REGULATORY OVERVIEW OF HEALTH CARE: DEFINING THE ROLES OF REGULATORY OVERSIGHT FROM WHO TO LOCAL HEALTH DEPARTMENTS

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I. INTRODUCTION

There are literally hundreds of international, federal, and state agencies that are involved with promoting and protecting the health of the American public. This paper identifies and briefly examines various state and federal agencies, as well as private regulatory organizations, that are involved in regulating health care, but is by no means an attempt to address all relevant health agencies.

II. WORLD HEALTH ORGANIZATION

The World Health Organization (WHO) is an agency of the United Nations officially created in 1948 when UN members signed its constitution on April 7, 1948. Every year since then, April 7 has been recognized as World Health Day. The WHO's purpose, as stated in the UN's Constitution, is promoting "the highest possible level of health" for all people. The WHO defines health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." The WHO has been committed to combating disease including smallpox, malaria, cholera, typhoid, AIDS, and Severe Acute Respiratory Syndrome (SARS).

The WHO operates in over 140 countries throughout the world, including the United States. The WHO's Regional Office for the Americas, known as the Pan American Health Organization (PAHO), is headquartered in Washington, D.C. The PAHO's mission is to "strengthen national and local health systems and improve the health of the peoples of the Americas, in collaboration with the Ministries of Health, other government and international agencies, nongovernmental organizations, universities, social security agencies, community groups, and many others."[1]

International Health Regulations (IHR)

The International Health Regulations (IHR) are an international legal instrument which is legally binding on all WHO Member States who have not rejected them and all Non-Member States of WHO that have agreed to be bound by them. In May, 2005, the WHO's 59th World Health Assembly revised its International Health Regulations, referred to as the IHR(2005), as an international treaty. Prior to this revision, the current regulations IHR(1969) were more limited in their focus on three global diseases: yellow fever, plague, and cholera, but were not addressing more current global health issues such as avian influenza or pandemic influenza. The new IHR (2005) regulations are scheduled to replace the current IHR(1969) in June, 2007. The purpose of the IHR(2005) is to "prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade."[2]

To rapidly respond to the spread of disease, the IHR(2005) has created a legal framework to gather information to determine when a disease outbreak constitutes a "public health emergency of international concern."[3] The IHR(2005) reporting procedures of health emergencies of international concern constitute a broader requirement than the previous requirement of Member States notifying the WHO of the outbreak of specific diseases. Whether an event is a public health emergency of international concern, the IHR(2005) have

[1] *See* http://www.paho.org/english/paho/What-PAHO.htm (Last visited on Sept. 6, 2006).

[2] *See* http://www.who.int/en/ (Last visited on Sept. 6, 2006).

[3] *See* IHR(2005) Article 6.1.

established 4 criteria:

> (1) Is the public health impact serious?
>
> (2) Is the event unusual or unexpected?
>
> (3) Is there a significant risk of international spread?
>
> (4) Is there a significant risk of international trade or travel restrictions?

The goal of the WHO by implementing the IHR(2005) is to create a global surveillance system enabling a world-wide approach to the prevention of pandemic disease such as influenza and SARS.

III. FEDERAL AGENCIES WITH HEALTH CARE REGULATORY OVERSIGHT

A. Department of Health and Human Services[4]

The Department of Health and Human Services (HHS) is the United States Government's "principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves."[5] The HHS has over 67,000 employees and has a $698 billion budget for the 2007 fiscal year. The HHS includes more than 300 programs covering a wide variety of activities including: disease prevention; assuring food and drug safety; Medicare; Medicaid; child abuse and domestic violence prevention; services for older Americans; and medical preparedness for emergencies, including potential terrorism. The HHS's programs are carried out through eleven operating divisions, including eight agencies in the U.S. Public Health Service and three human services agencies.[6] Included in the U.S. Public Health Service Agencies that are under the HHS are the National Institute of Health (NIH), the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the Agency for Healthcare Research and Quality (AHRQ). Also, the human service agencies under the direction of HHS are the Administration for Children and Families (ACF), the Administration on Aging (AoA), and the Centers for Medicare & Medicaid Services (CMS).[7]**1. The National Institute of Health (NIH)[8]**

The NIH is the primary Federal agency that finances medical research for the United States government. Its mission "is science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability."[9] With over 18,000 employees, the NIH annual budget exceeds $28 billion for medical research alone. Over 80% of NIH funding is awarded through grants to researchers at over 2,800 universities, medical schools and other research institutions throughout the United States and the world.[10]

The NIH is comprised of 27 institutes and

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[4]To contact HHS, its mailing address its national and state address are The U.S. Department of Health and Human Services, 200 Independence Ave., S.W., Washington, D.C., 2020; Telephone: 202-619-0257,toll free: 1-877-696-6775. Texas Health and Human Services Commission Office of the Ombudsman, MC H-700, P.O. Box 13247, Austin, TX 78711-3247.

