

BELOW THE RADAR: HEALTH CARE PROVIDERS' RELIGIOUS REFUSALS CAN ENDANGER PREGNANT WOMEN'S LIVES AND HEALTH

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INTRODUCTION

AMANDA'S STORY*

Amanda goes to her local emergency room, and is diagnosed as having an ectopic pregnancy. She is unaware that the hospital's religious affiliation will determine the care she gets. There are treatment options that might increase her chances of having a child in the future, but she never learns of them, because the hospital has determined that those treatments violate the hospital's religious principles. Not only can she not receive the treatments, the hospital won't even tell her these other treatments exist.

Amanda waits patiently while more tests are run. She does not know that these tests have nothing to do with her medical condition and do not provide the doctors with any information on how best to treat her. Rather, they are being done simply to document what the doctors already know from a large body of medical evidence and their own experience—her pregnancy is not viable. They are doing these tests only to insure that if the hospital's ethics committee reviews her case, there will be sufficient evidence supporting their treatment decision as an ethical, not a medical matter. While Amanda waits for these tests to be done, the risk of her ectopic pregnancy causing a hemorrhage goes up. Luckily, they treat her in time, but because the hospital has limited treatment options due to its religious affiliation, she had unnecessary surgery instead of being treated with medication.

BARBARA'S STORY

Barbara goes to her local emergency room, and is diagnosed as having an ectopic pregnancy. While the hospital is religiously-affiliated, it has taken measures to ensure that it complies with laws that protect patients' right to receive the information and health services they need. Barbara is told of the best medical treatment options available, given her condition and her future plans to have children. She is also told that if the treatment option that she believes is best for her is unavailable at the hospital because of its religious affiliation, she can be transferred elsewhere if she is in a stable condition and the delay would not place her in any danger. If there is no alternative facility for her to be transferred to, or if the delay resulting from the transfer would place her at risk, Barbara will receive that treatment if it is the medical standard of care, despite the hospital's religious affiliation.

Barbara asks questions about the range of options available for her condition and her doctor answers them fully. She then picks a treatment and receives it. She is upset by the experience of pregnancy loss, but confident that she received the best available medical care, and enough information about her treatment options in order to make the best possible decision. Fortunately, it was not an emergency. If it had been, Barbara would have gotten immediate treatment to stabilize her condition according to the standard of care, regardless of any religious objection the hospital may have had to such treatment.

*Amanda and Barbara are fictional women, but the treatment experiences described are derived from actual cases and treatment protocols that comport with the medical standard of care and legal requirements.



A serious but little known problem is putting women's health and lives at risk: because of their religious beliefs, certain health care providers do not give appropriate treatment to women experiencing serious pregnancy complications. Every woman seeking treatment for pregnancy complications should have Barbara's experience. Unfortunately, this is not the case. A recent study entitled "Assessing hospital policies & practices regarding ectopic pregnancy & miscarriage management" investigated whether and how doctors' treatment decisions regarding these potentially dangerous conditions are affected by working in religiously-affiliated hospitals.¹ This Study focuses on Catholic hospitals as the largest religiously-affiliated provider in the United States,² and uncovers disturbing examples of treatment practices that increase the odds of medical complications that place women's lives and health at risk.

The religiously-based limitations on doctors' treatment of serious pregnancy complications documented in the Study contravene core principles underlying federal, and sometimes state, laws that are intended to protect patients. These laws require that patients receive adequate information on all treatment options before giving consent to be treated, even if the provider has a religious objection to those treatment options. Patients are also entitled to receive treatment according to the "standard of care" or "medical practice standard" which describes the best medical treatment for a particular condition based on established evidence of good patient outcomes.³

Patients who are not experiencing medical emergencies are entitled to receive the standard of care or be transferred elsewhere to receive the standard of care if a transfer is possible. Patients who are experiencing emergency medical conditions must receive the standard of care even if that care conflicts with the providers' religious beliefs. Similarly, if a patient is not having a medical emergency, but cannot be transferred elsewhere, then the patient must be treated by the provider according to the standard of care, despite any religious objections to that care.

Instead of receiving treatment according to these principles, the Study revealed four serious lapses in care resulting from religious restrictions:

- Doctors performed medically unnecessary tests, resulting in delays in care and additional medical complications for patients. These tests were done solely to address hospital administrators' concerns that the treatment complied with religious doctrine.
- Doctors transferred patients with pregnancy complications because their hospitals' religious affiliation prohibited them from promptly providing the medically-indicated standard of care.
- Hospital administrators interfered with doctors' ability to promptly provide patients with the standard of care.
- Hospital administrators interfered with doctors' ability to provide patients with relevant information about their treatment options.

This Study focused on cases where there was no medical intervention possible that would allow the patient to continue her pregnancy: even with the best possible treatment, the fetus would not survive. Rather, at issue was whether, given the unfortunate medical realities, women received the information and care to which they were entitled. The Study and this White Paper highlight ways in which religiously-affiliated hospitals impose a straightjacket on doctors' ability to provide the standard of care and give their patients complete information on their treatment options. Pregnant women can suffer harmful consequences as a result.

This White Paper provides background information on the treatment of the pregnancy complications at issue in the Study, identifies specific laws that apply to ensure that women with pregnancy complications receive prompt medical treatment and necessary information, and sets forth a call to action to end these dangerous

practices. Among the actions being taken by the National Women's Law Center are: filing a complaint⁴ with the Department of Health and Human Services (HHS) requesting that it provide clarification on existing laws that require hospitals to provide the standard of care, obtain informed consent and provide care in emergency situations. The Center is also asking HHS officials to resolve pending complaints on this issue, investigate these practices, and require hospitals to institute policies and procedures to ensure compliance with the law. And finally, the Center is calling upon state governments, hospital associations and individual hospitals to prevent these serious lapses in the treatment of pregnancy complications..

II. THE EFFECT OF RELIGIOUS RESTRICTIONS ON HOSPITALS' TREATMENT OF MISCARRIAGE AND ECTOPIC PREGNANCY

Both individual and institutional refusals to provide specific aspects of reproductive health care due to religious, moral or ethical beliefs have been repeatedly documented.⁵ Some individuals and institutions, for example, share a religiously-based opposition to certain medical interventions that would end a pregnancy even if those interventions are necessary to avoid serious harm to a woman's health or even life.⁶ Both this paper and the Study address situations where the pregnancy is not viable and there is nothing doctors can do that would allow a woman to continue her pregnancy. Medical intervention in these cases is necessary in order to preserve a woman's health or even life, and at most hastens what is the inevitable end of the pregnancy.

The Study concentrates on Catholic-affiliated hospitals' treatment of pregnancy complications, given the sizeable number of such health care providers in the country. Approximately fifteen percent of hospital beds are in Catholic-affiliated hospitals.⁷ But the legal analysis and need for corrective action urged in this White Paper apply to any institution delaying or denying treatment based on its religious or ethical beliefs, as well as any institution employing someone with religious or ethical beliefs that lead to delays in treatment or denial of treatment or information on treatment options.⁸

With respect to Catholic-affiliated hospitals, they are governed by the *Ethical and Religious Directives for Catholic Health Care Services*, which provide guidance on a range of reproductive health services including surgical sterilization, family planning, infertility treatment and abortion.⁹

Most individuals and even many health providers presume that the *Directives'* prohibition on the provision of a range of abortion services applies only to non-emergency pregnancy terminations of otherwise viable pregnancies. But the Study is consistent with anecdotal accounts that provide strong evidence that some hospitals and health care providers have interpreted the *Directives*

Yvonne Shelton, a nurse employed in the labor and delivery unit at a nonsectarian hospital in New Jersey, refused to assist in two cases of women experiencing serious pregnancy complications: an emergency hysterectomy of a woman who was eighteen weeks pregnant and experiencing a life threatening condition, and another patient, also with an pregnancy that was not viable, who needed to have labor induced in order to save her life.⁸³ Based on her religious beliefs, Shelton refused to assist in any procedure that terminated fetal life. She considered such procedures to be unacceptable abortions, even though nothing could be done to save the pregnancies and the procedures were necessary to save the women's lives.

