 1995	Initial	Yes	
		May 1995	Complaint	No	Patients not given information on gestational age of fetus.
New Woman Medical Center	Jackson	July 1992	Initial	Yes	
		May 1993	Resurvey	Yes	
		June 1994	Complaint	Yes	
		July 1994	Resurvey	Yes	
		July 1995	Resurvey	Yes	
MS Women's Medical Clinic**	Jackson	February 1992	Initial	Yes	
		March 1993	Resurvey	No	Counseling/Consent Forms signed before session began; some forms had no evidence that physician was present to conduct counseling.
		April 1994	Resurvey	No	Informed Consent form not signed by doctor.
Tri-State Woman's Medical Center**	Southaven	February 1992	Initial	Yes	
		May 1992	Resurvey	Yes	
		April 1993	Resurvey	Yes	
		October 1993	Followup/Complaint	No	Informed Consent forms signed less than 24 hours before abortion performed.
		December 1993	Followup	Yes	
		February 1994	Resurvey	Yes	

*Initial Inspections are done before a facility opens; resurveys are the regular annual inspections; complaint inspections are the result of a consumer complaint, although not necessarily about the particular facility being inspected.

**Facility now closed.

SOURCE: PEER analysis of State Department of Health records.

facility's compliance with informed consent laws. Unlike inspections for other health care facilities, such as nursing homes and hospitals, the Department of Health has not developed written operational and enforcement inspection standards relative to informed consent. Therefore, abortion facilities and department inspectors have no specific standards with which to operate and conduct inspections of compliance.

Department of Health staff offered the following explanations as to why the department has not developed standards for informed consent compliance.

- Written operational and inspection procedures are not needed because MISS. CODE ANN. § 41-41-33 is sufficiently clear on its face.
- One department inspector who is knowledgeable of the state's informed consent laws can easily monitor informed consent compliance at the state's only two licensed abortion facilities.
- Until recently, the issue of informed consent compliance has not been a source of controversy for the department.

While the department may consider the interpretation of MISS. CODE ANN. § 41-41-33 to be clear and self-evident, the department's lack of policies interpreting the section contributed to the recent controversy relative to informed consent. At least one abortion facility interpreted § 41-41-33 to allow the facility to provide all of the information described in the section by the use of a videotape rather than in-person by a physician. Concerned citizen groups registered their dissatisfaction with this method of presentation to legislators and directly to the Department of Health. Following these protests, the Department of Health concluded that it would be inconsistent with state informed consent laws for an abortion facility to exclusively use videotaped presentations to present the required information. The department then sought an Attorney General's opinion as to whether the information required by the statute could be provided by telephone conferences rather than videotape or whether all conversations between physician and patient had to be in the form of face-to-face counseling. The Attorney General's office concluded that counseling by telephone was acceptable. Had the department interpreted § 41-41-33 through written policies, the recent controversy may have been averted because interested parties would have had input into the department's regulations through the state's Administrative Procedures Act.

Although the department's abortion facility inspector may be knowledgeable of the state's informed consent laws, it is not practical to expect such inspections to be conducted without specific standards and regulations. Should another employee with less informed consent knowledge and experience be assigned to conduct the inspections, the department has no assurance that such inspections would be conducted

consistent with those of the veteran inspector due to an absence of written standards and regulations.

MISS. CODE ANN. § 41-75-13 authorizes the Department of Health to create written policies and procedures governing abortion facilities. Section 41-3-17 also provides general authorization for the Board of Health to “make and publish all reasonable rules and regulations necessary to enable it to discharge its duties and powers and to carry out the purposes and objectives of its creation.” The development of department policies and inspection processes should not be guided by the presence or absence of controversy.

While the Department of Health must be commended for assuming responsibility for enforcing informed consent compliance at abortion facilities in the state, the department must also assume responsibility for establishing clear standards and regulations to govern the enforcement process.

The Department of Health has complied with MISS. CODE ANN. § 41-41-35 by compiling and making available an informed consent information booklet. However, the department has no policy to ensure the accuracy and timeliness of the information contained in the booklet.