Texas Health and Human Services Commission Office of the Ombudsman, MC H-700,P O Box 13247 Austin, TX 78711-3247, toll free: (877) 787-8999. HHS public information can also be found at http://www.hhs.gov/.

[5]http://www.hhs.gov/about/whatwedo.html (revised on March 8, 2006 [Last visited on Sept. 4, 2006]).

[6]*Id.*

[7]*See* 42 C.F.R. (Public Health), 45 C.F.R. (Public Welfare) subtitle A, 1-199.

[8]The National Institute of Health is located at 9000 Rockville Pike, Bethesda, MD 20892. Its website is http://www.nih.gov/.

[9]*See* http://www.nih.gov/about.

[10]http://www.nih.gov/about/NIHoverview.html.

centers, including: National Cancer Institute; National Heart, Lung, and Blood Institute; National Human Genome Research Institute; National Institute of Diabetes and Digestive and Kidney Diseases; National Institute of General Medical Sciences; and National Institute of Nursing Research.[11]

NIH support of scientific research at universities, medical schools, and other research institutions has resulted in scientific advances in disease prevention, diagnosis, and treatment. For example:

> a. A nationwide clinical trial has shown that children age seven through 17 with amblyopia (lazy eye) may benefit from treatment more often used on younger children. Previously, eye care professionals thought treating amblyopia in older children would be of little benefit.[12]
>
> b. A substance found in the urine of pregnant women can be measured to predict the later development of preeclampsia. Researchers found that women were likely to develop preeclampsia if they had low levels of substance known as placental growth factor in their urine.[13]
>
> c. Persons with more copies of a gene that helps to fight HIV are less likely to become infected with the virus or to develop AIDS than those who have fewer copies. This finding helps explain why some people are more prone to HIV/AIDS than others.[14]

2. Food and Drug Administration (FDA)

The FDA was created by the enactment of the 1906 Pure Foods and Drugs Act. The FDA's mission is to protect "the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health."[15]

a. Examples of FDA Regulation: Warning Labels

One of the main ways the FDA tries to promote public and safety is through the use of warning labels on products and foods that are consumed by the general public. For example:

> (1) Due to some individuals being at risk of severe anaphylactic reaction to natural latex proteins, the FDA requires the labeling of medical devices containing natural rubber latex that contacts humans. The rule requires labeling of medical devices containing natural rubber latex to state: "Caution: this Product Contains Natural

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[11] http://www.nih.gov/icd/ (Last reviewed August 10, 2006).

[12] http://www.nei.nih.gov/news/pressreleases/041105.asp (National Institute of Health, National Eye Institute Press release April 11, 2005).

[13] http://www.nichd.nih.gov/new/releases/sub_preeclampsia.cfm (Press release January 4, 2005)

[14] http://www3.niaid.nih.gov/news/newsreleases/2005/ccl3l1.htm# (National Institute of Allergy and Infectious Disease, Press release January 6, 2005) See 42 U.S.C § 201 et. seq. (Public Health and Welfare) (2002) (information from regulations.)

[15] *See* http://www.fda.gov/opacom/morechoices/mission.html ; 21 C.F.R. § 1-1404.

Rubber Latex Which May Cause Allergic Reactions."[16]

(2) The label and labeling of any food product in liquid, powdered, tablet, capsule, or similar forms that derives more than 50 percent of its total caloric value form either whole protein, protein hydrolystates, amino acid mixtures, or a combination of these and that is represented for use in reducing weight shall bear the following warning: WARNING: Very low calorie protein diets (below 400 calories per day) may cause serious illness or death. Do Not Use for Weight Reductions in Such Diets Without Medical Supervision. Not for use by infants, children, or pregnant or nursing women.[17]

(3) The labeling of any dietary supplement that contains iron or iron salts shall contain the following statement: WARNING: Accidental overdose of iron containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.[18]

(4) The label of a food packaged in a self-pressurized in a self-pressurized container and intended to be expelled from the package under pressure shall bear the following warning: WARNING: Avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120˚. Keep out of reach of children.

b. Future Legislation?