The hospital offered Shelton a transfer to another unit where she would avoid such conflicts, but she refused to make the change. After being fired, Shelton sued the hospital, claiming religious discrimination in violation of Title VII, the federal law prohibiting employment discrimination on the basis of religion. The court ruled in favor of the hospital. It found that the hospital's transfer solution had been a reasonable accommodation, and that its overriding responsibility was to protect a patient seeking emergency care.

to prohibit prompt, medically-indicated treatment of miscarriage and ectopic pregnancy, placing women's lives and health at additional and unnecessary risk.¹⁰

A. MISCARRIAGE: THE STANDARD OF CARE AND THE IMPACT OF RELIGIOUS RESTRICTIONS

Miscarriage, or pregnancy loss before twenty weeks gestation, occurs in ten to twenty percent of all diagnosed pregnancies.¹¹ The standard of care depends on the condition which caused the miscarriage as well as the particular circumstances of the patient. One factor is whether the patient is stable, or unstable. An unstable patient is one who is "within reasonable medical certainty" likely to experience a "material deterioration" of her condition during a transfer to another hospital.¹² Signs that a patient is unstable include heavy bleeding, severe pain, and a rising temperature — an indication of the onset of an infection.¹³

If it is determined that nothing can be done that would allow the woman to continue her pregnancy, the established standard of care for unstable patients who are miscarrying is an immediate surgical uterine evacuation.¹⁴ In the case of such a patient, immediate uterine evacuation reduces the patient's risk of complications, including blood loss, hemorrhage, infection, and the loss of future fertility.¹⁵ A delay in treatment may subject a woman to unnecessary blood transfusions, risk of infection, hysterectomy or even death.¹⁶

Some Catholic hospitals, contrary to the opinion of leading Catholic ethicists and theologians,¹⁷ apply the *Directives* to prohibit doctors from providing any treatment to a woman having a miscarriage if there are still fetal heart tones, even when a doctor has determined that nothing can be done to save the pregnancy and the woman's health is placed at risk by delaying immediate treatment. These hospitals will require that doctors withhold treatment until there are no fetal heart tones, or there are specific indications that a woman's life is at risk, such as the onset of a serious infection. Some hospitals will transfer the patient elsewhere for medical treatment if the woman's life is not yet at risk, despite the current threats to her health. As shown in the Study, some hospitals will allow treatment only after doctors perform additional unnecessary viability tests, despite doctors' existing medical certainty that the fetus is not viable. In these cases patients are being denied emergency care to which they are legally entitled, as further described below.

For patients who are stable, the standard of care is either uterine evacuation or expectant management (waiting for the patient's body to expel the fetus), depending on the patient's preference.¹⁸ A patient that has other provider options could request a transfer to receive a uterine evacuation procedure that a religious institution may not provide. A patient who is unable to travel to another facility may be required by some religious institutions to wait until she expels the fetal remains, a process that can take as long as one month and may significantly compound the emotional trauma she is already experiencing due to the pregnancy loss.¹⁹ In these cases there is no medical benefit to delaying treatment for either the woman or the fetus.²⁰

Because expectant management can be within the standard of care, such delays in treatment do not necessarily constitute legal violations. Nonetheless, for the patient who would prefer immediate treatment, transfers and denial of treatment in cases where nothing can be done that would allow her to continue her pregnancy may cause additional and unnecessary emotional trauma, at a minimum. A woman may return to the hospital for treatment if she begins bleeding, shows signs of infection or other symptoms that her condition is no longer stable.

B. ECTOPIC PREGNANCY: THE STANDARD OF CARE AND THE IMPACT OF RELIGIOUS RESTRICTIONS

Ectopic pregnancy is the leading cause of maternal death in the first trimester of pregnancy.²¹ Ninety-seven percent of ectopic pregnancies grow in a fallopian tube.²² These pregnancies are not viable, and are likely to result in the rupture of the tube if not treated.²³ Because of the possibility of rupture, certain medical symptoms make

ectopic pregnancies an emergency in need of immediate treatment, including when the ectopic pregnancy is diagnosed, the patients' blood pressure and hormone levels, and the estimated gestation of the embryo.²⁴ In these cases the hospital is required to provide immediate stabilizing treatment, typically emergency surgery.²⁵

There are four possible treatment options for a stable ectopic pregnancy that is not showing signs of imminent rupture, one or more of which may meet the standard of care depending on the circumstances: to remove the embryo by administering a single shot of a drug, methotrexate, which dissolves the embryo; to surgically remove the embryo while keeping the fallopian tube intact (hereinafter tube-sparing surgery); to remove the entire section of the fallopian tube containing the embryo; or "expectant management," which postpones all treatment to observe how the condition evolves.²⁶ Fallopian tube rupture is a risk in certain cases where expectant management is used despite medical indications that the patient needs some type of medical intervention.²⁷

While the best treatment option depends on factors such as hormone levels and the patient's desire for future pregnancies,²⁸ two treatments have considerable advantages. When treatment with methotrexate is medically indicated, it allows the patient to avoid more costly and invasive surgery.²⁹ Medical studies about the long-term effect on fertility of tube-sparing surgery and/or medical treatment are not conclusive, but some suggest that they improve a woman's likelihood of having a normal pregnancy in the future.³⁰

Despite the serious risks of delaying treatment for certain patients, doctors in the Study reported that treatment of patients with ectopic pregnancies was delayed by unnecessary tests, even for patients presenting with symptoms which indicated a need for immediate surgical treatment.³¹ Doctors performed these tests in order to comply with how their hospitals interpreted the *Directive* addressing the treatment of tubal pregnancy.³² One doctor believed that her hospital's policies actually resulted in several cases of tubal rupture, indicating that these patients had an emergency condition that went untreated.

The Study also showed that some hospitals, contrary to even the most conservative readings of the *Directives*,³³ prohibit the use of methotrexate, which dissolves the embryo, or tube-sparing surgery, even in cases where it would be the standard of care and the best medical option for the patient. This is because both are considered "direct" action against the embryo.³⁴ While at one time tube sparing surgery and methotrexate were prohibited under the *Directives*, the current consensus as reported by the Catholic Health Association is that both treatments are ethically permissible.³⁵ Yet, both the Study and anecdotal reports suggest that some doctors will transfer patients for whom methotrexate or tube-sparing surgery is medically indicated, despite the fact that nothing in the *Directives* prohibits these treatment options.³⁶ Such transfers can be legally permissible, since only stable patients are candidates for methotrexate and tube sparing surgery. Nonetheless, it appears that patients are being unnecessarily denied care at Catholic hospitals when Catholic ethicists have determined that such care is ethically permissible, and in fact can be required according to medical ethics.

C. DUTY TO PROVIDE THE STANDARD OF CARE

The American College of Obstetricians and Gynecologists has opined that a religious objection "should be accommodated only if the primary duty to the patient can be fulfilled."³⁷ This duty encompasses providing "medically indicated and requested care regardless of the provider's personal moral objections."³⁸ In remote areas, stable patients with ectopic pregnancies may not have another facility to which they can be transferred. Likewise, patients may be in a geographic area with only religiously-affiliated hospitals. Given the inherently dangerous situation presented by ectopic pregnancies, religiously-affiliated hospitals have a duty to treat patients with ectopic pregnancies according to the standard of care if these patients have nowhere else to turn for treatment. If the patient prefers tube-sparing surgery or methotrexate, the patient should receive her preferred treatment, despite the health care provider's ethical, religious or moral objections to it.

There will also be emergency cases where a hospital is legally required to treat the patient as described in further detail below. In these cases, the health care provider has an ethical and legal duty to promptly treat the patient according to the standard of care. This means that if the patient is experiencing a medical emergency, she is entitled not just to any medical treatment, but treatment according to the standard of care, despite the provider's religious objection to providing such care.

D. INFORMED CONSENT IN THE TREATMENT OF MISCARRIAGES AND ECTOPIC PREGNANCY

For patients to give their informed consent to medical treatment, it is essential that they be told of all of the treatment options that are available, based on their condition, as well as the risks and benefits of those treatment options. In treating pregnancy complications, two important risks and benefits to be assessed are: if any treatment

In an essay in the *Journal of the American Medical Association*,⁸⁴ a psychiatrist describes the ways in which a Baptist hospital placed its religious beliefs above the medical needs of his wife when she began to miscarry at twenty-one weeks. Doctors agreed that nothing could be done to save the pregnancy, but refused to induce labor in the absence of an existing life-threatening infection. He and his wife were not willing to risk an infection that would likely threaten her future fertility and perhaps even her life. They transferred to another hospital where labor was induced, and the twins were stillborn. In contrast to Catholic hospitals, Baptist hospitals do not have written directives. But as this case illustrates, various religions' beliefs can affect the availability of care.

will increase the chances of a woman continuing her pregnancy; and if the patient wishes to become pregnant in the future, how the treatment will affect her ability to do so.

Religious restrictions can interfere with the provision of informed consent in several ways. Patients may not be told of the existence of particular treatment options because those options are prohibited by the providers' religious beliefs. As described above, certain options may be more favorable if a woman wishes to have children, so that a failure to disclose options that might allow her to do so is an especially egregious violation of the principle of informed consent.

