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**Legal Compliance Program**  
**Policy Manual**

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# Wise Regional Health System

## Legal Compliance Program

### POLICY MANUAL

#### Part I - Introduction; General Policies and Procedures

##### *1.1 Introduction*

Wise Regional Health System (the "Hospital") is committed to the compliance with all state and federal laws governing its operations in the provision of services in the health care arena. Further, Hospital has endeavored and will continue to endeavor to adhere to the highest standards of business and professional ethics. Therefore, this policy has been formulated and adopted to evidence and ensure this commitment to our patients, the community, regulatory and law enforcement agencies, and to ourselves.

The Hospital has also established a legal and regulatory Compliance Program in order to ensure that the Hospital's compliance policies are consistently applied. The program is directed by a Compliance Committee and Compliance Officer, who are responsible for reviewing the Hospital's compliance policies and specific compliance situations that may arise. Following the Hospital's commitment to full compliance with the laws, regulations, and standards that govern its operation, this Manual, and the Hospital's Compliance Program, have been reviewed to ensure that those standards expressed in the United States Department of Health and Human Services' Office of Inspector General's Compliance Program Guidance for Hospitals are embodied and adequately addressed. Through the adoption and implementation of this Manual and the Compliance Program, it is the Hospital's goal to achieve the following:

- to concretely demonstrate to employees and the community at large the Hospital's strong commitment to honest and responsible provider and corporate conduct;
- to provide a more accurate view of employee and contractor behavior relating to fraud and abuse of federal health care programs;
- to identify and prevent criminal and unethical conduct by tailoring a compliance program to our Hospital's specific needs;
- to improve the quality of patient care;
- to create a centralized source for distributing information on health care statutes, regulations and other program directives related to fraud and abuse and other issues affecting;

- to develop a methodology that encourages employees to report potential problems;
- to develop procedures that allow the prompt, thorough investigation of alleged misconduct by corporate officers, managers, employees, independent contractors, physicians, other health care professionals and consultants;
- to initiate immediate and appropriate corrective action;
- to, through early detection and reporting, minimize the loss to the government and other payor sources from false claims, and thereby reduce the Hospital's exposure to civil damages and penalties, criminal sanctions, and administrative remedies, such as program exclusion;
- to comply with the requirements of the Deficit Reduction Act of 2005 ("DRA") by providing Hospital employees and professional staff members detailed information about the Federal False Claims Act established under Sections 3729 through 3733 of Title 31 of the United States Code, administrative remedies for false claims and statements established under Chapter 38 of Title 31 of the United States Code, Texas laws pertaining to civil or criminal penalties for false claims or statements, and whistleblower protections under such laws with respect to the role such of such laws in preventing and detecting fraud, waste, and abuse; and
- to comply with the requirements of the DRA by providing detailed information about the Hospital's policies and procedures for detecting and preventing fraud, waste and abuse, thereby educating Hospital employees and professional staff members about such policies and procedures.

This Manual includes statements of the Hospital's policy in a number of specific areas, including but not limited to policies designed to detect and prevent fraud and abuse. All employees and professional staff members must comply with these policies, which define the scope of Hospital employment and professional staff membership. Conduct that does not comply with these statements is not authorized by the Hospital, is outside the scope of Hospital employment and professional staff membership, and may subject employees and professional staff members to disciplinary action. If a question arises as to whether any action complies with Hospital policies or applicable law, an employee should present that question to that employee's supervisor or to the Hospital's Compliance Officer, a member of the Compliance Committee, or to the Administrator of the Hospital. All employees should review this Manual from time to time and become familiar with them to ensure that their actions are consistent with these policies and the Hospital's Compliance Program.

This Manual deals only generally with some of the more important legal principles that affect the Hospital's operations. Their mention is not intended to minimize the importance of other applicable laws, professional standards, or ethical principles, which may be covered in other Hospital policies. Consequently, any employee who is in doubt as to the propriety of a

course of action must promptly communicate with his or her supervisor, or with the Compliance Officer, before taking action.

