

January 20, 2011

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Dear Ms. Tavenner, Mr. Hamilton and Dr. Farris;

The National Women's Law Center (the Center) is a public interest, non-profit organization dedicated to advancing the rights of women and girls. We are writing to bring to your attention a serious problem concerning the treatment of the pregnancy complications of miscarriage and ectopic pregnancy. Below we provide several examples of how both institutional and individual health care providers are violating their obligations under the Medicare Conditions of Participation (CoPs), and endangering the lives and health of patients. Each of the following reports, surveys and studies present the specter of potentially widespread violations of the CoPs due to both providers' and institutions' belief that their legal obligation to disclose all treatment options, provide the standard of care and provide emergency care may be ignored in the interest of their religious objections to providing needed medical care.

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We urge you to take immediate action because these conflicts may arise even more often as a result of the well-publicized case in Phoenix, Arizona at the Catholic-affiliated St. Joseph's Hospital.¹ The ethics committee of St. Joseph's allowed medical personnel to terminate the pregnancy of a mother of four who had a medical condition that would result in her death if she continued her pregnancy.² Because the patient could not be safely transferred to another hospital, St. Joseph's failure to provide the necessary stabilizing care due to its religious affiliation would have violated federal law.³ The Bishop presiding over the diocese where the hospital is located demanded that the hospital agree to refuse needed care in similar future circumstances.⁴ The hospital would not do so, and the Bishop revoked its Catholic affiliation.⁵ This case may prompt other Bishops to call upon the hospitals in their diocese to withhold treatment in violation of the law.

Additionally, given that both federal and state laws allow the refusal of care in certain limited circumstances,⁶ it is especially important for CMS to inform providers that such refusals are limited to the extent that they conflict with providers' existing legal obligations. We urge you to protect patients from the life endangering consequences of refusals to provide care to women experiencing miscarriage and ectopic pregnancy in circumstances where the law requires their protection.

Therefore, we are writing to request that you take several actions to ensure that the laws designed to protect patients' health are properly applied and enforced. First, we urge that the Director of the Certification and Survey Group issue a notification reminding hospitals that they are bound by all CoPs, and that this legal obligation remains regardless of any apparent or perceived conflict with any personal or institutional policies, preferences or considerations. Second, we urge the Administrator of the Consortium for Quality Improvement and Survey and Certification Operations to require hospitals to have in place policies and procedures to protect patients' legally enforceable rights. And finally, we request that the Principal Deputy Administrator direct the Regional Administrators to investigate the practices described below and take all necessary corrective action to prevent further violations of the CoPs.

¹A complaint regarding this case is pending before CMS. 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.

²Michael Clancy, *Nun at St. Joseph's Hospital Rebuked Over Abortion to Save Woman*, ARIZ. REPUBLIC, May 19, 2010, available at <http://www.azcentral.com/arizonarepublic/news/articles/2010/05/15/20100515phoenix-catholic-nun-abortion.html>. The facts in this case are, however, distinguishable from the circumstances described in further detail herein, in which the fetus or embryo's death is inevitable, apart from the medical condition of the pregnant woman. In the St. Joseph's case, the fetus's death would have eventually resulted from the mother's death.

³Because the patient was admitted to the hospital, technically, EMTALA did not apply. Instead, the Medicare Condition of Participation requiring hospitals to follow "acceptable standards of practice" in the provision of surgical services would apply to require immediate treatment. 42 C.F.R. § 482.51 (2010).

⁴Michael Clancy, *Phoenix Bishop Warns St. Joseph's Hospital on Health Care*, ARIZ. REPUBLIC, Dec. 15, 2010, available at <http://www.azcentral.com/community/phoenix/articles/2010/12/15/20101215phoenix-bishop-st-josephs-hospital.html>.

⁵Michael Clancy, *Phoenix Diocese Strips St. Joseph's Hospital of Catholic Status*, ARIZ. REPUBLIC, Dec. 22, 2010, available at <http://www.azcentral.com/community/phoenix/articles/2010/12/21/20101221phoenix-diocese-strips-st-josephs-hospital-catholic-status.html>.