The FDA's commitment to protecting the public health and safety is also seen in its encouragement of the use of modern technology that electronically stages product packaging. Radio-frequency identification (RFID) allows manufacturers and distributors to track drug products through their supply chain. It is the FDA's viewpoint that RFID will make it easier to create an 'electronic pedigree,' a record of the chain of custody from manufacturing to dispensing that will improve patient safety by allowing wholesalers and retailers to identify, quarantine and report couterfeit drugs as well as conduct targeted recalls.[19] The FDA has published a compliance policy guide for implementing RFID studies. So far Johnson & Johnson, Pfizer, GlaxoSmithKline, and Purdue Pharma have begun their own initiatives in the use of RFID technology. The FDA's report "Combating Counterfeit Drugs" recommended that RFID technology be in widespread use throughout the pharmacy industry by 2007.[20]

3. Center for Disease Control and Prevention (CDC) "Healthy People in a Healthy World-Through Prevention"[21]

The mission for the Centers for Disease Control (CDC) is "to promote health and quality of life by preventing and controlling disease, injury, and disability." [22]Notably, the CDC has been involved in issuing guidelines and recommendations for reducing the risk of the

[16]*See* 21 C.F.R. § 801.437 (a)-(j).

[17]*Id.* § 101.17 (d).

[18]*Id.* § 101.17 (e).

[19]*See Radio-frequency Identification Technology:* Protecting the Drug Supply, FDA Consumer Magazine (March-April 2005).

[20]*Id.*

[21]The CDC is located at 1600 Clifton Rd., Atlanta, GA, 30333, (404) 639-3534, (800) 311-3435.

[22]*See* http://www.cdc.gov.

Human Immunodeficiency Virus (HIV) transmission as a public health issue. Below are two examples of the CDC's approach to educating the public about HIV transmission.

HIV and Health Care Workers

The CDC is responsible for the recommendation of guidelines to prevent transmission of HIV to health care workers. As preventive strategies, the CDC recommends that health care personnel should assume that blood and other body fluids from patients are potentially infectious. Accordingly, the CDC recommends that health care workers adhere to infection control precautions at all times. These precautions include: using of barriers (such as gloves and goggles when anticipating contact with blood or body fluids); the washing of hands and skin that has been in contact with blood or body fluids; and careful handling and disposing of sharp instruments such as needles.[23]

4. Agency for Healthcare Research and Quality

The Agency for Healthcare Research and Quality (AHRQ) is the leading "Federal agency for research on health care quality, costs, outcomes, and patient safety." The AHRQ is the "health services research arm" of the HHS. The AHRQ defines health services research as "how people get access to health care, how much care costs, and what happens to patients as a result of this care."[24] AHRQ is responsible for the creation of the National Guideline Clearinghouse ™ (NGC), a public resource for clinical practice guidelines. [25] The mission of the NGC is "to provide physicians and other health professionals, health care providers, health plans . . . an accessible mechanism for obtaining objective, detailed information on clinical practice guidelines and to further their dissemination, implementation and use."[26]

The NGC website is a useful tool for health care practitioners as it contains links to full-text guidelines, where available, as well as an electronic forum for discussion of practice guidelines, their development and use. Currently, the NGC contains 2,034 indiviual summaries of health care topics from health care organizations and associations such as: American Academy of Allegy, Asthma and Immunology; American Academy of Neurology; American Academy of Pediatrics; American College of Radiology; and the American Society of Anesthesiologists, just to name a few.

5. Centers for Medicare & Medicaid Services (CMS)

CMS is the federal agency that administers Medicare and Medicaid programs. HHS estimates that approximately one out of every four Americans relies on Medicare and/or Medicaid for health care services.

Medicare provides health insurance to over forty million the elderly and disabled Americans. Medicare is available for: people age 65 or older; people under the age of 65 with certain disabilities; and people of all ages with End-Stage Renal Disease, defined as permanent kidney failure requiring dialysis or a kidney transplant. Overall, Medicare services are divided into to parts for recipients, Medicare Part A and Part B. Medicare Part A is hospital insurance that is usually paid for by recipients or their spouse through payroll taxes while employed. Medicare Part A helps cover hospital inpatient care, skilled nursing facilities, hospice care, and some home health care.