Legal requirements imposed due to the Hospital's participation in Medicare and Medicaid are discussed at length in this Policy Manual. Put simply, Medicare is a federal program that provides health insurance to the aged and disabled, and Medicaid is a joint federal/state program that provides health care coverage to low income persons. The right to bill the Medicare and Medicaid programs, conferred through the award of a provider or supplier number, carries a responsibility that may not be abused. The federal government and the State of Texas have enacted numerous laws and regulations to protect the integrity of Medicare and Medicaid, and it is the Hospital's policy that the Hospital and its employees and professional staff members abide by these rules and regulations, as well as other laws and regulations designed to prevent fraud, abuse and waste of government funds.

In 2005 the federal government enacted the Deficit Reduction Act (the "DRA"). This law mandates that the Hospital provide employees and professional staff members detailed information about the Federal False Claims Act (the "FCA"), administrative remedies for false claims and statements established under chapter 38 of title 31 of the United States Code, Texas laws pertaining to civil or criminal penalties for false claims or statements, and whistleblower protections under such laws with respect to the role such of such laws in preventing and detecting fraud, waste, and abuse. Section 2.1 of this Manual serves to comply with this requirement. The DRA also mandates that the Hospital provide Personnel and Affiliates detailed information about the Hospital's policies and procedures for detecting and preventing fraud, waste and abuse. Sections 2.2-2.4 of this Manual, in particular, serve to comply with this requirement. The Manual as a whole provides significant detail about laws, regulations and Hospital policy and procedure designed to detect and prevent fraud, waste and abuse (based on false claims and other areas).

This Manual is not designed merely to comply with legal requirements, but is also meant to foster an environment of accountability in which the Hospital will serve the community according to the highest standards of business and professional ethics. As such, the Manual covers much more than issues related to fraud and abuse. However, preventing and detecting fraud, waste and abuse is a major focus of the Manual. This focus, and the inclusion of certain other legal issues, is not meant to minimize the importance of other applicable laws, professional standards, or ethical principles, which may be covered in other Hospital policies. Personnel and Affiliates should review this Manual from time to time to make sure that these policies guide their actions on behalf of the Hospital.

## ***1.2 Reporting Requirements and Response by Hospital***

If at any time any employee or professional staff member becomes aware of any apparent violation of the Hospital's policies, he or she must report it to his or her supervisor or to the Compliance Officer. All persons making such reports are assured that such reports are treated as confidential to the fullest extent possible and will be shared only on a bona fide need-to-know basis. The Hospital will take no adverse action against persons making such reports, regardless of whether the report ultimately proves to be well-founded. If an employee or professional staff

member does not report conduct violating the Hospital's policies, that employee or professional staff member may be subject to disciplinary action, up to and including termination of employment or revocation of privileges.

The effectiveness of the compliance program is largely measured by the Hospital's response to such reports of violations. Therefore, the Hospital shall promptly respond to reports of suspected violations in a manner consistent with these policies, and shall take all reasonable steps to modify the Hospital's procedures and practices so that the likelihood of a violation recurring is reduced.

### ***1.3 Consequences of Violations***

All Hospital employees, as well as those professionals who enjoy professional staff membership, must carry out their duties for the Hospital in accordance with this policy. Any violation of applicable law, or deviation from appropriate standards, will subject an employee or independent professional to disciplinary action, which may include oral or written warning, disciplinary probation, suspension, reduction in salary, demotion, dismissal from employment, or revocation of privileges. These disciplinary actions may apply to individuals who fail to report or investigate concerns that should have been apparent. These disciplinary actions also may apply to an employee's supervisor who directs or approves the employee's improper actions, or is aware of those actions but does not act appropriately to correct them, or who otherwise fails to exercise appropriate supervision.

### ***1.4 Compliance Officer and Compliance Committee***

This manual contains numerous references and instructions relating to the Compliance Officer. The Compliance Officer shall be appointed by the Hospital Administrator from the senior administrative staff of the Hospital. The Administrator may appoint himself or herself as the Compliance Officer. The Compliance Officer should be in a position to influence behavior and Hospital practices, and shall be responsible and accountable for the Hospital's compliance activities. Compliance activities should be a major portion of the Compliance Officer's job description and a basis for evaluation of job performance.