⁶See Department of Health and Human Services, *Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law; Final Rule*, 73 Fed. Reg. 78,071 (Dec. 19, 2008). HHS has sought comments regarding the rescission of this rule. Department of Health and Human Services, *Rescission Proposal*, 74 Fed. Reg. 10,207 (Mar. 10, 2009). For a current summary of refusal laws, please visit the Guttmacher Institute, *State Policies in Brief, Refusing to Provide Health Services* (as of January 1, 2011), available at http://www.guttmacher.org/statecenter/spibs/spib_RPHS.pdf.

I. Background

A. Treatment of Pregnancy Complications Under the *Ethical and Religious Directives for Catholic Health Care Services*

Both individual and institutional providers have repeatedly refused to participate in, refer for or provide information to patients about particular reproductive health services. In many instances, these refusals contravene federal as well as other laws and regulations governing the care of patients. Federal laws and regulations require that patients receive the standard of care,⁷ adequate information on their treatment options,⁸ and emergency medical care.⁹ To focus on two particularly dangerous problems the National Women's Law Center has found from its research, review of published and peer reviewed journals, and individuals and health care providers who have contacted the Center – patients who have miscarriages and ectopic pregnancies are not receiving the care to which they are legally entitled due to the religiously based practices of institutions and individual health care providers. Moreover, it appears that providers may not disclose to patients all of the available medically appropriate treatment options, which is necessary for providers to obtain patients' adequate informed consent to treatment.

The Center's concerns are illustrated by practices within Catholic hospitals, as they are the largest provider of religiously-restricted health care in the United States.¹⁰ These hospitals follow the *Ethical and Religious Directives for Catholic Health Care Services*.¹¹ The *Directives* have been applied to deny women experiencing both ectopic pregnancies and miscarriages the treatment and information to which they are legally entitled, even when doctors have determined that there is no

⁷The Medicare Conditions of Participation state that participating hospitals "must meet the emergency needs of patients in accordance with acceptable standards of practice." Condition of participation, Emergency services, 42 C.F.R. § 482.55 (2010). This same condition also applies to Condition of participation: Surgical services, 42 C.F.R. § 482.51 (2010), and Condition of participation: Outpatient services, 42 C.F.R. § 482.54 (2010).

⁸All hospitals receiving Medicare funds must obtain informed consent from all patients prior to treatment:

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.

Hospital Conditions of Participation: Patients' Rights, 42 C.F.R. § 482.13(b)(2) (2010).

⁹EMTALA requires hospitals to provide stabilizing treatment to patients with emergency medical conditions who seek care at emergency rooms. An "emergency medical condition," is defined as:

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.

42 U.S.C. § 1395dd(e)(1).

Furthermore, EMTALA prohibits hospitals from transferring patients when they are unstable. An unstable patient is one who "within reasonable medical certainty" is likely to experience a "material deterioration" of her condition during a transfer to another hospital. 42 U.S.C. § 1395dd(e)(3)(B).

¹⁰Of 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, at 18, 24 (June 7, 2010) (annual survey of hospital systems).

¹¹The *Ethical and Religious Directives for Catholic Health Care Services* (hereinafter "*Directives*"), issued by the United States Conference of Catholic Bishops, provide guidance on the provision of health care in Catholic-affiliated institutions. The *Directives* can be found at <http://www.usccb.org/bishops/directives.shtml>.

medical intervention possible that would allow the patient to continue her pregnancy, and delaying care would only endanger the patient's health or life.¹²

Miscarriage Management

In certain circumstances, the medical standard of care requires that women experiencing miscarriage receive immediate treatment with either a medical or surgical uterine evacuation.¹³ This treatment is necessary to stabilize the woman's condition, prevent further hemorrhaging and the onset of potentially life threatening infections.¹⁴ Despite the medically accepted standard of care, it appears that some hospitals delay treatment of women experiencing miscarriages until there is no longer a fetal heartbeat, wait until the patient is actually showing symptoms of a life threatening infection, or transfer these patients to other hospitals for treatment.¹⁵ These transfers and delays in treatment deny these patients the standard of care, and present possible violations of the Emergency Medical Treatment and Active Labor Act (EMTALA).¹⁶