Medicare Part B is medical insurance that recipients pay for usually through monthly premium payments. Medicare Part B helps to cover doctor's visits, and other medical services

[23] *See* CDC, *Preventing Occupational HIV Transmission to Healthcare Personnel*, (February, 2002).

[24] *What is AHRQ? Agency for Healthcare Research and Quality, Rockville, MD,* AHRQ Publication No. 02-0011 (February 2002). *See* http://www.ahrq.gov/about/whatis.htm.

[25] http://www.guideline.gov.

[26] http://www.guideline.gov/about/mission.aspx (Last visited Sept. 6, 2006).

that Medicare Part A does not cover. As of January 1, 2006, all recipients of Medicare are eligible for prescription drug coverage insurance that is to be provided by private companies. It is up to the beneficiary of medicare to choose the drug plan and to pay a monthly premium for this service.[27]

Medicaid is a joint state-federal program that provides health coverage and nursing-home coverage for low-income persons, including the elderly. Although the Federal government creates the Medicaid guidelines, the Medicaid requirements for eligibility are established by each individual state. Therefore whether a person is elibible for Medicaid varies on the state where the applicant resides. Overall, states are required to provide services for certain eligibility groups and at their discretion, may include others. Eligibility groups are organized into three catagories: the categorically needy; medicaly needy; and special groups. The categorically needy includes pregnant women and children under age 6 whose family income is at or below 133% of the Federal poverty level. The medically needy by definition have too much money to be eligible to be categorically needy and eligible for Medicaid. Therefore it is up to the state to determine if it will have a medically needy program. If it does, it must include pregnant women, including a 60-day postpartum period, and children under age 18. States have the option of providing Medicaid to children under age 21 who are full time students, persons age 65 and older, blind persons, and disabled persons. Texas has a medically needy program, however, this program only covers the "mandatory" medically needy groups. Texas does not automatically cover the aged, blind, or disabled in its Medicaid program.

In regards to special groups eligible for Medicaid, there are two eligibility groups related to medical conditions that states may include under their Medicaid plans: a time-limited eligibility group for women who have breast or cervical cancer and people who have tuberculosis who are uninsured. Texas has determined that women with breast or cervical cancer are eligible for Medicaid services. Texas has not included persons with tuberculosis as a special group eligible for Medicaid services.[28]

CMS is also responsible for administrating the States Children's Health Insurance Program (SCHIP), created by Title XXI of the Social Security Act. Families who earn too much to qualify for Medicaid may be able to qualify for SCHIP. Overall, families that do not have health insurance may be eligible for SCHIP. Although each state determines the design of its SCHIP, in most states uninsured children under the age of 19 whose family earns approximatley $36,200 a year (for a family of four) are eligible. SCHIP is implemented with little or no cost to the enrolled families, and pays for doctor visits, immuizations, hospitilzations, and emergency room visits.

In Texas, two government regulated health insurance programs for low income residents are offered by TexCare, including its state health insurance program (CHIP) and Children's Medicaid. In addtion to services addressed above, CHIP also covers prescription drugs, x-rays, physical/speech/occupational therapies, and surgery. To qualify for CHIP, a child must be, under age 19, a Texas resident, a US citizen or legal permanent resident. The citizenship or immigration status of the parents does not affect a child's eligibility for CHIP. To be eligible for CHIP in Texas, a family of four's income may not exceed $40,000. To be eligible for Medicaid for children in Texas, a family of four's income may not exceed $37,000.[29]

B. Enforcement: Office of Inspector General (OIG)

1. Overview

The mission of the OIG, is to "protect the

[27] *See* http://www.cms.hhs.gov/MedicareGenInfo.

[28] *See* http://www.cms.hhs.gov/MedicaidGenInfo/.