Even if patients are told about treatment options that the hospital will not provide due to religious restrictions, some hospitals may refuse to tell patients that they can request a transfer to a hospital that will provide them. Additionally, patients many never learn that a delay in their care was because of religious restrictions. Even if

patients do learn that religious restrictions are the cause of a delay in treatment, for example due to unnecessary medical testing or while waiting for fetal demise, it may be too late at that point to seek care at a non-sectarian health care provider. In cases where there was, in fact, another provider to which the patient could be transferred without incurring risks due to the delay, these patients have been denied critical information about their ability to get more prompt treatment, or a medically-preferable treatment option that comports with the standard of care, and have therefore been denied informed consent.

And finally, in cases where expectant management is presented as a treatment option, patients may be under the mistaken belief that withholding medical intervention improves their chances of continuing the pregnancy, despite the fact that they are experiencing unavoidable pregnancy loss. While expectant management is sometimes a legitimate option that meets the standard of care for some patients, it does not improve their chances of continuing their pregnancies. The principle of futility in medical ethics states that doctors are not ethically obligated to provide care that has no reasonable chance of benefiting the patient.³⁹ Withholding care, if done in an effort to prevent what is an inevitable miscarriage, would be futile.⁴⁰

To obtain full informed consent in treatment of pregnancy complications, at a minimum, a woman should be told by her doctor:

- (1) all of the medical treatments that are available based on her condition and the risks and benefits of each of those treatments, including how they might affect her future fertility;
- (2) how each treatment option affects her chances of continuing her current pregnancy to term, given her condition and the best available medical evidence;
- (3) whether there are any treatments that are not available at the hospital due to individual or institutional religious beliefs;
- (4) whether, due to individual or institutional religious beliefs, her care is being delayed until she shows particular signs of life or health endangerment or for the performance of medically-unnecessary tests;
- (5) if there is another facility to which she could be transferred to receive the standard of care or more prompt care than what is available due to religious restrictions, that she has the option to transfer, and the risks and benefits of transferring.

III. MAJOR FINDINGS OF THE STUDY

Despite hospitals' legal obligations, religious restrictions result in patients being denied their right to receive critical information before consenting to treatment, their right to receive the standard of care and their right to receive emergency treatment. The Study reveals cases where doctors did not tell patients that certain treatment options were available for their condition, but not offered by the hospital because of religious restrictions. The Study reveals that some doctors do not disclose certain treatment options to their patients, or do so only surreptitiously, because their hospitals prohibit those treatments due to the *Directives*. Without the disclosure of all treatment options, patients are not able to make fully informed medical decisions, and are thus unable to give informed consent.⁴¹

Similarly, the Study highlights stark cases where doctors noted a discrepancy between the medically-accepted standard of care for miscarriage and ectopic pregnancies, and the treatment provided by hospitals due to their religious affiliation. Even in clear-cut cases where doctors determined that the embryo or fetus was not viable, doctors were required to perform tests that were not medically necessary or transfer patients to other hospitals. Disturbingly, doctors were also required to delay treatment needed to prevent the onset of serious medical complications because their patient's lives were not yet in danger, even though their health was at risk.

1. DOCTORS PERFORMED MEDICALLY UNNECESSARY TESTS, RESULTING IN DELAYS IN CARE AND ADDITIONAL MEDICAL COMPLICATIONS FOR PATIENTS. THESE TESTS WERE DONE SOLELY TO ADDRESS HOSPITAL ADMINISTRATORS' CONCERNS THAT THE TREATMENT COMPLIED WITH RELIGIOUS DOCTRINE.

- Dr. Y, an ob/gyn in a Catholic-affiliated California hospital stated that as a result of additional medically unnecessary viability testing in order to avoid possible censure or reprimand, "patients [experiencing miscarriages] are often bleeding very heavily before dilation and curettage is allowed." This loss of blood can require the patient to receive transfusions in order to prevent anemia.
- Dr. Y believes that her Catholic-affiliated hospital's interpretation of the *Directives* is responsible for several cases of tubal rupture among patients with ectopic pregnancies. Dr. Y said that her hospital requires additional tests that are not medically warranted, resulting in delays in treatment. Despite these ruptures, her hospital had not reviewed its policies regarding the care of ectopic pregnancies or provided any further guidance to physicians.

- Several doctors in Catholic-affiliated hospitals stated that they go out of their way to run unnecessary tests because they are acutely aware of nurses and other members of the health care team closely observing them to make sure they are strictly adhering to the *Directives*.

2. DOCTORS TRANSFERRED PATIENTS WITH PREGNANCY COMPLICATIONS BECAUSE THEIR HOSPITALS' RELIGIOUS AFFILIATION PROHIBITED THEM FROM PROMPTLY PROVIDING THE MEDICALLY-INDICATED STANDARD OF CARE.⁴²

- Dr Z reported that doctors in his longstanding Catholic-affiliated hospital are prohibited from inducing labor when a patient is miscarrying but there is still a fetal heartbeat. They routinely transfer these patients to another hospital, causing delays in care.
- Dr. S, an emergency room physician in a Catholic-affiliated Pennsylvania hospital, stated that patients with ectopic pregnancies are routinely transferred to hospitals where they can be treated with methotrexate, since the only available treatment in Dr. S's hospital is unnecessary, invasive surgery that possibly reduces future fertility.⁴³

3. HOSPITAL ADMINISTRATORS INTERFERED WITH DOCTORS' ABILITY TO PROMPTLY PROVIDE PATIENTS WITH THE STANDARD OF CARE.

- When asked if he would be prevented from performing a uterine evacuation, the standard of care in nonviable pregnancies even when there are fetal heart tones, Dr. Z said, "Yes, we would be shot. I don't know if it's written, but [according to the hospital's administrators] clearly that is against the Ethical Directives of the Catholic Church."
- When word spreads that the hospital has reprimanded a doctor for performing a certain procedure to treat an ectopic pregnancy or miscarriage, other doctors, fearing reprimand, assume that the procedure is off-limits.
- Several doctors reported that their hospital's interpretation of the *Directives* "absolutely" compromises the treatment of ectopic pregnancy because several hospitals ban methotrexate, an effective way to treat certain cases. Dr. J said doctors practicing in his Catholic-affiliated hospital often use expectant management, which places women at risk of tubal rupture, because they are restricted from administering other preferred treatments.
- Dr. Z reported that his medical training instructed him to induce miscarriage patients whose pregnancies would not be able to reach twenty-four weeks gestation. His Catholic-affiliated hospital bars this established protocol due to the *Directives*.

4. HOSPITAL ADMINISTRATORS INTERFERED WITH DOCTORS' ABILITY TO PROVIDE PATIENTS WITH RELEVANT INFORMATION ABOUT THEIR TREATMENT OPTIONS.

- Dr. Y, practicing in a Catholic-affiliated hospital in California, said she often takes patients aside and reviews all of their treatment options, including those forbidden by the hospital, even though this level of disclosure is not allowed. She reported that other physicians at the hospital offer referrals and information "under the radar" as well.
- It is unclear from the Study's findings the degree to which patients were informed that their treatment was delayed due to the religious affiliation of the hospital and whether they were told they had a right to be transferred elsewhere to receive the standard of care, if a transfer was a safe option.

There are additional examples beyond those highlighted in the Study also demonstrating these troubling patterns.⁴⁴ In these examples, hospital administrators would only allow doctors to initiate treatment when they identified specific signs that a woman's life was at risk. It is very likely that at least some of these women and the women whose treatment was described in the Study were in an unstable condition.

Furthermore, despite the presence of serious symptoms that needed to be stabilized, and that the hospital was equipped to treat, some doctors transferred patients elsewhere in an effort to get them faster treatment or treatment according to the standard of care. As described in further detail below, these hospitals were legally required to treat these patients immediately.