An article in the *American Journal of Public Health (AJPH)* reports numerous instances of women who suffered delays in receiving stabilizing care for miscarriages at Catholic hospitals.¹⁷ According to this article, treatment was delayed due to the *Directives*, and not because of the medical needs of the patients or the capacity of the hospital or its staff.¹⁸ The *AJPH* article provides a case study of a patient having a miscarriage who was transferred in an "unstable condition," according to the receiving hospital's doctor.¹⁹ The receiving doctor asked the doctor at the Catholic hospital who was attempting to transfer the patient why the hospital would not provide the uterine evacuation necessary to stabilize the patient. The physician stated that the hospital's religious affiliation

¹²Refusals to treat in these circumstances are therefore not protected by the Church Amendment, 42 U.S.C. § 300a-7, which protects individuals and institutions that refuse to participate in abortion or sterilization services.

¹³Royal College of Obstetricians and Gynaecologists, *The Management of Early Pregnancy Loss, Guideline 25*, at 1 (Oct. 2006); Craig P. Griebel, M.D. et al., *Management of Spontaneous Abortion*, 72 *Am. Fam. Physician* 1243, 1248 (Oct. 2005).

¹⁴*Id.*

¹⁵While 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. 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.

¹⁶Emergency Medical Treatment and Active Labor Act, 42 U.S.C. § 1395dd(e)(1).

¹⁷Lori R. Freedman, et al., *When There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals*, 98 *Am. J. of Pub. Health* 1774 (Oct. 2008).

¹⁸In these cases, because doctors could still detect a fetal heartbeat, and hospital administrators and ethics committees stated that any intervention was tantamount to an abortion under the *Directives*. *Id.* at 1777.

¹⁹*Id.*

prohibited the doctors from doing anything other than providing blood transfusions, which was insufficient to stabilize the patient.²⁰ This case describes an apparent violation of EMTALA.

Such delays and denials in the treatment of miscarriages have also been recently confirmed by a study conducted by Ibis Reproductive Health, a clinical and social science research organization, on behalf of the Center.²¹ The Ibis Study showed that doctors' ability to promptly treat women experiencing miscarriages according to the standard of care is hindered by their religiously-affiliated hospitals' imposition of treatment protocols that have nothing to do with patients' medical needs or hospitals' or staffs' ability to render treatment. For example, in order to avoid possible censure should their case be reviewed by hospital administrators, doctors reported performing medically unnecessary tests to confirm that a fetus was not viable, even when doctors were already certain of the fact, thus unnecessarily delaying the patient's care.²²

Furthermore, certain authorities have urged interpretations of the *Directives* that would subject patients to treatments that do not meet the standard of care. One guide for interpreting the *Directives* states that dilation and curettage (D&C) should never be used to complete a miscarriage,²³ yet there are circumstances where a D&C would be required by the standard of care.²⁴

The *Directives* have even been applied to forbid the treatment of a woman who had suffered a miscarriage, even though the fetus no longer had a heartbeat. A woman contacted the Center to report that she was denied a D&C at St. Vincent's Hospital in New York. This hospital has since closed, but this case provides an additional example of a patient with a pregnancy complication being refused care in violation of the CoPs due to a doctor's restrictive and in this case, blatantly wrong,²⁵ interpretation of the *Directives*. In the course of this refusal, the patient was denied adequate information about her condition, which hindered her ability to seek care at another facility.²⁶ Additionally, hospital personnel also failed to assist the patient in utilizing the services

²⁰ *Id.*

²¹ 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 "Ibis Study"), available at <http://www.ibisreproductivehealth.org/news/documents/Summaryofqualitativestudy.pdf>.

²² *Id.* at 2.

²³ See, e.g., *Catholic Health Care Ethics: A Manual for Practitioners* 113 (Edward J. Furton, Peter J. Cataldo & Albert S. Moraczewski, eds., National Catholic Bioethics Center 2^d ed., 2009).

²⁴ Royal College of Obstetricians and Gynaecologists, *The Management of Early Pregnancy Loss, Guideline 25*, at 1 (Oct. 2006); Craig P. Griebel, M.D. et al., *Management of Spontaneous Abortion*, 72 *Am. Fam. Physician* 1243, 1248 (Oct. 2005). A D&C is a common gynecological procedure often used to either stop bleeding or to clear the uterus after a miscarriage in order to prevent infection. American College of Obstetrics and Gynecology, *Dilation and Curettage*, available at http://www.acog.org/publications/patient_education/bp062.cfm.