The Compliance Officer shall determine the membership of the Compliance Committee, which shall include at least one other member of the senior administrative staff of the Hospital and should include the directors or other representatives from the departments which most substantially affect the Hospital's compliance efforts. The Compliance Committee shall be responsible for the implementation of and continued adherence to the Compliance Program in the Hospital. It shall also periodically review the Compliance Policies and the Hospital's Compliance Program in order to ensure that its provisions and the implementation of the program remain current.

### ***1.5 Delegation of Discretionary Authority***

An integral part of implementing and/or maintaining compliance with applicable legal standards is reliance on the Hospital's employees to familiarize themselves with these standards

and to act accordingly. Therefore, it is vital that the Hospital take due care not to delegate substantial discretionary authority to individuals who may have a propensity to engage in illegal activity or fail to follow the concepts embodied in these policies and the Compliance Program. The Compliance Officer and the Compliance Committee should develop appropriate safeguards to implement this requirement, which may include criminal history inquiries on applicants for or persons in positions with substantial supervisory authority or substantial discretion within the Hospital. Consideration should be made for the removal of individuals who have shown a disregard for relevant program standards from positions of substantial authority or discretion. The Hospital should avoid hiring or associating with individuals on the Inspector General's list of people excluded from the Medicare and Medicaid programs.

### ***1.6 Monitoring and Auditing Systems***

In implementing its compliance program, the Hospital shall utilize monitoring and auditing systems reasonably designed to detect criminal or improper conduct by its employees or independent professionals. In the case of billing activities, this shall include a review of every part of the claims process from patient registration to submission of the claim to Medicare or Medicaid. This process is a key aspect of the Hospital's policies and procedures designed to detect and prevent fraud, waste and abuse in compliance with the DRA. In other areas, the Compliance Committee shall work with the relevant departments in developing monitoring and/or auditing systems to ensure continued compliance.

### ***1.7 Education and Communication***

The Hospital shall ensure that these policies have been reviewed by all employees and independent professionals and all other persons who may affect compliance, directly or indirectly. Additionally, the Hospital, through the Compliance Committee, shall ensure that all such persons are properly educated on the laws affecting their particular job or activities at the Hospital. Such educational programs and participation in the educational process shall be carefully documented. Education and training techniques may include, to the extent necessary, presentations by internal and external experts, oral presentations, videos and testing.

### ***1.8 Fraud, Waste and Abuse***

The Hospital is committed to its role in preventing health care fraud and abuse and complying with applicable state and federal laws related thereto. The DRA requires the Hospital to provide detailed information about the federal False Claims Act and other laws, including state laws, dealing with fraud, waste and abuse, as well as whistleblower protections for reporting those issues. To ensure compliance with such laws, the Hospital has policies and procedures in place to detect and prevent fraud, waste and abuse. The Manual provides an overview of these policies and procedures and outlines the Federal Civil False Claims Act, the Program Fraud Civil Remedies Act, similarly applicable state laws, and other laws and issues related to detecting and preventing fraud, waste and abuse.

## **Part II - Substantive Compliance Concepts**

### **2.1 *Federal and State False Claims and Whistleblower Protection Laws***

#### 2.1.1 Education Regarding and the Role of Federal and State Laws in Preventing Fraud, Waste, and Abuse

The Centers for Medicare and Medicaid Services (“CMS”) defines “fraud” as the intentional deception or misrepresentation that an individual knows to be false (or does not believe to be true) and makes, knowing that the deception could result in an unauthorized benefit to himself or another person. CMS defines “abuse” as incidents or practices of providers that are inconsistent with sound medical practice and may result in unnecessary costs, improper payment, or the payment for services that either fail to meet professionally recognized standards of care or are medically unnecessary.

The federal government and the State of Texas have enacted criminal and civil laws pertaining to the submission of false or fraudulent claims for payment or approval to the federal and state governments and to private payors. These false claims laws, which provide for criminal, civil, and administrative penalties, provide governmental authorities with broad authority to investigate and prosecute potentially fraudulent activities, and also provide anti-retaliation provisions for individuals who make good faith reports of waste, fraud, and abuse (“whistleblowers”). Together, these laws create incentives for individuals to come forward upon witnessing fraud and abuse, and protection for persons who do so in good faith. These laws also create incentives for the private prosecution of lawsuits by parties seeking to protect the integrity of government-funded health care, and allow governmental entities to protect the integrity of government-funded health care by prosecuting, both civilly and criminal, those who would abuse the public by defrauding governmental expenditure on health care.