IV. RELIGIOUSLY-MOTIVATED DELAYS IN TREATMENT AND DENIALS OF BOTH TREATMENT AND INFORMATION CAN VIOLATE HOSPITALS' LEGAL OBLIGATIONS

A. HOSPITALS ENGAGING IN RELIGIOUSLY-BASED REFUSALS CAN DENY PATIENTS THEIR RIGHT TO RECEIVE THE STANDARD OF CARE

The Medicare Conditions of Participation, federal regulations that hospitals must follow if they accept Medicare beneficiaries, state that if a hospital maintains an emergency department, "the hospital must meet the emergency needs of patients in accordance with acceptable standards of practice."⁴⁵ The same condition requiring hospitals to provide care "in accordance with acceptable standards of practice" applies to hospitals providing surgical services, which include surgery to manage both ectopic pregnancies and miscarriages,⁴⁶ as well as to hospitals providing outpatient services.⁴⁷

B. HOSPITALS ENGAGING IN RELIGIOUSLY-BASED REFUSALS CAN DENY PATIENTS CRUCIAL INFORMATION ABOUT THEIR TREATMENT OPTIONS.

The Supreme Court has held that the fundamental, constitutionally-protected right to make personal medical decisions is grounded in the guarantees of liberty and privacy in the Fourteenth Amendment to the U.S. Constitution.⁴⁸ Essential to this right is a patient's knowledge of the range of available treatment options. The right to informed consent is firmly established in medical ethics,⁴⁹ with special concern given to matters of reproductive health, "where so many key decisions are irreversible."⁵⁰ Moreover, most state statutes allow a patient to sue for malpractice when the patient is harmed as a result of not being told of all available treatment options and the risks and benefits of those options.⁵¹

Federal regulations explicitly require all hospitals receiving Medicare funds to obtain informed consent from all patients:

The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.⁵²

At a minimum,⁵³ patients must be given the full range of medically appropriate treatment options for their condition and told the risks and benefits of each alternative prior to their treatment.⁵⁴ ACOG states that the adequacy of disclosure may be evaluated using the "common practice of the profession,"—meaning what other practitioners typically disclose regarding a patient's treatment options for a particular condition.⁵⁵

C. HOSPITALS ENGAGING IN RELIGIOUSLY-BASED REFUSALS AND DELAYS IN CARE CAN DEPRIVE PATIENTS OF THEIR RIGHT TO RECEIVE PROMPT TREATMENT OF EMERGENCY MEDICAL CONDITIONS IN VIOLATION OF EMTALA, THE EMERGENCY MEDICAL TREATMENT AND ACTIVE LABOR ACT.

EMTALA requires hospitals to provide stabilizing treatment to patients with emergency medical conditions who seek care at emergency rooms. Regulations for EMTALA are also Conditions of Participation for hospitals receiving Medicare patients. An “emergency medical condition,” is defined as follows:

A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in (A) placing the patient’s health in serious jeopardy, (B) serious impairment to bodily functions, or (C) serious dysfunction of any bodily organ or part.⁵⁶

Furthermore, EMTALA prohibits hospitals from transferring patients when they are unstable. An unstable patient is one who is “within reasonable medical certainty” likely to experience a “material deterioration” of her condition during a transfer to another hospital.⁵⁷ EMTALA requires that patients experiencing severe symptoms be given “immediate medical attention” if evidence reasonably indicates that their health will be seriously damaged if they do not receive treatment. The law does not allow a hospital to wait until the patient’s health has reached the point where it has actually become jeopardized.

While EMTALA makes an exception for hospitals that are unable to provide certain medical care, allowing them to transfer patients to another facility with the necessary equipment or expertise, the law provides no exceptions for hospitals that are simply unwilling to provide care due their religious objections.⁵⁸

V. WOMEN DESERVE BETTER

A. STATE AND FEDERAL AUTHORITIES MUST REQUIRE HOSPITALS TO PROVIDE THE STANDARD OF CARE, INFORMED CONSENT AND EMERGENCY CARE TO WOMEN EXPERIENCING PREGNANCY COMPLICATIONS

The Study suggests a failure on the part of the hospitals investigated to ensure that patients experiencing pregnancy complications received the standard of care, informed consent, and prompt treatment of emergency medical conditions. Doctors are reluctant to report hospital practices that harm patients or violate the law, especially when they have played a direct role. Patients may never know why their treatment was delayed, why they were transferred, or that additional treatment options were automatically disregarded due to religious restrictions. Patients, unaware that they were denied necessary, let alone legally required care or medical information, are not able to bring violations to the attention of enforcement authorities or pursue other legal claims.

State and federal authorities must be vigilant to ensure that patients who experience pregnancy complications receive the care to which they are legally entitled. It is incumbent upon state and federal governments to enforce existing laws intended to protect patients. Furthermore, all hospitals, including those operating under the *Directives* have a duty to comply with the law, and to ensure that their medical staff understands that the *Directives* or other any other institutional or individual religious beliefs do not excuse hospitals from their legal obligations.

1. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

The Centers for Medicare & Medicaid Services (CMS) of HHS is charged with the responsibility of ensuring providers’ compliance with the requirements of Medicare and Medicaid. This includes EMTALA, and the

Medicare Conditions of Participation (CoPs), which require that hospitals obtain informed consent and provide the standard of care. CMS has the authority to assess hospitals' compliance, issue guidance, investigate current hospital practices, review complaints against hospitals, and determine what questions investigators should ask of hospitals to ensure that they have the proper procedures in place to comply with the law

Interpretive Guidelines of Existing Conditions of Participation:⁵⁹ The Director of the Survey and Certification Group (the Director) should issue a statement clarifying hospitals' duty to obtain informed consent from patients who present with pregnancy complications.⁶⁰ This guidance should advise hospitals that they must disclose all of the possible treatment options for the patient's condition; they must give patients the option to transfer in non-emergency situations if the standard of care is not available at the hospital; and they must provide the standard of care in emergencies. Since ectopic pregnancies are an extremely dangerous condition, if there is no other hospital that can treat the patient in a timely manner, the religiously-affiliated hospital must treat the patient according to the standard of care.

Considering the problems that the Study authors and others have identified, it is particularly urgent that the Director inform hospitals of their duty to stabilize women experiencing emergency pregnancy conditions. This stabilizing treatment must follow the standard of care. Guidance should clarify that there is no exemption in EMTALA for religious beliefs. A hospital has a duty to stabilize patients presenting with emergency medical conditions, and may not legally transfer an unstable patient merely because the hospital (or an employee) has a moral or religious objection to providing the standard of care.

Resolution of complaints:⁶¹ CMS receives complaints of alleged violations of the CoPs and EMTALA from patients, providers and others who believe that a violation has occurred, and has the authority to issue fines and require corrective action if the investigation reveals a violation has been committed.⁶² In addition to a complaint filed by the Center,⁶³ CMS has received at least one other complaint concerning the *Directives'* impact on the treatment of pregnancy complications.⁶⁴ CMS must rigorously investigate each complaint it receives regarding delays in care or deviation from the standard of care in the treatment of pregnancy complications. This will also provide CMS with crucial evidence of potentially harmful practices and policies that may exist at other hospitals so that CMS can take further corrective action.

Investigations of current hospital practices:⁶⁵ CMS has jurisdiction to investigate hospitals' policies regarding the treatment of women experiencing pregnancy complications. One of CMS's principal duties is to "promote the timely and economic delivery of appropriate quality of care to eligible beneficiaries."⁶⁶ Under this broad authority, CMS can initiate investigations of any provider practice that

In southern Arizona, a woman who was fifteen weeks pregnant presented at the emergency room of a hospital that had recently affiliated with a Catholic health system. She reported that she had passed a fetus at home, but that she was pregnant with twins. Her cervix was dilated, and the umbilical cord and placenta from the passed fetus remained in her uterus. The emergency room physician, consulting with a perinatologist, determined that nothing could be done that would allow the patient to continue the pregnancy. The woman and her husband agreed to treatment with a medication that would complete the miscarriage.

The doctor informed his hospital's administration about the case, the prognosis, and agreed upon treatment. The doctor was told that the patient could not be treated because the remaining fetus still had a heartbeat. Instead the patient was transferred by ambulance to a hospital eighty miles away, delaying her care by approximately three and a half hours.

Because this patient was in a stable condition, the hospital did not commit a violation of EMTALA. Nonetheless, this case presents an example of how women are being denied the standard of care at Catholic-affiliated hospitals, even in circumstances where Catholic ethicists would agree that the medically-necessary treatment is ethically permissible.

diminishes the quality of care or increases costs to the Medicaid or Medicare programs.⁶⁷ Hospitals' policies regarding miscarriage management affect both health care quality and cost. For example, patients may suffer loss of blood that requires transfusions or develop infections that require additional treatment. Patients with ectopic pregnancies who are denied treatment with methotrexate may instead receive invasive and costly surgery. The unnecessary tests that are referenced in the Study also increase the cost of care.

Additionally, CMS should conduct a comparative analysis of all cases where women with pregnancy complications were transferred to other hospitals. CMS should identify the final outcomes of these transfers, including how these women fared compared to patients who were not transferred and how many women were readmitted for complications following their treatment.⁶⁸ CMS should also determine how many women with ectopic pregnancy diagnoses received invasive, expensive and unnecessary surgical procedures due to delays in care that rendered women ineligible for treatment with methotrexate.

Development of Specific Survey Procedures on the Treatment of Pregnancy Complications.⁶⁹ The Administrator of the Consortium for Quality Improvement and Survey and Certification Operations should develop survey protocols to identify whether hospitals have procedures in place to comply with the CoPs and EMTALA when treating women experiencing pregnancy complications. Survey protocols should also inquire as to whether hospitals have adequate procedures to ensure the provision of adequate informed consent, including procedures to ensure that hospitals disclose when they do not provide the standard of care for the patient's condition.