²⁵ There is nothing in the *Directives* that prohibits a Catholic institution from performing a D&C, which is a procedure commonly used in both the diagnosis and treatment of various gynecological conditions. A review of materials interpreting *Directive 45* regarding abortion did not identify any interpretations that considered the performance of a D&C an abortion in cases where the fetus is no longer alive.

²⁶ This patient was not informed that her fetus had died at ten weeks gestation. When trying to find a provider to perform a D&C, she was requesting a D&C at thirteen weeks gestation, which some providers did not do, thus delaying her ability to find care.

that were available at St. Vincent's²⁷ to ensure that she got the most prompt care possible, another violation of the CoPs.²⁸

Ectopic Pregnancy

Ectopic pregnancies, most which occur in a fallopian tube, are another area of serious concern. An untreated ectopic pregnancy can cause a rupture of the fallopian tube, which can be fatal.²⁹ Nonetheless, it appears that patients with ectopic pregnancies are being subjected to unnecessary treatment delays, and refusals to provide the standard of care in religiously-affiliated hospitals. The Ibis Study revealed that doctors attempting to comply with the *Directives* and avoid hospital censure subjected patients with ectopic pregnancies to medically unnecessary tests, and therefore needless delays in care, ordered solely to establish compliance with the *Directives*.³⁰ One doctor reported that several instances of tubal rupture had occurred as a result of these delays.³¹

Furthermore, doctors in this study report that two medically indicated treatments for ectopic pregnancies are prohibited by their hospitals due solely to religious and not medical concerns – a medication called methotrexate and surgery that removes the embryo while sparing the fallopian tube.³² Yet these are two treatment options that may actually be required for certain patients to receive the standard of care.³³ Furthermore, both treatments are less invasive than other options allowed by these hospitals, and may increase patients' chances of successful pregnancy outcomes in the future.³⁴

²⁷ The hospital's website indicated that the hospital performed routine gynecological surgery, which includes the D&C procedure.

²⁸ 42 C.F.R. § 482.54 (2010) states:

If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice.

(a) Standard: Organization. Outpatient services must be appropriately organized and integrated with inpatient services.

(b) Standard: Personnel. The hospitals must (1) Assign an individual to be responsible for outpatient services; and (2) Have appropriate professional and nonprofessional personnel available.

²⁹ 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).

³⁰ 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).

³¹ *Id.*

³² *Id.* The Catholic Health Association has explicitly stated that ectopic pregnancies should be treated immediately and that no particular method of treatment is banned by the *Directives*. 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, at 36, 39 (Sept. - Oct. 1995). Holding an opposing view is the National Catholic Bioethics Center, which opines that these options are not permitted under the *Directives*. *Catholic Health Care Ethics*, *supra* note 23, at Chapter 10, Ectopic Pregnancy, A. Arguments Against Salpingostomy and Methotrexate. *But see Catholic Health Care Ethics*, *supra* note 23, Chapter 10, Ectopic Pregnancy, B. Arguments in Favor of Salpingostomy and Methotrexate (agreeing with the position of the Catholic Health Association).

³³ Anne-Marie Lozeau & Beth Potter, *Diagnosis and Management of Ectopic Pregnancy*, 72 Am. Fam. Physician 1707, (2005); Royal College of Obstetricians and Gynaecologists, *The Management of Tubal Pregnancy, Guideline 21* (May 2004).

³⁴ *Id.*

B. Individual and Institutional Refusals to Treat Pregnancy Complications Beyond the Directives

The problem of refusals to treat pregnancy complications is not just limited to hospitals operated under the *Directives*. In an essay in the *Journal of the American Medical Association*,³⁵ a doctor writes of his shock at how a Baptist hospital placed its religious beliefs above the needs of his wife, who was miscarrying at twenty-one weeks gestation. Doctors determined that nothing could be done to save the pregnancy, but she was not yet showing signs of a life threatening infection, so the hospital refused to induce labor. The hospital considered that to be an abortion, which it would not provide. She was eventually transferred to another hospital where labor was induced, and the twins were stillborn. While Baptist hospitals do not have written policies as do Catholic hospitals, this case shows that some apparently enforce a prohibition on abortion in a potentially dangerous manner, in violation of their legal obligations.