[29] *See* http://www.texcarepartnership.com.

integrity of Department of Health and Human Services programs, as well as the health and welfare of the beneficiaries of those programs. The OIG has a responsibility to report both to the Secretary of the Department of Health and Human Services and to the Congress program and management problems and recommendations to correct them. The OIG's duties are carried out through a nationwide network of audits, investigations, inspections and other mission-related functions performed by OIG components." To achieve its mission, the OIG:

> (a) conducts and supervises audits, investigations, inspections and evaluations relating to HHS programs and operations;
>
> (b) identifies systemic weaknesses giving rise to opportunities for fraud and abuse in HHS programs and operations and makes recommendations to prevent their recurrence or reoccurrence;
>
> (c) leads and coordinates activities to prevent and detect fraud and abuse in HHS programs and operations;
>
> (d) detects wrongdoers and abusers of HHS programs and beneficiaries so appropriate remedies may be brought to bear; and
>
> (e) keeps the Secretary and the Congress fully and currently informed about problems and deficiencies in the administration of HHS programs and operations and about the need for and progress of corrective action, including imposing sanctions against providers of health care under Medicare and Medicaid who commit certain prohibited acts.[30]

2. Abuse and Recovery: The Department of Health and Human Services And The Department of Justice Health Care Fraud and Abuse Control Program

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) established a national Health Care Fraud and Abuse Control Program ("HCFAC"). Under the joint direction of the Attorney General and HHS, acting through the OIG, HCFAC was designed to coordinate federal, state, and local law enforcement activities with respect to health care fraud and abuse. In 2004, the Centers for Medicare and Medicaid Services (CMS) collected over $802 million in restitution/compensatory damages.[31] Below are some examples of HCFAC Program Accomplishments:

1. A South Carolina Hospital agreed to pay $9.5 million to resolve improper Medicare billing for home health programs, hospice programs, and durable medical equipment.

2. A national retail pharmacy chain paid $7 million to settle allegations of submitting false prescription claims to government health insurance programs. The pharmacy chain was accused of billing Medicaid, TRICARE Military Health Plan, and the Federal Employee Health Benefits Program (FEHBP) for drugs that were never delivered to the enrollees of the government programs.

3. In Texas, five defendants are convicted as a result of "Operation Roll Over," a scheme that involved Medicare beneficiary information being used to file fraudulent claims. The participants in the scheme told Medicare beneficiaries that in exchange for their Medicare information, they would receive free electric wheelchairs and scooters. The Defendants were charged with health

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[30] *See* http://www.oig.hhs.gov/organization/OIGmission.html (Last visited on Sept. 4, 2006).

[31] *See* http://www.oig.hhs.gov/publications/docs/hcfac/hcfacreport2004.htm (Last visited on Sept. 4, 2006).

care, mail fraud, and money laundering.

C. Medicare Participation and the Emergency Medical Treatment & Labor Act (EMTALA)

1. Overview

In 1986, Congress enacted the Emergency Medical Treatment and Labor Act (EMTALA) for the purpose of ensuring access to emergency services regardless of a patient's ability to pay. Section 1867 of the Social Security Act imposes requirements on Medicare-participating hospitals that offer emergency services to provide a medical screening examination or treatment for a emergency medical condition. EMTALA applies to all individuals, not just Medicare beneficiaries, who attempt to access a hospital for emergency care. Hospitals are also required to provide stabilizing treatment for patients with emergency medical conditions. EMTALA regulations define "hospital with an emergency department" as a hospital with a "dedicated emergency department", meaning the hospital or department is (1) licensed by the state as an emergency department; (2) held out to the public as providing treatment for emergency medical conditions; or (3) in the preceding calendar year, one-third of the visits to the department provided treatment for emergency medical conditions on an urgent basis.

The enforcement of EMTALA is a complaint driven process. Investigating a hospital's policies and procedures and resulting sanctions, if any, are initiated by a complaint. If upon the conclusion of investigating a complaint the hospital is found to have violated the "anti-dumping" provisions of EMTALA, the hospital risks the termination of its provider agreement and possible monetary penalties.[32]

As per EMTALA regulations, hospitals participating in Medicare provider agreements with dedicated emergency departments are required to:

1. post signs in its emergency department stating the rights of individuals with emergency medical conditions and women in labor seeking health care services, and state on its sign whether the hospital participates in the Medicare program;

2. keep a central log of person's seeking treatment and indicate whether these individuals refused treatment, were denied treatment, or were treated, admitted, stabilized, and/or transferred or were discharged;

3. keep medical records pertaining to individuals transferred to and from the hospital for a period of five years from the date of transfer;

4. provide for a medical screening examination;

5. provide for stabilizing treatment for emergency medical conditions and labor based upon the hospital's capability and capacity.