As directed by MISS. CODE ANN. § 41-41-35, the Department of Health published the first set of printed informed consent materials in August 1991, within the sixty-day period mandated by statute. The department printed the second version of the booklet in March 1995. Both versions of the printed materials contain the elements required by § 41-41-35, as noted below:

- Geographically indexed listing of public and private agencies that assist women through the pregnancy and childbirth process, including a description of services and telephone numbers, or a toll-free telephone number for patients to call to obtain a listing of these services and their telephone numbers.
- Anatomical and physiological characteristics of the unborn child, at two week increments, from the time a woman can be known to be pregnant to full term, including any relevant information on the possibility of the unborn child’s survival.

The Department of Health maintains a supply of several thousand informed consent booklets that are provided to abortion clinics for distribution to patients and are available directly to prospective abortion patients upon request. The department provides a supply of the informed consent booklets to abortion clinics upon their initial openings and during each annual inspection. MISS. CODE ANN. § 41-41-33 makes physicians or their agents responsible for informing the prospective abortion patient

about the printed materials and providing a copy of the informed consent booklet to the patient upon request.

In comparing the 1991 and 1995 versions of the informed consent booklets, PEER noted at least forty-five changes of information ranging from address and telephone number changes to addition and deletion of adoption/counseling agencies. (See Exhibit 2 below.)

Exhibit 2	
Number of Changes From 1991 to 1995 Editions of Printed Materials*	
telephone number changes	12
name changes	1
address changes	23
addition of pregnancy assistance agencies	2
deletion of pregnancy assistance agencies	6
text change	<u>1</u>
Total	45

* Some pregnancy assistance agencies had more than one type of change that accounts for the total of forty-five--i.e., telephone number and address change.

The text change listed in Exhibit 2 is actually a text omission from the 1991 to the 1995 version of the informed consent booklets. The 1991 booklet listed resources available, such as "abortion facilities," "crisis pregnancy centers," and "licensed adoption agencies." The booklet defined each resource with a one-paragraph definition. The 1995 version of the booklet did not contain a definition for the "abortion facilities" resource. Department of Health staff stated that they inadvertently omitted the term "abortion facilities" from the 1995 list of available resources.

Although the Department of Health has a Publications Review Committee that approves new agency publications and updates existing publications, the committee did not review the 1995 revision of the informed consent booklet because the department considered the booklet's revision to be minor. In general, the department has no policy to ensure the accuracy and timeliness of the information contained in the department's informed consent booklet. While it is not practical to expect the department to update its informed consent materials every time any possible item of information in the booklet changes, it is practical to expect the department to have a policy requiring a periodic review and revision of the booklet.

While MISS. CODE ANN. § 41-41-35 only mandates the compilation and availability of informed consent printed materials, it is reasonable to

conclude that the Legislature intends for the information to be as accurate and timely as possible. Because the printed materials are intended to provide information on pregnancies, abortions, and abortion alternatives for women across the state, information in the booklet must be reliable. Due to information changes that occurred between the first and second versions of the booklet, particularly those relating to the addition or deletion of pregnancy assistance agencies, it is possible that women who sought abortion or adoption information did not receive it because of erroneous or missing information in the booklet.

Recommendations

1. If the Legislature intends for the Department of Health to enforce compliance with the state's informed consent laws, the Legislature should amend § 41-41-33, MISS. CODE ANN. (1972), to make the department's authority and responsibility in this area of abortion regulation explicit. (See proposed legislation in Appendix C, page 20.)
2. By December 31, 1995, the Department of Health should promulgate written policies and procedures concerning informed consent for abortion. These policies and procedures should be used to inform facilities of elements of compliance and guide inspectors in enforcement efforts. (See Appendix D, page 23, for PEER's list of criteria that should be satisfied for these policies and procedures.)
3. The Legislature should amend § 41-41-35 of the MISS. CODE ANN. to require the Department of Health to review the printed materials required by that statute on an annual basis to assess whether the materials should be revised or updated.
4. The Department of Health should immediately establish written guidelines for reviewing annually, and if needed, revising and updating the printed materials mandated by § 41-41-35.