#### 2.1.2 The Federal Civil False Claims Act

The Civil False Claims Act (31 U.S.C. § 3729 *et seq.*) is a statute that imposes civil liability on any person who:

- knowingly presents, or causes to be presented, a false or fraudulent claim, record, or statement for payment or approval;
- conspires to defraud the government by getting a false or fraudulent claim allowed or paid;
- uses a false record or statement to avoid or decrease an obligation to pay the government; and;
- commits other fraudulent acts enumerated in the statute.

The term “knowingly” as defined in the Civil False Claims Act (the “FCA”) includes a person who has actual knowledge of the information, acts in deliberate ignorance of the truth or falsity of the information, or acts in reckless disregard of the truth or falsity of the information.

No proof of specific intent to defraud is required. The term “claim” includes any request or demand for money or property if the United States Government provides any portion of the money requested or demanded. It is also unlawful to conceal or fail to disclose the occurrence of an event affecting the right to payment with the intent to secure payment that is not due.

Potential civil liability under the FCA currently includes penalties of between \$5,500 and \$10,000 per claim, treble damages, and the costs of any civil action to recover such penalties or damages. The person (as well as the Hospital) may be excluded from participating in the Medicare and Medicaid programs. A provider or supplier who violates the false claims rules is guilty of a felony, and may be subject to fines of up to \$25,000 per offense, imprisonment for up to five years, or both. Violations of the billing assignment and reassignment rules are misdemeanors carrying fines of up to \$2,000 and imprisonment of up to six months, or both.

The Attorney General of the United States is required to diligently investigate violations of the FCA, and may bring a civil action against a violator. Before filing suit, the Attorney General may issue an investigative demand requiring production of documents, written answers and oral testimony.

The FCA also provides for actions by private persons (*qui tam* lawsuits) who can bring a civil action in the name of the government for a violation of the Acts. Generally, the action may not be brought more than six years after the violation, but in no event more than ten years after the violation. When the action is filed, it remains under seal for at least sixty (60) days. The United States Government may choose to intervene in the lawsuit and assume primary responsibility for prosecuting, dismissing, or settling the action. If the government chooses not to intervene, the private party who initiated the lawsuit has the right to conduct the actions.

In the event the government intervenes, the *qui tam* plaintiff may receive 15-25% of the recovery. In either case, the plaintiff may also receive an amount for reasonable expenses plus reasonable attorneys’ fees and costs. If the civil action is frivolous, clearly vexatious, or brought primarily for harassment, the plaintiff may have to pay the defendant its fees and costs. If the plaintiff planned or initiated the violation, the share of proceeds may be reduced and, if found guilty of a crime associated with the violation, no share will be awarded the plaintiff.

**Whistleblower Protection.** The FCA also provides for protection for employees from retaliation. An employee who is discharged, demoted, suspended, threatened, harassed, or discriminated against in terms and conditions of employment because of lawful acts conducted in furtherance of an action under the FCA may bring an action in Federal District Court seeking reinstatement, two times the amount of back pay plus interest, and other enumerated costs, damages, and fees.

### 2.1.3 Federal Program Fraud Civil Remedies Act of 1986

The Program Fraud Civil Remedies Act of 1986 (“Administrative Remedies for False Claims and Statements” at 38 U.S.C. § 3801, *et seq.*) is a statute that establishes an administrative remedy against any person who presents or causes to be presented a claim or written statement that the person knows or has reason to know is false, fictitious, or fraudulent

due to an assertion or omission to certain federal agencies (including the Department of Health and Human Services).

The term “knows or has reason to know” is defined in the Act as a person who has actual knowledge of the information, acts in deliberate ignorance of the truth or falsity of the information, or acts in reckless disregard of the truth or falsity of the information. As with the FCA, no proof of specific intent to defraud is required. The term “claim” includes any request or demand for property or money, e.g., grants, loans, insurance or benefits, when the United States Government provides or will reimburse any portion of the money.