In addition, the hospital may not do the following:

1. delay medical screening examination and/or stabilizing treatment in order to inquire about payment status;

2. accept appropriate transfer of patients with an emergency medical condition if the hospital has the capabilities, facilities, and capacity to treat such patients;

3. penalize a physician or other medical personnel for refusing to authorize a transfer of a person with an emergency medical condition that is not medically stable; or

4. penalize a physician or other medical personnel who reports a

[32] See the Social SecurityAct's accompanying regulations at 42 CFR §489.24, and 42 CFR § 489.20 (l), (m), (q), and (r).

violation of these requirements.

Furthermore, hospitals are required to report to CMS or its state survey agency any time it has reason to believe it may have received an individual who has been transferred in an unstable emergency medical condition for another hospital.[33]

2. EMTALA and Litigation

Hospitals that have entered into Medicare provider agreements may be found liable if they fail to provide proper emergency medical care and inappropriately transfer a patient in violation of EMTALA's requirements.[34] In addition, recent federal case law has held that Centers for Medicare and Medicaid Services (CMS) investigation reports were admissible in court in a pregnant woman's lawsuit against a hospital under EMTALA.

In the recent federal court case *Henderson v. Medical Center Enterprise*,[35] Plaintiff Ginger Henderson filed a complaint with the state of Alabama after being refused treatment at Medical Center Enterprise hospital although she was experiencing labor contractions two minutes apart upon being in a car accident. Upon refusal of treatment, Plaintiff and her husband had to drive to another hospital that was approximately a forty minute drive away to deliver their child. CMS conducted an investigation into Mrs. Henderson's treatment at Medical Center Enterprise and found that the hospital failed to adhere to EMTALA's regulations. Plaintiff then sought to recover damages for emotional distress as a result of the alleged EMTALA violations. In her lawsuit, Plaintff claimed that she was worried that something had happened to her baby during the car accident and that she might deliver her child before she could reach the second hospital.

The U.S. District Court for the Middle District of Alabama denied defendant's motion for summary judgment, finding that the CMS investigation is admissible evidence, and that whether it was reasonably foreseeable that Plaintiff was placed at risk of physical injury and whether she suffered emotional distress is a question for the jury to decide.

IV. STATE REGULATION OF HEALTH CARE IN TEXAS

A. Department of State Health Services (DSHS)

Mission Statement

The Texas Department of State Health Services promotes optimal health for individuals and communities while providing effective health, mental health, and substance abuse services to Texas. On September 1, 2004, as directed by House Bill 2292, the Texas Department of State Health Services (DSHS) was created by combining four state agencies: the Texas Department of Health; Mental Health Programs of Texas Department of Mental Health and Mental Retardation; Texas Commission on Alcohol and Drug Abuse; and the Texas Health Care Information Council into one.

B. Texas Medical Board

1. Introduction

The Texas Medical Board ("Board") is the state agency of the executive branch of the Texas state government that has the power to regulate the practice of medicine.[36] The Board consists of nineteen members, twelve physicians and seven members of the public who are appointed by the governor and serve staggered six year terms.[37] The powers of the Board over physicians' practice in Texas is all encompassing. For example, the Board has the power to enact the passing of rules and guidelines effecting daily practice, such as the ability to establish the period for which patient records must be maintained, and the dispensing of free samples of drugs to patients.

2. Board Violations and Discipline

Included in the Board's regulatory powers, the

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[33] *See* 42 CFR § 489.24(e).

[34] *See* 42 U.S.C. § 1395dd(b).

[35] 2006 WL 235567.

[36] *See* TEX. OCC. CODE ANN. § 152.001.

[37] *Id.* §§ 152.002, 152.005(a).