Appendix A

Section 41-41-33, MISS. CODE ANN. (1972)

§ 41-41-33. Consent; written certification.

No abortion shall be performed or induced except with the voluntary and informed consent of the woman upon whom the abortion is to be performed or induced. Except in the case of a medical emergency, consent to an abortion is voluntary and informed if and only if:

(a) The woman is told the following by the physician who is to perform or induce the abortion or by the referring physician, at least twenty-four (24) hours before the abortion:

(i) The name of the physician who will perform or induce the abortion;

(ii) The particular medical risks associated with the particular abortion procedure to be employed including, when medically accurate, the risks of infection, hemorrhage, danger to subsequent pregnancies and infertility;

(iii) The probable gestational age of the unborn child at the time the abortion is to be performed or induced; and

(iv) The medical risks associated with carrying her child to term.

(b) The woman is informed, by the physician or his agent, at least twenty-four (24) hours before the abortion:

(i) That medical assistance benefits may be available for prenatal care, childbirth and neonatal care;

(ii) That the father is liable to assist in the support of her child, even in instances in which the father has offered to pay for the abortion;

(iii) That there are available services provided by public and private agencies which provide pregnancy prevention counseling and medical referrals for obtaining pregnancy prevention medications or devices; and

(iv) That she has the right to review the printed materials described in Section 41-41-35. The physician or his agent shall orally inform the woman that the materials have been provided by the State of Mississippi and that they describe the unborn child and list agencies that offer alternatives to abortion. If the woman chooses to view the materials, copies of them shall be furnished to her. The physician or his agent may

disassociate himself or themselves from the materials, and may comment or refrain from comment on them as he chooses.

(c) The woman certifies in writing before the abortion that the information described in paragraphs (a) and (b) of this section has been furnished to her, and that she has been informed of her opportunity to review the information referred to in subparagraph (iv) of paragraph (b) of this section.

(d) Before the abortion is performed or induced, the physician who is to perform or induce the abortion receives a copy of the written certification prescribed by this section.

SOURCES: Laws, 1991, Ch. 439, § 2, eff. from and after July 1, 1991 (Governor's veto overridden by the Legislature on March 28, 1991).

Appendix B

Section 41-41-35, MISS. CODE ANN. (1972)

§ 41-41-35. Duties of State Department of Health; printed materials.

(1) The State Department of Health shall cause to be published in English within sixty (60) days after July 1, 1991, the following easily comprehensible printed materials:

(a) Geographically indexed materials designed to inform the woman of public and private agencies and services available to assist a woman through pregnancy, upon childbirth and while the child is dependent, including adoption agencies, which shall include a comprehensive list of the agencies available, a description of the services they offer and a description of the manner, including telephone numbers, in which they might be contacted, or, at the option of the Department of Health, printed materials including a toll-free, twenty-four-hour-a-day telephone number which may be called to obtain, orally, such a list and description of agencies in the locality of the caller and of the services they offer.

(b) Materials designed to inform the woman of the probable anatomical and physiological characteristics of the unborn child at two-week gestational increments from the time when a woman can be known to be pregnant to full term, including any relevant information on the possibility of the unborn child's survival. The materials shall be objective, non-judgmental and designed to convey only accurate scientific information about the unborn child at the various gestational ages.

(2) The materials shall be printed in a typeface large enough to be clearly legible.

(3) The materials required under this section shall be available at no cost from the Department of Health upon request and in appropriate number to any person, facility or hospital.

SOURCES: Laws, 1991, Ch. 439, § 3, eff. from and after July 1, 1991 (Governor's veto overridden by the Legislature on March 28, 1991).

Appendix C

**Proposed Legislation Clarifying the State Department of Health's
Authority for the Enforcement of Informed Consent
Compliance in the State of Mississippi**

MISSISSIPPI LEGISLATURE

REGULAR SESSION, 1996

BY:

BILL

AN ACT TO AMEND SECTIONS 41-41-33, 41-41-35, AND 41-75-13, MISSISSIPPI CODE OF 1972, BY CLARIFYING THE STATE DEPARTMENT OF HEALTH'S RESPONSIBILITIES FOR THE ENFORCEMENT OF INFORMED CONSENT COMPLIANCE IN THE STATE OF MISSISSIPPI; AND FOR RELATED PURPOSES.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MISSISSIPPI:

Section 1. Section 41-41-33, Mississippi Code of 1972, is amended as follows:

§ 41-41-33. Consent; written certification; enforcement.