#### 2.1.4 Other Federal Laws; Summary

Numerous other federal laws prohibit false statements or inadequate disclosure to the government and mandate exclusion from the Medicare and Medicaid programs. For instance, neither the Hospital nor its agents are permitted to make, or induce others to make, false statements in connection with the Hospital's Medicare certification. Persons doing so are guilty of a felony and may be subject to fines of up to \$25,000 and imprisonment for up to five years. The Hospital or individual health care providers will be excluded from the Medicare and Medicaid programs for at least five years if convicted of a Medicare or Medicaid-related crime, or any crime relating to patient abuse. Medicare and Medicaid exclusion may result if the Hospital or a provider is convicted of fraud, theft, embezzlement, or other financial misconduct in connection with any government-financed program. It is illegal to make any false statement to the federal government, including statements on Medicare or Medicaid claim forms. It is illegal to use the U.S. mail in a scheme to defraud the government. Any agreement between two or more people to submit false claims may be prosecuted as a conspiracy to defraud the government.

The Hospital promotes full compliance with each of the relevant laws by maintaining a strict policy of ethics, integrity, and accuracy in all its financial dealings. All Personnel and Affiliates, including outside consultants, involved in submitting charges, preparing claims, billing, and documenting services is expected to maintain the highest standards of personal, professional, and institutional responsibility.

#### 2.1.5 State Criminal, Civil, and Administrative False Claims and Whistleblower Laws

In addition to federal penalties, state statutes and regulations also impose both civil and criminal penalties for fraudulent Medicaid billing. Chapter 36 of the Texas Human Resources Code (“Chapter 36”) relates to false claims and other “unlawful acts” under the state Medicaid program. There is a wide range of prohibited conduct that falls under the definition of “unlawful acts” including billing activities, providing false information with respect to a patient's eligibility for coverage under the Medicaid program, and failure to provide and maintain quality services to Medicaid recipients. Overall, Chapter 36 is very similar to the FCA. Like the FCA, Chapter 36 allows a private party to bring a civil action against a person or entity that has committed an unlawful act, and Section 36.115 within Chapter 36 protects whistleblowers. Such persons may file suit and, if successful, obtain not less than two times back pay, attorneys’ fees, and reinstatement at the same level as before the retaliatory act. One distinction between Texas’ law

and the FCA is that under Chapter 36, the minimum and maximum civil penalties per unlawful act are increased for acts that result in injury to a person that is elderly, disabled or under 18 years of age.

Chapter 32 of the Texas Human Resources Code creates a similar program to prevent false claims for other federally funded health care programs (Chapter 36 applies only to Medicaid). Chapter 531 of the Texas Government Code gives the state Health and Human Services Commission the discretion to, “grant an award to an individual who reports activity that constitutes fraud or abuse of the funds in the state Medicaid program or reports overcharges...” The award must be equal to not less than 10 percent of the savings to the state that result from the disclosure. Finally, Chapter 544 of the Government Code prohibits retaliation against whistleblowers in general, not just those that disclose false medical claim activity.

In addition to civil monetary penalties, criminal sanctions can be imposed on fraudulent activity within the Medicaid program. Violations of the illegal remuneration and patient referral act is a Class A misdemeanor. If a person has previously been convicted of such an offense, a subsequent offense is a felony of the third degree. Also, general fraud provisions of the Texas Penal Code may have application to alleged fraudulent billing under the Medicaid program. Finally, the Texas Penal Code contains a chapter relating specifically to fraudulent billing activities to health care insurance companies. An offense under that chapter ranges from a Class C misdemeanor if the value of the claim is less than \$20, to a felony of the first degree if the value of the claim is \$200,000 or more. In addition, when separate fraudulent claims are communicated to a health insurance company, each communication may be considered an individual offense, with the value of the claims added together to determine the classification of offense, thus rendering it a more serious offense.