Nor is the refusal to treat certain pregnancy conditions limited to only religiously-affiliated institutions. Yvonne Shelton, a nurse employed in the labor and delivery unit at a nonsectarian hospital in New Jersey, refused to assist in an emergency hysterectomy for a woman who was eighteen weeks pregnant and experiencing placenta previa, a condition that endangered her life.³⁶ She believed, based on her Pentecostal faith, that any intervention that terminated fetal life was an abortion, which she would not provide. In this case, the hospital took appropriate action to ensure that no future patients suffered delays in care as a result of the beliefs of employees such as Ms. Shelton. Nonetheless, there remains the possibility that hospitals would not take adequate measures to ensure that patients are protected.

II. Request for Corrective and Preventive Action

While most of the examples provided above took place in religiously-affiliated hospitals, it is imperative that the following corrective and preventive measures apply to all hospitals bound by the Medicare Conditions of Participation. As shown by the *Shelton* case, individual employees can also impede the prompt treatment of pregnancy complications.

First, we request that the Director of the Survey and Certification group issue a notice to all hospitals that are bound by the CoPs to remind them that they are required to comply with the CoPs when treating patients presenting with miscarriage or ectopic pregnancy.³⁷ CoPs require that all

³⁵Ramesh Raghavan, MD, PhD, *A Question of Faith*, 297 JAMA 1412 (2007).

³⁶*Shelton v. University of Med. and Dentistry of N.J.*, 223 F.3d 220, 227 (3rd Cir. 2000). The hospital fired Shelton when she refused a transfer to another unit where she would not have to deal with such conflicts. She sued the hospital, claiming religious discrimination in violation of Title VII, the federal law prohibiting employment discrimination. The court found that the hospital's offer to transfer her to another unit was a reasonable accommodation, and that it had a responsibility to protect patients seeking emergency care from a nurse that refused to treat them. 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.

³⁷CMS 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

hospitals provide prompt treatment to women presenting with pregnancy-related medical conditions, despite any individual or institution's perceived or actual objections to certain procedures.

Furthermore, we request that hospitals be informed that if a patient is not presenting with an emergency medical condition, and is therefore not entitled to immediate stabilizing treatment under EMTALA, the Patient's Rights provision of the CoPs regarding informed decision-making still requires that she be given all pertinent information about her condition and comprehensive information on all available treatment options, even if those options are not provided by the hospital. Any treatment that the patient receives must conform to the standard of care, even if such treatment is in conflict with the religious or moral beliefs of an institution or individual.

Second, we request that the Consortium for Quality Improvement and Survey and Certification Operations require that all hospitals bound by the CoPs have procedures in place to ensure that women experiencing pregnancy complications are receiving the care to which they are entitled under federal law.³⁸

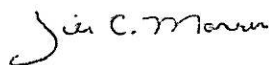
And finally, it is imperative that the Principal Deputy Administrator order all Regional Administrators³⁹ to investigate this serious lapse in the provision of health care and order immediate corrective action where violations are found.⁴⁰ Given the deviation from the standard of care, it is likely that these practices are resulting in poorer health outcomes and increased health care costs.

Thank you in advance for your careful consideration of this matter. We look forward to your response. If you have any further questions, Jill Morrison can be reached at 202-588-7616.

Sincerely,



Judy Waxman
Vice President Health and Reproductive Rights



Jill C. Morrison
Senior Counsel

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/surveyscertificationgeninfo/pmsr/itemdetail.asp?itemid=CMS022614>.*

³⁸CMS routinely issues specific guidance to clarify particular procedures that hospitals are required to have in place. Centers for Medicare and Medicaid Services, *State Operations Manual*, Chapter 1 - Program Background and Responsibilities (Rev. 1, 05-21-04).

³⁹Hospitals operated under the *Directives* are present in every region. *See Catholic Health Association of the United States, Catholic Healthcare in the United States* (Jan. 2010).

⁴⁰CMS contracts with State Survey Agencies (SAs) to periodically assess compliance with the CoPs, and report violations to CMS. Centers for Medicare and Medicaid Services, *State Operations Manual*, Chapter 1 - Program Background and Responsibilities (Rev. 1, 05-21-04), Section 1010.