2. ADDITIONAL STATE ENFORCEMENT

Rigorous enforcement is needed at the state level to ensure that patients get the information, and in cases of emergency, the treatment to which they are legally entitled. States have laws that address informed consent,⁷⁰ standards of care⁷¹ and emergency care,⁷² and may provide additional penalties for offenders and offer a private cause of action for individuals beyond those available under federal law.

3. FEDERAL AND STATE OVERSIGHT OF HOSPITAL MERGERS AND SALES

Catholic hospitals continue to expand their patient base by purchasing and merging with nonsectarian hospitals. In most mergers the *Directives* are applied and dictate overall policy. In addition to ensuring that Catholic hospitals comply with existing laws, the federal and state antitrust agencies and state hospital licensing bureaus must take into account the possible and serious impact on health care access and quality of treatment before allowing mergers and sales to take place.⁷³ As a condition of the merger or sale, authorities should require Catholic hospitals to establish clear policies on the treatment of these conditions to ensure protection of patients' health and safety.

B. THE CATHOLIC HEALTH ASSOCIATION OF THE UNITED STATES SHOULD PROVIDE GUIDANCE AND TRAINING TO ITS MEMBERS TO ENSURE THAT WOMEN RECEIVE APPROPRIATE TREATMENT FOR PREGNANCY COMPLICATIONS, AND TO RESOLVE LACK OF CLARITY REGARDING THE *DIRECTIVES*.

The Catholic Health Association of the United States (CHA), the association for the vast majority of Catholic hospitals, can play a crucial role in eliminating practices that place women's health and lives at risk. While it would be especially efficient for CHA to take the lead in clarification, education and training, individual Catholic hospitals also have a duty to take affirmative steps to ensure that they are complying with the law. These recommendations therefore apply to all Catholic-affiliated hospitals, whether or not CHA takes leadership on this important matter of patient care.

CHA provides ethical guidance to its members and assists them in furthering CHA's mission.⁷⁴ CHA does not dictate individual hospitals' policies and has no enforcement power over its member-hospitals, but it functions as a critical resource for education and training. CHA employs ethicists and attorneys to respond to the needs of its member-hospitals in developing procedures that comply with the *Directives*, and minimize legal risks. In this capacity CHA provides an influential and respected source of technical support and ethical guidance.⁷⁵ For example, as described in greater detail below, CHA issued a report clarifying that the use of emergency contraception is ethically permissible under the *Directives*.

CHA responded to a study published in the American Journal of Public Health regarding delays and denials of care in the treatment of unstable patients experiencing miscarriages. CHA cited possible "misinterpretation" by some hospitals and doctors who were apparently under the belief that a woman's life had to be in danger before she could be treated if there were still fetal heart tones.⁷⁶ CHA has since clarified that a woman should be treated if her health is endangered and that treatment should not be delayed until there are signs of life endangerment.⁷⁷

According to CHA, "conflicts often are heightened by an inadequate understanding and application of the Directives in concrete situations."⁷⁸ The *Directives* do not prohibit the use of tube-sparing surgery or methotrexate to treat ectopic pregnancies, or require that a woman's life be in danger before she receives treatment,⁷⁹ yet patients are suffering the consequences of what could be a possible misinterpretation of the *Directives*. It is incumbent upon CHA to clarify these misunderstandings and educate its hospitals and providers to ensure that women's lives and health are not placed at risk.

1. ETHICAL GUIDANCE PROVIDED BY CHA ON EMERGENCY CONTRACEPTION OFFERS A MODEL FOR IMPROVING THE TREATMENT OF WOMEN EXPERIENCING PREGNANCY COMPLICATIONS AT CHA MEMBER HOSPITALS

CHA's response to its members' confusion on providing Plan B (the emergency contraceptive medication) to rape victims provides a template of how CHA can improve the treatment of patients with pregnancy complications. CHA published four articles in a "Special Report," which addressed emergency contraception.⁸⁰ The CHA ethicist drew this conclusion:

Given what is currently known about Plan B from scientific research, Catholic hospitals can respond with sensitivity, compassion and assistance to women who have been raped and are in need of care, while being confident that they are also remaining true to Catholicism's fundamental respect for human life.⁸¹

While it is too soon to tell to what degree this Special Report has improved hospitals' policies' regarding the treatment of rape survivors, it still presents a model of how CHA offers guidance to its members on the *Directives*. CHA should provide similar guidance and training on the treatment of pregnancy complications. It should also clarify compliance with standard of care and informed consent principles in both emergency and non-emergency situations.

2. SPECIFIC RECOMMENDATIONS FOR EDUCATION AND TRAINING

Hospital personnel and staff should be informed that the law requires prompt treatment of emergency medical conditions and what factors legally constitute such a condition. CHA should inform its members that the standard of care treatment must be provided immediately to patients whose pregnancy complications present an emergency medical situation. Under EMTALA, this includes any situation where a delay in treatment would place the "patient's health in serious jeopardy," would result in "serious impairment to bodily functions," or would result in "serious dysfunction of any bodily organ or part."⁸²

In cases that do not qualify as medical emergencies, CHA should direct its member hospital administrators to ensure that personnel inform patients that their treatment is being delayed or is otherwise departing from the standard of care due to the *Directives* and to inform patients who do not require emergency care that they have an option to transfer to another hospital where they can receive the standard of care or more prompt care, along with full disclosure of the risks and benefits of a transfer.

In the case of ectopic pregnancies, CHA should direct its hospitals to tell patients about the availability of methotrexate to treat their condition, or the availability of surgery that would leave a fallopian tube intact. CHA has declared that these treatments are ethically permissible, yet it appears from the Study that some hospitals are unaware of CHA's determination.

Miscarriage patients who are in a stable condition should be informed if there is a treatment that will improve their chances of continuing the pregnancy, or if they are being denied an immediate treatment despite the fact that nothing can be done that would allow their pregnancies to continue. Patients should also be informed of all medical risks they face by postponing treatment.

CHA should also encourage its member-hospitals to clarify their policies and procedures. Medical staff should be given the opportunity to ask questions on how to comply with the *Directives*. Efforts should be made to shed light on situations that have created confusion in the past. CHA plays a critical role in providing hospitals with resources on applying the *Directives*, and educating its members on their existing legal obligations. Moreover, CHA must ensure that its member-hospitals are adequately conveying to their staff members and potential staff members how the *Directives* affect patient care, so they can consider whether or not they wish to practice under these constraints.

C. ALL HOSPITALS SHOULD TAKE IMMEDIATE ACTION TO ENSURE THAT THE TREATMENT OF PREGNANCY COMPLICATIONS IS NOT BEING EFFECTED BY THE RELIGIOUS BELIEFS OF THEIR EMPLOYEES.

While the Study focused on Catholic-affiliated hospitals, all hospitals should immediately review their current practices and procedures and identify potential violations of patients' rights in the area of pregnancy complications. All hospitals have the responsibility to ensure that patients receive information on all medically appropriate treatment options, and are offered transfers when there is no emergency condition present and the hospital does not offer a particular treatment option that the patient would prefer.

Hospitals must clarify their policies and procedures and legal duties to current employees and inform employees who may have ethical, religious or moral objections to certain treatments of pregnancy complications that accommodation or reassignment is available.

VI. CONCLUSION

The Study documents further evidence that religious refusals to provide reproductive health care can place women's lives and health at risk. While women may not be entitled to care in non-emergency situations, they are certainly entitled to adequate information about their treatment options. And in emergency situations (or when the patient cannot be transferred to another facility), a patient is entitled to receive the standard of care, despite any individual or institutions' religious objections. All responsible parties, including CHA, individual hospitals, and the governmental agencies charged with enforcing the relevant laws must take immediate action.

Furthermore, there is also evidence that individual providers outside of Catholic-affiliated hospitals have also raised religious objections to certain treatments for pregnancy complications, including in emergency situations.

The Center calls on all hospitals to undertake proactive measures to address current failures in providing women the care to which they are legally entitled.

Women experiencing pregnancy complications must receive the full protection of laws intended to ensure that they receive the standard of care, prompt emergency treatment for health-endangering conditions and treatment for which they have given their informed consent. Federal and state officials must enforce existing laws to ensure that women will no longer be subjected to the delays and denial in treatment that risk their health and well-being.