## ***2.2 Billing and Claims for Payment***

### **2.2.1 General Policies and Procedures for Detecting and Preventing Fraud, Waste and Abuse**

When claiming payment for Hospital or professional services, the Hospital has an obligation to its patients, third party payors, and the state and federal governments to exercise diligence, care, and integrity. The right to bill the Medicare and Medicaid programs under the Hospital’s provider or supplier number carries a responsibility that may not be abused. The Hospital is committed to maintaining the accuracy of every claim it processes and submits. Many people, throughout the Hospital, have responsibility for entering charges and procedure codes. Each of these individuals is expected to monitor compliance with applicable billing rules. Any false, inaccurate, or questionable claims should be reported immediately to a supervisor or to the Compliance Officer.

False billing is a serious offense. Medicare and Medicaid rules prohibit knowingly and willfully making or causing to be made any false statement or representation of a material fact in an application for benefits or payment. It is also unlawful to conceal or fail to disclose the

occurrence of an event affecting the right to payment with the intent to secure payment that is not due.

### 2.2.2 Specific Areas of Concern

The Office of the Inspector General (“OIG”) of the U.S. Department of Health and Human Services (“DHHS”) has identified areas of special concern for false claims. Although this list is not all-inclusive, it is Hospital Policy that the Hospital and Hospital Personnel and Affiliates avoid the following improper and/or illegal billing practices and follow procedures outlined below to avoid such practices:

- (a) Billing for items or services not actually rendered. This form of billing fraud occurs in many health care entities, including hospitals and nursing homes, and represents a significant part of the OIG’s investigative caseload.
- (b) Billing on an outpatient basis for “inpatient-only” procedures. CMS has identified procedures for which reimbursement is typically allowed only if the service is performed in an inpatient setting. The Compliance Officer should develop procedures to ensure that “inpatient-only” procedures are not billed as outpatient services.
- (c) Improper billing for supplemental payments. Under the Medicare program, in certain limited situations, hospitals may claim payments in addition to, or in some cases in lieu of, the normal reimbursement available to hospitals under the regular payment systems. Eligibility for these payments depends on compliance with specific criteria. Hospitals that claim supplemental payments improperly are liable for fines and penalties under federal law. The following items have been targeted by the OIG as risk areas which merit special attention: “pass-through” items, Diagnosis Related Group (“DRG”) outlier payments, claims for “provider-based” entities, clinical trials, organ acquisitions, and cardiac rehabilitation.
- (d) Billing substantially in excess of usual charges. Hospitals who routinely charge Medicare or Medicaid substantially more than they usually charge others may be excluded from participation in federally funded healthcare programs.
- (e) Medical necessity. A claim requesting payment for a medically unnecessary service intentionally seeks reimbursement for a service that is not warranted by the patient’s current and documented medical condition. Claims should only be submitted for services that the Hospital has reason to believe are medically necessary and that were ordered by a physician<sup>1</sup> or other appropriately licensed individual. The Medicare program and the OIG recognize that licensed health care professionals must be able to order any services that are appropriate for the treatment of their patients. However,

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<sup>1</sup> For Medicare reimbursement purposes, a physician is defined as: (1) a doctor of medicine or osteopathy; (2) a doctor of dental surgery or of dental medicine; (3) a podiatrist; (4) an optometrist; and (5) a chiropractor, all of whom must be appropriately licensed by the state. 42 U.S.C. § 1395x(r).

Medicare and other government and private health care plans will only pay for those services that meet appropriate medical necessity standards (in the case of Medicare, i.e., reasonable and necessary services). The Hospital may not bill for services that do not meet the applicable standards. The OIG has indicated that the Hospital is in a unique position to deliver this information to the health care professionals on its staff. The Hospital should therefore be able to provide documentation, such as patients' medical records and physicians' orders, to support the medical necessity of a service that the Hospital has provided. The Compliance Officer should ensure that a clear, comprehensive summary of the "medical necessity" definitions and rules of the various government and private plans is prepared and disseminated appropriately.

On every CMS claim form, a physician must certify that the services were medically necessary for the health of the beneficiary. Each fiscal intermediary<sup>2</sup> publishes local policies, including local coverage determinations ("LCDs") that identify certain procedures that are only reimbursable when specific conditions are present. In addition to relying on a physician's sound clinical judgment with respect to the appropriateness of a proposed course of treatment, the Hospital should regularly review and become familiar with LCDs and incorporate the LCDs into the Hospital's regular coding and billing operations.