Board has the authority to impose disciplinary sanctions against physicians who are found to be in violation of its regulations or violations of Texas law. The Board's disciplinary decisions range in severity from reprimands to revocation of licensure.[38] In 2005, the Board issued 304 disciplinary decisions against physicians, including 32 revocations/surrenders of licensure.[39] In furtherance of its objective in regulating the practice of medicine, the Board has defined what it considers to be grounds for refusing to issue a license to practice medicine or possible disciplinary action against a licensed physician. [40] Agency-licensure revocations proceedings are civil in nature, and the proper standard of proof in agency determinations is the preponderance of evidence standard.[41] If a physician wishes to challenge imposed disciplinary action, the appellate court will presume that the Board's order is valid, placing the burden of proof on appeal with the physician.[42]

C. Board of Nurse Examiners

1. Introduction

The Board of Nurse Examiners ("Nurse Board") is the state agency of the executive branch of the Texas state government that has the power to regulate the practice of nursing in Texas. The Nurse Board has thirteen members appointed by the governor, six nurse members, three nurse faculty, and four members of the public.[43]

"The mission of the Board of Nurse Examiners for the State of Texas is to protect and promote the welfare of the people of Texas by ensuring that each person holding a license as a nurse in the State of Texas is competent to practice safely. The Board fulfills its mission through the regulation of the practice of nursing and the approval of nursing education programs. This mission, derived from the Nursing Practice Act, supersedes the interest of any individual, the nursing profession, or any special interest group."[44]

2. Board Violations and Discipline

Similar to the Texas Medical Board, the Nurse Board has also defined what is considers to be grounds for denial of licensure or disciplinary action.[45] In addition to listing prohibited conduct in its Nursing Practice Act, the Nurse Board has recently created four Disciplinary Sanction Policies addressing sanctions for chemical dependency, sexual misconduct, fraud, theft and deception, and lying and falsification.[46] Below is a brief summary of these policies.

Disciplinary Sanctions for Sexual Misconduct

In adopting this policy, the Nurse Board adopted several assumptions as the basis for its position:

(1) Patients under the care of a nurse are vulnerable by virtue of conditions such as illness, injury, and dependent nature of the nurse-patient relationship.

(2) Persons who are especially vulnerable include the elderly, children, the mentally ill, sedated patients, those whose mental or cognitive ability is compromised and patients who are disabled or immobilized.

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[38] *Id.* §§ 164.051, 164.057, 164.058.

[39] Enforement statistics from Texas Medical Board Website for fiscal year 2005, http://www.tmb.state.tx.us./agency/statistics/enforce/mbd.php.

[40] *See* TEX. OCC. CODE ANN. §§ 164.051, 164.052.

[41] *Granek v. Texas State Bd. of Med. Exam.*, 172 S.W.3d 761, 777 (Tex. App.–Austin 2005).

[42] *Hinkley v. Texas State Bd. of Med. Exam.*, 140 S.W.3d 737, 743 (Tex.App.-Austin 2004).

[43] TEX OCC. CODE ANN. § 301.051 (2005).

[44] http://www.bne.state.tx.us/

[45] *See* TEX. OCC. CODE ANN. §§ 301.452(b), 301.4535(a).

[46] http://www.bne.state.tx.us/nparr.htm,Board of Nurse examiner website update as of August 4, 2006

(3) Critical care, geriatric, and pediatric patients are particularly vulnerable given the level of vigilance demanded under the circumstances of their health condition.

(4) Nurses are able to provide care in private homes and home-like setting without direct supervision.

(5) Nurses who are chemically dependent or who abuse drugs or alcohol and whose judgment may be impaired while caring for patients are at risk for harming patients.

(6) The disease of chemical dependence is a treatable disease. Nurses who are in active recovery may be able to safely provide care to vulnerable patients. Recovery is a process of learning new behaviors, attitudes and life style which takes time after initial treatment to assure that the person is in a stable state of recovery.

V. CONCLUSION

The state and federal agencies mentioned above represent some of the better known and faster growing agencies dedicated to improving the health industry. Even in this brief sampling, the overlap and interplay of regulatory agencies has become apparent. Collaboration between state and local governments, as well as with nonprofit organizations, private businesses, and individuals ensures health and safety in the United States. Additionally, each of these agencies also works with foreign countries to assist in global education and disease prevention. As developments improve through regulation, these agencies will narrow their focus to finance personal health services and research in ways that accord priority to prevention, patient safety, and a population health perspective. Regulation is developing to make sustained investments in the nation's public health infrastructure and attempt to increase access to health information. In an effort to continue the growth of agencies incentives may be offered for partnerships between communities and government to improve health. All of this while looking to strengthen the capacity of government to manage the promotion and protection of health by reducing fragmentation within the federal government and improving coordination and collaboration across government health care organizations.