ENDNOTES

- 1 This study was initiated by the National Women's Law Center and conducted by Ibis Reproductive Health, a clinical and social science research organization. Angel M. Foster, Amanda Dennis & Fiona Smith, *Assessing Hospital Policies & Practices Regarding Ectopic Pregnancy & Miscarriage Management: Results of a National Qualitative Study* (Ibis Reproductive Health, 2009) (hereinafter Study), available at <http://www.ibisreproductivehealth.org/news/documents/Summaryofqualitativestudy.pdf>. Ibis selected a sampling of geographically diverse Catholic, non-Catholic and recently-merged hospitals. Researchers conducted in-depth phone interviews with doctors, asking about their knowledge of hospital policies and practices regarding the treatment of ectopic pregnancies and miscarriages, as well as their perceptions of how these policies affected their treatment decisions and the quality of patient care. The study team conducted twenty-five interviews with physicians, physician-administrators, and non-physician administrators at sixteen hospitals in ten states. Eight of the sixteen hospitals in the sample operate under the Directives. A manuscript reporting the findings of the ectopic pregnancy study is currently under review. Angel M. Foster, Amanda Dennis & Fiona Smith, *Do Religious Restrictions Influence Ectopic Pregnancy Management? Results From a National Qualitative Study*, 20 Women's Health Issues (Jacob's Institute of Women's Health, forthcoming).
- 2 Of the top ten largest healthcare systems by number of hospitals, Catholic-affiliated systems rank fourth, fifth and ninth. Only one other religiously-affiliated system makes the top ten, and it comes in tenth. The top ten Catholic health care systems comprise a total of 372 hospitals. The top ten non-Catholic religiously-affiliated systems have a total of 133 hospitals. Joe Carlson and Vince Galloro, *Special Feature, Big Dividends*, Mod. Healthcare, June 7, 2010, at 18, 24 (annual survey of hospital systems).
- 3 Cynthia D. Mulrow & Kathleen N. Lohr, *Proof and Policy From Medical Research Evidence*, 26 J. of Health Pol. Pol'y & L. 249 (2001).
- 4 See National Women's Law Center, *Complaint regarding the treatment of miscarriage and ectopic pregnancy to Marilyn Tavenner, Thomas E. Hamilton and James Randolph Farris, M.D.* Jan. 9, 2011, available at <http://www.nwlc.org/cmscomplaintJan2011>.
- 5 See, e.g., Rob Stein, *Pharmacists' Rights at Front of New Debate*, Wash. Post, Mar. 28, 2005, at A1 (noting trend of pharmacist interfering with women's access to contraceptives); see also Farr A. Curlin et al., *Religion, Conscience, and Controversial Clinical Practices*, 256 New Eng. J. Med. 593, 593 (2007) (eighteen percent of doctors believe they have the right to deny a referral for treatment to which they are religiously or morally opposed; while eight percent believe it is acceptable to withhold information about the existence of such treatments).
- 6 See, e.g., Edward J. Furton, Peter J. Cataldo & Albert S. Moraczewski, eds., *Catholic Health Care Ethics: A Manual for Practitioners* (National Catholic Bioethics Center 2d ed., 2009) (hereinafter *Catholic Health Care Ethics*).
- 7 More than thirty percent of all patients in Washington, South Dakota, Iowa, Wisconsin and Alaska are served by Catholic hospitals. Catholic Health Association of the United States, *Catholic Healthcare in the United States* (Jan. 2010).
- 8 Employees' right to assert their religious beliefs in the workplace is protected by Title VII of the Civil Rights Act of 1964. Religious beliefs only must be accommodated by an employer to the extent that an accommodation does not impose an undue hardship. Courts have found that employers of health care workers own a duty of care to their patients who may be harmed by religiously-based refusals to provide care. *Shelton v. University of Med. and Dentistry of N.J.*, 223 F.3d 220 (3^d Cir. 2000) (affirming summary judgment in favor of defendant; hospital offered reasonable accommodation to transfer a nurse to a different ward when she refused to treat certain pregnancy complications); *Noesen v. Medical Staffing Network, Inc.*, 2006 WL 1529664 (W.D. Wis.) (granting summary judgment to defendant; employer offered pharmacist who refused to fill contraceptive prescriptions a reasonable accommodation; pharmacist violated the agreement when he refused to notify other members of the staff that a customer was waiting to have such a prescription filled), *aff'd*, 2007 WL 1302118, 100 Fair Empl. Prac. Cas. (BNA) 926 (7th Cir.) (slip op.); *Grant v. Fairview Hosp.*, 2004 WL 326694, 93 Fair Empl. Prac. Cas. (BNA) 685 (D. Minn. 2006) (granting defendant's motion for summary

judgment; employer did not have to accommodate ultrasound technician's religiously based need to "counsel" pregnant patients who were considering abortions, risking harm to third parties owed a duty of care by the defendant).

- 9 United States Conference of Catholic Bishops, *Ethical and Religious Directives for Catholic Health Care Services* (2001), available at www.usccb.org/bishops/directives.shtml. The *Directives* set forth principles that govern the delivery of health care services at Catholic-affiliated health care institutions. Each hospital's administration, the local diocese and the Bishop presiding over the hospital interpret these guidelines and establish their specific policies and practices.
- 10 See Chris LaFortune, *Hospital Rules Prompt Pregnancy Transfers*, Oak Leaves (Oak Park, Ill.), Oct. 13, 2004, at 5 (reporting on the transfer of one patient with premature rupture of the membranes and another with an ectopic pregnancy due to application of the Directives at a newly Catholic-affiliated hospital).
- 11 Royal College of Obstetricians and Gynaecologists, *The Management of Early Pregnancy Loss, Guideline 25*, Oct. 2006, at 1 (hereinafter *The Management of Early Pregnancy Loss*). Miscarriage is also referred to as spontaneous abortion. Craig P. Griebel, M.D. et al., *Management of Spontaneous Abortion*, 72 Am. Fam. Physician 1243, 1248 (Oct. 2005) (hereinafter *Management of Spontaneous Abortion*).
- 12 42 U.S.C. 1395dd(e)(3) (B).
- 13 Miscarriages are often accompanied by the physical trauma of significant pain, cramping and bleeding. *Management of Spontaneous Abortion*, at 1248.
- 14 *Management of Spontaneous Abortion*, at 1246.
- 15 This is typically done through dilation and curettage (D&C), but can also be done with medication. *Management of Spontaneous Abortion*, at 1246; *The Management of Early Pregnancy Loss*, at 6.
- 16 *Management of Spontaneous Abortion*, at 1248. Sepsis is a risk of delaying treatment. Some hospitals require evidence of sepsis, a potentially deadly blood infection, before they will intervene.
- 17 Sr. Jean duBlois & Fr. Kevin D. O'Rourke, *Care for the Beginning of Life: The Revised Ethical and Religious Directives Discuss Abortion, Contraception and Assisted Reproduction*, Catholic Health Association of the United States, Health Progress, Sept.–Oct. 1995, at 36, 39 (hereinafter *Care for the Beginning of Life*) (interventions prior to life-threatening symptoms are appropriate).
- 18 *Management of Spontaneous Abortion*, at 1246.
- 19 Amanda T. Rodemann, et al., *Management of Early Spontaneous Pregnancy Loss*, Journal Watch Women's Health, Apr. 1, 2010.
- 20 *Management of Spontaneous Abortion*, at 1248.
- 21 Ectopic pregnancies account for ten to fifteen percent of all maternal deaths in the United States. Anne-Marie Lozeau & Beth Potter, *Diagnosis and Management of Ectopic Pregnancy*, 72 Am. Fam. Physician 1707, 1707 (2005) (hereinafter *Diagnosis and Management of Ectopic Pregnancy*).
- 22 *Id.*
- 23 *Id.*
- 24 *Id.* at 1709
- 25 *Id.* at 1711.
- 26 Royal College of Obstetricians and Gynaecologists, *The Management of Tubal Pregnancy, Guideline 21*, May 2004, at 6 (hereinafter *The Management of Tubal Pregnancy*) ("expectant management should only be used for asymptomatic women"); *Diagnosis and Management of Ectopic Pregnancy*, at 1707 (expectant management is only appropriate when the patient has "low and declining" hormone levels).
- 27 *The Management of Tubal Pregnancy*, at 5.
- 28 *Diagnosis and Management of Ectopic Pregnancy*, at 1713 (noting reduced fertility resulting from removal of fallopian tube).
- 29 *Id.* This would include both salpingostomy (removal of the embryo from the tube) or salpingectomy (removal of the section of the tube).
- 30 Kurt T. Barnhart, *Ectopic Pregnancy*, 361 New Eng. J. Med. 379, 384 (July 2009).
- 31 *The Management of Tubal Pregnancy*, at 2 (identifying symptoms where immediate treatment is indicated).
- 32 *Directive 48* states "In case of extrauterine pregnancy, no intervention is morally licit which constitutes a direct abortion."
- 33 Both tube-sparing surgery and methotrexate are deemed permissible by the Catholic Health Association of the United States, as the intent of either treatment is not to terminate the pregnancy, but to prevent the woman from suffering severe organ damage or even death. Furthermore, an ethicist for the National Catholic Bioethics Center, which takes a more conservative approach to the *Directives*, has also supported the use of both tube-sparing surgery and methotrexate. *Catholic Health Care Ethics*, Chapter 10B. The Ethics of Treating Ectopic Pregnancy, Arguments in Favor of Salpingostomy.
- 34 The more restrictive view is, however, supported by some theologians. See *Catholic Health Care Ethics*, Chapter 10B. The Ethics of Treating Ectopic Pregnancy. Arguments Against Salpingostomy and Methotrexate.
- 35 *Care for the Beginning of Life*, at 39 ("Newer interventions directly address the pathological condition understood now as the point of attachment of the embryo to the wall of the fallopian tube), cure the condition, and preserve fertility. As in the past, the resulting death of the embryo is deemed an indirect consequence"); and Rev. Kevin O'Rourke, *Applying the Directives: The Ethical and Religious Directives Concerning Three Medical Situations Require Some Elucidation*, Catholic Health Association of the United States, Health Progress, July–August 1998, at 64 (referring to the use of methotrexate, Rev. O'Rourke said "[I]t seems well within moral probity for the obstetrician to intend the removal of the trophoblast and to employ the means to fulfill the intention, even though that means the death of the fetus will result.>").
- 36 This may legally permissible in some circumstances since these patients are, by definition, stable.