(f) Upcoding. This is the practice of using a billing code that provides a higher payment rate than the billing code that actually reflects the service furnished to the patient. Upcoding has been a major focus of the OIG's enforcement efforts. In addition, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") added another civil monetary penalty to those that OIG can impose for upcoding violations. See 42 U.S.C. § 1320a-7a(a)(1)(A).

(g) DRG creep. Like upcoding, "DRG creep" is the practice of billing with a code that provides a higher payment rate than the DRG code that accurately reflects the service furnished to the patient.

(h) Improper coding. Charge Description Masters ("CDMs") list all of a hospital's charges for items and services and include the underlying procedure codes necessary to bill for those items and services. Outdated CDMs create significant compliance risk for hospitals. Because the Healthcare Common Procedure Coding System ("HCPCS") codes and ambulatory payment classifications ("APCs") are updated regularly, the Hospital should pay particular attention to the task of updating the CDM to ensure the assignment of correct codes to outpatient claims. This will include timely updates, proper use of modifiers, and correct associations between procedure codes and revenue codes. The Hospital should also use proper codes to describe the evaluation and management ("E/M") services provided. The Hospital's E/M coding guidelines should ensure that

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<sup>2</sup> The Medicare fiscal intermediaries are private insurance companies that serve as the federal government's agents in the administration of the Medicare program, including the payment of claims. There are two primary functions for the fiscal intermediary: (1) reimbursement review and (2) medical coverage review.

services are medically necessary and sufficiently documented and that the codes accurately reflect the intensity of Hospital resources required to deliver the services.

(i) Outpatient services rendered in connection with inpatient stays. The Medicare program has special billing rules for outpatient services rendered in connection with an inpatient stay. Hospitals that submit claims for non-physician outpatient services that were already included in the hospital's inpatient payment under the Prospective Payment System ("PPS") are in effect submitting duplicate claims. The Hospital will implement measures designed to demonstrate its good faith efforts to comply with these rules, including some or all of the following:

- installing and maintaining computer software that will identify those outpatient services that may not be billed separately from an inpatient stay;
- implementing a periodic manual review to determine the appropriateness of billing each outpatient service claim, to be conducted by one or more appropriately trained individuals familiar with applicable billing rules;
- with regard to each inpatient stay, scrutinizing the propriety of any potential bills for outpatient services rendered to that patient at the hospital, within the applicable time period.

In addition to the pre-submission undertakings described above, the Hospital may implement a post-submission testing process, as follows:

- implement and maintain a periodic post-submission random testing process that examines or re-examines previously submitted claims for accuracy;
- inform the fiscal intermediary and any other appropriate government fiscal agents of the hospital's testing process; and
- advise the fiscal intermediary and any other appropriate government fiscal agents, in accordance with current regulations or program instructions about overpayments or any incorrectly submitted or paid claims and, if the claim has already been paid, promptly reimburse the fiscal intermediary and the beneficiary for the amount of the claim paid by the government payor and any applicable deductibles or copayments, as appropriate.

(j) Admissions and discharge policies. The Hospital shall continually review internal billing systems and procedures to ensure that they are not submitting multiple claims for Outpatient Prospective Payment Services ("OPPS") delivered to the same patient on the same day. Same-day discharges and readmissions may indicate premature discharges, medically unnecessary readmissions, or incorrect discharge coding. Hospital employees and professional staff should review discharges and admissions carefully to ensure that they reflect prudent clinical decision-making and are properly coded.

(k) Duplicate billing. Duplicate billing occurs when a hospital submits more than one claim for the same service, or a bill is submitted to more than one primary payor at the same time. Although duplicate billing can occur due to simple error, systematic or repeated double billing may be viewed as a false claim, particularly if any overpayment is not promptly refunded. CMS developed the National Correct Coding Initiative (“NCCI”) to promote correct coding methodologies. The NCCI identifies certain codes that should not be used together because they are either mutually exclusive or one is a component of another. Intentional manipulation of code assignments to maximize payments and avoid NCCI edits constitutes fraud. To minimize risk, the Hospital shall ensure that its coding software includes up-to-date NCCI edit files.