No abortion shall be performed or induced except with the voluntary and informed consent of the woman upon whom the abortion is to be performed or induced. Except in the case of a medical emergency, consent to an abortion is voluntary and informed if and only if:

(a) The woman is told the following by the physician who is to perform or induce the abortion or by the referring physician, at least twenty-four (24) hours before the abortion:

(i) The name of the physician who will perform or induce the abortion;

(ii) The particular medical risks associated with the particular abortion procedure to be employed including, when medically accurate, the risks of infection, hemorrhage, danger to subsequent pregnancies and infertility;

(iii) The probable gestational age of the unborn child at the time the abortion is to be performed or induced; and

(iv) The medical risks associated with carrying her child to term.

(b) The woman is informed, by the physician or his agent, at least twenty-four (24) hours before the abortion:

(i) That medical assistance benefits may be available for prenatal care, childbirth and neonatal care;

(ii) That the father is liable to assist in the support of her child, even in instances in which the father has offered to pay for the abortion;

(iii) That there are available services provided by public and private agencies which provide pregnancy prevention counseling and medical referrals for obtaining pregnancy prevention medications or devices; and

(iv) That she has the right to review the printed materials described in Section 41-41-35. The physician or his agent shall orally inform the woman that the materials have been provided by the State of Mississippi and that they describe the unborn child and list agencies that offer alternatives to abortion. If the woman chooses to view the materials, copies of them shall be furnished to her. The physician or his agent may disassociate himself or themselves from the materials, and may comment or refrain from comment on them as he chooses.

(c) The woman certifies in writing before the abortion that the information described in paragraphs (a) and (b) of this section has been furnished to her, and that she has been informed of her opportunity to review the information referred to in subparagraph (iv) of paragraph (b) of this section.

(d) Before the abortion is performed or induced, the physician who is to perform or induce the abortion receives a copy of the written certification prescribed by this section.

(e) The Mississippi State Department of Health shall have the authority to enforce the provisions of this chapter in so much as they apply to abortion facilities, as defined in § 41-75-1.

Section 2. Section 41-41-35, Mississippi Code of 1972, is amended as follows:

§ 41-41-35. Duties of State Department of Health; printed materials.

(1) The State Department of Health shall cause to be published in English within sixty (60) days after July 1, 1991, the following easily comprehensible printed materials:

(a) Geographically indexed materials designed to inform the woman of public and private agencies and services available to assist a woman through pregnancy, upon childbirth and while the child is dependent, including adoption agencies, which shall include a comprehensive list of the agencies available, a description of the services they offer and a description of the manner, including telephone numbers, in which they might be contacted, or, at the option of the Department of Health, printed materials including a toll-free, twenty-four-hour-a-day telephone number which may be called to obtain, orally, such a list and description of agencies in the locality of the caller and of the services they offer.

(b) Materials designed to inform the woman of the probable anatomical and physiological characteristics of the unborn child at two-week gestational increments from the time when a woman can be known to be pregnant to full term, including any relevant information on the possibility of the unborn child's survival. The materials shall be objective, nonjudgmental and designed to convey only accurate scientific information about the unborn child at the various gestational ages.

(2) The materials shall be printed in a typeface large enough to be clearly legible.

(3) The materials required under this section shall be available at no cost from the Department of Health upon request and in appropriate number to any person, facility or hospital.

(4) The State Department of Health shall review the printed materials described under § 41-41-35 (1)(a) and (b) on an annual basis in order to determine if changes are needed in the contents therein, and shall promulgate any necessary rules and regulations for considering and making such changes.

Section 3. Section 41-75-13, Mississippi Code of 1972, is amended as follows:

§ 41-75-13. Promulgation of rules, regulations and standards.