- 37 Committee on Ethics, *The Limits of Conscientious Refusal in Reproductive Medicine*, American College of Obstetricians and Gynecologists, Nov. 2007, at 5, reaffirmed 2010.
- 38 *Id.*
- 39 American Medical Association, *Code of Medical Ethics, Opinion 2.035, Futile Care*, June 1994. In this instance, a woman is making treatment decisions on behalf of herself and her fetus. See Frank A. Chervenak & Laurence B. McCullough, *An Ethically Justified Practice Approach to Offering, Recommending, Performing, and Referring for Induced Abortion and Feticide*, 201 Am. J. Obstetrics & Gynecology 560 (Dec. 2009).
- 40 While the principle of informed consent requires a physician to disclose all medical options, this obligation “does not compel a physician to provide interventions that in his view would be harmful, without effect or ‘medically in appropriate.’” *Casey v. St. Francis Med. Ctr.*, 719 So.2d 1072, 1075 (La. App. 2 Cir. 8/26/98).
- 41 Providing treatment without advising a patient of alternative treatments can also breach a providers’ duty of care, especially when the treatment alternative is “less invasive or risk prone.” See, e.g., *Guebard v. Jabaay*, 117 Ill. App. 3d 1, 72 Ill. Dec. 498, 452 N.E.2d 751 (2^d Dist. 1983) (patient not advised that alternative operation could be performed and would likely be successful); *Marino v. Ballestas*, 749 F.2d 162 (3^d Cir. 1984) [physician failed to tell plaintiff’s parents that waiting for a nerve to regenerate was the favored treatment option]; *Zacher v. Petty*, 312 Or. 590, 826 P.2d 619 (1992) (patient not told of non-surgical alternatives to a hysterectomy); see also 35 Causes of Action 2d 63, *Causes of Action Against Physicians for Failure to Obtain Patient’s Informed Consent* § 12 (2010).
- 42 A recent study confirms that doctors often see transfers as a solution, noting that eighty-six percent of those surveyed believe that when physicians’ clinic judgment conflicts with religiously based policies, patients should be transferred. The study did not, however, address how such conflicts are resolved in emergency situations. Debra B. Stulberg et al., *Physical Conflicts with Religious Hospital Policy*, J. Gen. Internal Med. (Apr. 2010).
- 43 But note that since this patient was a candidate for methotrexate, she was, by definition, in a stable condition and could be properly transferred under EMTALA. Only unstable patients are required to receive immediate treatment under EMTALA.
- 44 Lori R. Freedman, et al., *When There’s a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals*, 98 Am. J. of Pub. Health 1774 (Oct. 2008).
- 45 Centers for Medicare & Medicaid Services, 42 C.F.R. § 482.55, Condition of participation, Emergency services.
- 46 Centers for Medicare & Medicaid Services, 42 C.F.R. § 482.51, Condition of participation, Surgical services.
- 47 Centers for Medicare & Medicaid Services, 22 C.F.R. § 482.54, Conditions of participation, Outpatient Services.
- 48 *Cruzan v. Director, Missouri Dep’t of Health*, 497 U.S. 261 (1990).
- 49 According to the American Medical Association:
- [a] patient’s right of self-decision can be effectively exercised only if the patient possesses enough information to enable an informed choice Informed consent is a basic policy in both ethics and law that physicians must honor, unless the patient is unconscious or otherwise incapable of consenting and harm from failure to treat is imminent.
- AMA E-8.08.
- The AMA provides detailed guidance on what is required for full informed consent:
- Health care professionals should inform patients or their surrogates of their clinical impression or diagnosis; alternative treatments and consequences of treatments, including the consequence of no treatment; and recommendations for treatment. Full disclosure is appropriate in all cases, except in rare situations in which such information would, in the opinion of the health care professional, cause serious harm to the patient.
- American Medical Association, *Informed Consent and Decision-Making in Health Care*, H-140.989.
- The AMA is also clear that “withholding medical information from patients without their knowledge or consent is ethically unacceptable.” AMA, E-8.082 *Withholding Information from Patients*.
- 50 American College of Obstetricians and Gynecologists, *Informed Consent, Committee Opinion 439*, Aug. 2009, at 4.
- 51 See, e.g., Alaska Stat. § 47.30.837 (2007); Rev. Code Wash. § 7.70.050(1)(a) (2007); and Utah Code Ann. § 78B-3-406 (2008).
- 52 Centers for Medicare & Medicaid Services, 42 C.F.R. § 482.13(b)(2), Hospital Conditions of Participation: Patients’ Rights.
- 53 States taking a proactive approach specifically lay out the information required to obtain consent, albeit with varying levels of specificity. For example, in California, the common law requires that a patient receive sufficient information to make a “meaningful decision” regarding her own health care. *Cobbs v. Grant*, 8 Cal.3d 229 (Cal. 1972). In Alaska and Washington, a health care provider must disclose all “material” information or facts relevant to the patient’s decision to give or withhold consent. Alaska Stat. § 47.30.837 (2007); Wash. Rev. Code Ann. § 7.70.050 (2007). Connecticut, similarly focusing on materiality, specifies four components of information that must be provided to obtain consent: the nature of the procedure; its risks and hazards; alternatives to the procedure, and; its anticipated benefits. *Levesque v. Bristol Hosp.*, 286 Conn. 234, 253-54 (Conn. 2008). In Maryland, the law requires that, in acquiring consent, the physician must not substitute his own judgment for that of the patient. *Reed v. Campagnolo*, 332 Md. 226, 242 (Md. 1993).
- 54 Generally, a prima facie case for malpractice based on failure to obtain informed consent requires
1. the physician had a duty to disclose sufficient information about a proposed treatment to obtain the patient’s informed consent;
 2. the physician breached that duty;
 3. the physician’s failure to disclose adequate information was a proximate cause of the patient’s decision to consent to a treatment to which the patient would have withheld consent if he or she had been adequately informed; and

4. a potential adverse consequence of the treatment materialized, resulting in a detriment to the patient.
- 35 Causes of Action 2d 63 *Causes of Action Against Physicians for Failure to Obtain Patient's Informed Consent* (2010).
- 55 American College of Obstetricians and Gynecologists, *Informed Consent, Committee Opinion 439*, Aug. 2009, at 5.
- 56 42 U.S.C. § 1395dd(e)(1).
- 57 42 U.S.C. § 1395dd(e)(3) (B).
- 58 Centers for Medicare and Medicaid Services, State Operations Manual, Appendix V—Interpretive Guidelines—responsibilities of Medicare Participating Hospitals in Emergency Cases, Part II, Tag A-2407/C-2407, 489.24(d)(1)(i) states in relevant part:
 ...
 After the medical screening has been implemented and the hospital has determined that an emergency medical condition exists, the hospital must provide stabilizing treatment within its capability and capacity.
 Capabilities of a medical facility mean that there is physical space, equipment, supplies, and specialized services that the hospital provides (e.g., surgery, psychiatry, obstetrics, intensive care, pediatrics, trauma care).
 Capabilities of the staff of a facility means the level of care that the personnel of the hospital can provide within the training and scope of their professional licenses. This includes coverage available through the hospitals on-call roster.
- 59 CMS periodically issues interpretive guidelines on EMTALA to its regional offices, SAs and hospitals under its jurisdiction in the form of a “Survey and Certification Letter.” Centers for Medicare and Medicaid Services, State Operations Manual, Chapter 1 – Program Background and Responsibilities (Rev. 1, 05-21-04), Section 1006. Policy-making responsibility includes “establishing operational policy for the certification process’ and conveying operations instructions and official interpretations of policy to the SAs and CMS’ regional offices.” CMS has previously issued guidance regarding provider confusion on EMTALA requirements in an effort to ensure consistent enforcement. *See, e.g., Survey and Certification Letter from Director, Survey and Certification Group, Centers of Medicaid and State Operations to Associate Regional Administrators, Division of Medicaid and State Operations, Regions I – X. regarding On-Call Requirements-EMTALA, Jan. 28, 2008* (issuing clarification based on concerns brought to the Directors’ attention by “the medical community”), available at <http://www.cms.gov/surveycertificationgeninfo/pmsr/itemdetail.asp?itemid=CMS022614>.
- 60 CMS provides guidance to the State Survey Agency Directors regarding the requirements of the CoPs.
- 61 The State Survey Agencies are also authorized to conduct investigations of any complaints they receive. State Operations Manual, Chapter 1 – Program Background and Responsibilities (Rev. 1, 05-21-04), Section 1002.
- 62 When a complaint is received by a regional office, the regional office then assigns a State Survey Agency (SA) to investigate the complaint. Once the HHS’ Office of Inspector General (OIG) receives the findings of the SA investigation, it has the authority to hold hospitals accountable for their violations of the Medicare Conditions of Participation. Centers for Medicare and Medicaid Services, State Operations Manual, Appendix V – Interpretive Guidelines – Responsibilities of Medicare Participating Hospitals in Emergency Cases.
- 63 *See National Women’s Law Center, Complaint regarding the treatment of miscarriage and ectopic pregnancy to Marilyn Tavenner, Thomas E. Hamilton and James Randolph Farris, M.D.* Jan. 9, 2011, available at <http://www.nwlc.org/cmscomplaintJan2011>.
- 64 *See ACLU, Complaint to Marilyn Tavenner, Denial of Reproductive Health Care at Religious Hospitals*, July 1, 2010, available at http://www.aclu.org/files/assets/Letter_to_CMS_Final_PDF.pdf.
- 65 CMS contracts with State Survey Agencies (SAs) to periodically assess compliance with the CoPs, and report violations to CMS. State Operations Manual, Chapter 1 – Program Background and Responsibilities (Rev. 1, 05-21-04), Section 1010.
- 66 State Operations Manual, Chapter 1 – Program Background and Responsibilities (Rev. 1, 05-21-04).
- 67 For example, CMS investigated the health insurer Humana for telling Medicare enrollees that they would lose their benefits under health reform bills pending in Congress. Rebecca Vesely, *CMS probing Humana Letter Aimed at Seniors*, Mod. Healthcare, Sept. 21, 2009, available at <http://www.modernhealthcare.com/article/20090921/REG/309219941>. CMS followed its investigation with guidance to insurance companies regarding their communications with beneficiaries. Center for Medicare and Medicaid Services, *Press Release, Medicare Issues New Guidance to Insurance Companies on Medicare Mailings: Guidance Comes after Humana Distributed Potentially Misleading Materials*, Sept. 21, 2009, available at <http://www.cms.gov/apps/media/press/release.asp?Counter=3522&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&showAll=&pYear=&year=&desc=false&cboOrder=date>.
- 68 This issue may also be appropriate for a GAO investigation, or an investigation and report by the Institute of Medicine, a division of the National Academy of Sciences, which provides advice to the government regarding health and science policy matters.
- 69 CMS routinely issues specific guidance to clarify particular procedures that hospitals are required to have in place. State Operations Manual, Chapter 1 – Program Background and Responsibilities (Rev. 1, 05-21-04).
- 70 *See, e.g., Ga. Code Ann. § 31-9-6* (2009); *Idaho Code Ann. § 39-4503* (2007); *La. Rev. Stat. Ann. § 40:1299.40* (2009); *Or. Rev. Stat. § 677.097* (1977).
- 71 Fla. Admin. Code 59A-3.253(2)(d) (requiring the Agency for Health Care Administration to work with non-accredited hospitals during annual licensing inspection to “ensure compliance with standards of care.”); *Ky. Admin. Reg. 906 KAR 1:110, Critical Access Hospital Services, Administration and Operation Section 3 (10)(c)(5)-(7)*. states that critical access hospitals must ensure continuous and effective mechanisms for evaluating and improving the standard of care.

- 72 Cal. Health & Safety Code § 1317-7; Fla. Stat. Ann. § 395.1041; La. Rev. Stat. Ann. § 40:2113.4.; Md. Code Ann. Health-Gen. §§ 19-307.1(8), -308.2; Mich. Stat. Ann. §333.20201(2)(a); Nev. Rev. Stat. Ann. § 439B.410; N.H. Rev. Stat. Ann. §151:21; N.Y. Pub. Health Law § 2805-b; Wyo. Stat. Ann. § 35-2-115.
- 73 Judy Appelbaum and Jill Morrison, *Hospital Mergers and the Threat to Women's Reproductive Health Services: Applying the Antitrust Laws*, 26 N.Y.U. Rev. of L. & Soc. Change 1 (2000-2001).
- 74 According to CHA,
 CHA responds to the needs of its members with consultation services, educational programs, publications, and Web-based tools addressing strategic areas of mission, ethics, leadership formation, sponsorship, advocacy and community benefit.
 Catholic Health Association of the United States, *CHA Factsheet*, 6, available at <http://www.chausa.org/subhome.aspx?pageid=852>.
- 75 Ethical guidance provided by CHA includes “consultations, presentations, hosting dialogues and working groups, collaborating with our colleagues, developing and sharing resources, offering educational programs, and research and writing.” Catholic Health Association of the United States, *Our Work, Overview, Ethics*, available at http://www.chausa.org/pages/our_work/ethics/overview/.
- 76 See *Journal Misstates Catholic Principles Relating to Maternal Health Crises*, 25 Catholic Health World [original pagination unavailable], (May 1, 2009). CHA claimed that the hospitals misunderstood what was required by the *Directives* stating, “I think ethicists have a pretty good understanding of this. Doctors and nurses might be misinterpreting this, and ethics committees could at times be misinterpreting this.” Despite CHA’s support for providing immediate treatment in such cases, the National Catholic Bioethics Center states “There is ample published evidence...that when no clinical or laboratory evidence of infection is present, expectant management and use of antibiotics is an acceptable course that can result in fetal survival and acceptable maternal morbidity.” *Catholic Healthcare Ethics*, Chapter 9, *Early Induction of Labor*, at 112-13. This reading of the *Directives* is not as broad as CHA’s since it defines infection as the only symptom that a woman’s health is endangered. Applying the *Directives* in this manner could also violate EMTALA, since a woman could be in an unstable state without having signs of infection.
- 77 John Paul Slosar, Senior Director, Ethics, Ascension Health, *CHA Ethics Webinar: Ethics at the Beginning of Life: Complex Cases, Difficult Choices*, Nov. 2, 2010, available at <http://www.stream-express.com/se/Meetings/Playback.aspx?meeting.id=638728>.
- 78 *Care for the Beginning of Life*, at 36 (interventions prior to life-threatening symptoms are appropriate).
- 79 See *infra* notes 17 and 33.
- 80 Sr. Patricia Talone, *A Time of Special Need*, 91 Catholic Health Progress 55 (Jan.-Feb. 2010); Debra S. Holbrook, *Sexual Violence, A Medical Center Responds*, 91 Catholic Health Progress 56 (Jan.-Feb. 2010); Sandra E. Reznik, “*Plan B: How it Works—Science Shows it is not an Abortifacient*,” 91 Catholic Health Progress 59 (Jan.-Feb. 2010); Ron Hamel, *Thinking Ethically About Emergency Contraception*, 91 Catholic Health Progress 62 (Jan.-Feb. 2010).
- 81 Ron Hamel, PhD, *Thinking Ethically About Emergency Contraception*, 91 Catholic Health Progress 62, 66 (Jan.-Feb. 2010).
- 82 42 U.S.C. § 1395dd(e)(1).
- 83 *Shelton v. University of Med. and Dentistry of N.J.*, 223 F.3d 220, 227 (3^d Cir. 2000). The court concluded:
 It would seem unremarkable that public protectors such as police and firefighters must be neutral in providing their services. We would include public health care providers among such public protectors. Although we do not interpret Title VII to require a presumption of undue burden, we believe public trust and confidence requires that a public hospital’s health care practitioners—with professional ethical obligations to care for the sick and injured—will provide treatment in time of emergency.
- 84 Ramesh Raghavan, *A Question of Faith*, 297 JAMA 1412 (2007).



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