The licensing agency shall adopt, amend, promulgate and enforce rules, regulations and standards, including classifications, with respect to ambulatory surgical facilities and abortion facilities licensed, or which may be licensed, to further the accomplishment of the purpose of this chapter in protecting and promoting the health, safety and welfare of the public by ensuring adequate care of individuals receiving services from such facilities.

The licensing agency shall also adopt, amend, promulgate and enforce rules, regulations and standards with respect to the enforcement of informed consent compliance at abortion facilities.

Such rules, regulations and standards shall be adopted and promulgated by the licensing agency in accordance with the provisions of Section 25-43-1, et seq., Mississippi Code of 1972, and shall be recorded and indexed in a book to be maintained by the licensing agency in its main office in the State of Mississippi, entitled "Rules and Regulations for Operation of Ambulatory Surgical Facilities and Abortion Facilities." The book shall be open and available to all ambulatory surgical facilities and abortion facilities and the public during regular business hours.

Section 4. This act shall take effect and be in force from and after July 1, 1996.

Appendix D

Criteria and Standards for Informed Consent Policies and Procedures

One of PEER's findings in this review concerned the Department of Health's lack of written policies and procedures for enforcing informed consent compliance on the part of abortion facilities. Through a combination of the concerns that prompted this review, interviews with Department of Health personnel, and internally developed criteria, PEER has developed a list of subject areas to guide the Department of Health in developing its written policies and procedures. Once these policies and procedures for informed consent compliance are developed, the Department of Health should distribute them to facilities in much the same manner as its Minimum Standards of Operation for Abortion Facilities.

1. **Scheduling and conducting monitoring inspections in a fair and impartial manner**--All monitoring inspections should be carried out on an impartial basis, with no favoritism shown toward any particular facility. Inspections should be unannounced and the department should take care to minimize the predictability of inspections (e.g., the same time of year, every year.)
2. **Scheduling monitoring inspections on a frequent enough basis to insure facility compliance with informed consent provisions**--The Department of Health currently inspects facilities on an annual basis, exclusive of responding to complaints from the general public. The department should consider whether unannounced routine inspections should take place more often than once a year.
3. **Use of a checklist (or detailed survey form) to insure that each element of informed consent compliance under § 41-41-33 is being checked**--The Department of Health currently uses a fifty-three-page survey form for licensure inspections. However, as noted in the finding beginning on page 8, the form provides no detail for what elements of informed consent must be present to satisfy the licensing requirements. The survey form should list in detail each element of informed consent compliance, as defined under § 41-41-33 of the MISSISSIPPI CODE ANNOTATED.
4. **Penalties for wrongdoing**--This portion of the policies and procedures should address penalties for specific acts of wrongdoing, should describe the process for follow-up inspections when acts of wrongdoing are discovered, discuss further penalties for failure to correct deficiencies, and should also cover the procedure for appeals.
5. **Follow-up visits for acts of wrongdoing**--The policies and procedures should outline the process used for follow-up visits and what each

facility must do to show that the problem has been solved (formal plan of correction.)

6. **Acceptable forms of presentation for informed consent information (i.e., videotaping, etc.)**--Because this aspect of the informed consent process generated the citizen complaints to PEER, it should also be addressed. The Department of Health should clearly describe what forms of presentation are acceptable, in as much detail as possible. The department should also consider referencing the Attorney General's opinion on the use of telephone vs. face-to-face counseling of patients.
7. **Unannounced monitoring visits**--The policies and procedures should clearly state that all monitoring visits, whether routine or follow-up, will be unannounced.
8. **Printed material compliance**--Section 41-41-33 states that patients must be offered the option of reviewing the printed materials described under § 41-41-35. The Department of Health's written policies and procedures (and the survey form) should remind facilities that they are required by law to offer these materials to patients and that part of the Department of Health's inspection process is to pull patient records at random to ensure that patients are signing the informed consent forms to prove that the materials are being offered to them and that they do not wish to view them.



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F.E. Thompson, Jr., MD, MPH
State Health Officer

Agency Response

September 11, 1995

Mr. John Turcotte, Executive Director
PEER Committee
P. O. Box 1204
Jackson, Mississippi 39215-1204



RE: Response to PEER's "Review of the Mississippi State Department of Health's Enforcement of the Informed Consent Laws."

Dear Mr. Turcotte:

Thank you for allowing me and members of my staff to review the Executive Summary and PEER staff report concerning the Department of Health and Mississippi's informed consent laws. Since we have been given the opportunity to respond to the report, which was by and large very factual, I will do so as briefly as possible. I assure you that the Department intends to implement all of the staff's recommendations that fall within our authority.

We treat abortion facilities the same as other facilities regulated by the Department. Regular inspections are conducted. Facility surveyors also visit facilities unannounced to investigate complaints. When any facility is cited for a deficiency, unless a serious and immediate threat to patient or resident life or safety is present, the facility receives a statement of deficiencies. According to Department regulations, all of our licensed facilities, including abortion facilities, are then required to submit a plan of correction to eliminate or cure the deficiency. If the plan of correction adequately addresses the deficiency, a follow-up survey is scheduled to verify that the corrective action has, indeed, corrected the problem. Closing any health care facility is the solution of last resort, used if compliance is not achieved.

There are two areas where the Department of Health feels that clarification of the report is necessary. The first area deals with the statement that the Department of Health has not closed abortion facilities for violating the informed consent laws. That is a factual statement. Under the Department's methodology of dealing with non-compliant facilities, closure is an extreme measure, used only where violations are egregious, intentional, cumulative, and (in the case of a long-term care facility) threaten the life, health or safety of the patient or resident. As the report noted, the abortion facilities found non-compliant were cited for the licensure deficiency, required to submit a plan of correction, and to prove compliance. In each instance this was done. Compliance was achieved, so the Department took no further action against the licensee. Closure or license revocation was not necessary. This is not to say that the Department has never taken more serious action against an abortion

Mr. John Turcotte, Executive Director
September 11, 1995
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facility. Indeed, one facility was ordered closed and did close in June of this year, for licensure violations of a different nature. Your staff recognized the Department was following its facilities licensure regulations by requesting plans of correction when deficiencies were cited, and included language to that effect.

MSDH Response to PEER Staff Recommendations

Recommendation No. 1: *If the Legislature intends for the Department of Health to enforce compliance with the state's informed consent laws, the Legislature should amend §41-41-33, MISS. CODE ANN. (1972), to make the department's authority and responsibility in this area of abortion regulation explicit.*

The Department is supportive of this recommendation, and will enforce such laws as are passed by the Mississippi Legislature and enacted into law by the Governor.

Recommendation No. 2: *By December 31, 1995, the Department of Health should promulgate written policies and procedures concerning informed consent for abortion. These policies and procedures should be used to inform facilities of elements of compliance and guide inspectors in enforcement efforts.*

This is the second area of the report which the Department believes requires clarification. There is language in the report from which a reader might infer that the Department of Health has no regulations governing informed consent in an abortion facility. The Department has written rules and regulations governing the licensure of all health care facilities, including abortion facilities. Those regulations governing abortion facilities include several written inspection requirements to verify that facilities are, in fact, compliant with the informed consent statute. The Department does have written regulations governing informed consent in abortion facilities. However, the recommendations of the PEER Committee staff concerning regulations, found at Appendix D of the PEER report, are valid, useful, and will be implemented.

Recommendation No. 3: *The Legislature should amend §41-41-35 of the MISS. CODE ANN. to require the Department of Health to review the printed materials required by that statute on an annual basis to assess whether the materials should be revised or updated.*

The Department is supportive of this recommendation, and will enforce such laws as are passed by the Mississippi Legislature and enacted into law by the Governor.

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Recommendation No. 4: *The Department of Health should immediately establish written guidelines for reviewing annually, and if needed, revising and updating the printed materials required by §41-41-35.*

The Department is supportive of this recommendation and will review and, if necessary, update all printed materials, beginning immediately.

Sincerely,

A handwritten signature in cursive script that reads "F. E. Thompson, Jr. MD". The signature is written in black ink and is positioned below the word "Sincerely,".

F. E. Thompson, Jr., M.D., M.P.H.
State Health Officer

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