(l) False cost reports. The submission of false cost reports is usually limited to certain Part A providers, such as hospitals, skilled nursing facilities and home health agencies, which are reimbursed in part on the basis of their self-reported operating costs. An OIG audit report on misuse of fringe benefits and general and administrative costs identified millions of dollars in unallowable costs from providers’ lack of internal controls over costs in their Medicare cost reports. In addition, the OIG is aware of practices in which hospitals inappropriately shift certain costs to cost centers that are below their reimbursement cap and shift non-Medicare related costs to Medicare cost centers. The Hospital submits an annual cost report in connection with its participation in the Medicare program. The person or persons responsible for preparing and submitting the cost report should strive to ensure that:

- costs are not claimed unless based on appropriate and accurate documentation;
- allocations of costs to various cost centers are accurately made and supportable by verifiable and auditable data;
- unallowable costs are not claimed for reimbursement;
- accounts containing both allowable and unallowable costs are analyzed to determine the unallowable amount that should not be claimed for reimbursement;
- costs are properly classified;
- fiscal intermediary prior year audit adjustments are implemented and are either not claimed for reimbursement, or claimed for reimbursement and clearly identified as protested amounts on the cost report;
- all related parties are identified on appropriate forms submitted with the cost report and all related party charges are reduced to cost;
- requests for exceptions to Tax Equity and Fiscal Responsibility Act of 1982 limits and the “Routine Cost Limits” are properly documented and supported by verifiable and auditable data;

- the Hospital's procedures for reporting of bad debts on the cost report are in accordance with federal statutes, regulations, guidelines and policies (with regard to bad debts claimed on the Medicare cost report, see also section (xvii) below); and
- procedures are in place and documented for notifying promptly the Medicare fiscal intermediary (or any other applicable payor) of errors discovered after the submission of the cost report.

(m) Unbundling. This is the practice of submitting bills piecemeal or in fragmented fashion to maximize the reimbursement for various tests or procedures that are required to be billed together and therefore at a reduced cost.

(n) Billing for discharge in lieu of transfer. Under the Medicare regulations, when a PPS hospital transfers a patient to another PPS hospital, only the hospital to which the patient was transferred may charge the full DRG; the transferring hospital should charge Medicare only a per diem amount.

(o) Use of information technology. HIPAA Privacy and Security Rules, electronic claims submission, electronic prescribing, networked information sharing among providers, and systems for the tracking and reduction of medical errors, among others, will require the Hospital to depend more on information technologies. The Hospital should assess all new computer systems and software that may impact coding, billing, or the generation or transmission of information related to the federal health care programs or their beneficiaries.

(p) Submission of Claims for Laboratory Services. With respect to claims for laboratory services, certain procedures should be followed to ensure that all claims for clinical and diagnostic laboratory testing services are accurate and correctly identify the services ordered by the physician (or other authorized requestor) and subsequently performed by the laboratory. These policies and procedures should require, at a minimum, that:

- the Hospital bills for laboratory services only after they are performed;
- the Hospital bills only for medically necessary services;
- the Hospital bills only for those tests actually ordered by a physician and provided by the hospital laboratory;
- the Current Procedural Terminology ("CPT") or HCPCS code used by the billing staff accurately describes the service that was ordered by the physician and performed by the hospital laboratory;

- the coding staff: (1) only submit diagnostic information obtained from qualified personnel; and (2) contact the appropriate personnel to obtain diagnostic information in the event that the individual who ordered the test has failed to provide such information; and
- where diagnostic information is obtained from a physician or the physician's staff after receipt of the specimen and request for services, the receipt of such information is documented and maintained.

(q) Bad Debts. In accordance with the requirements of the Medicare program, the Hospital shall develop a mechanism (e.g., contract with an independent professional organization, such as an accounting, law or consulting firm) to review, at least annually, whether the Hospital is properly reporting bad debts to Medicare, and all Medicare bad debt expenses claimed, to ensure that the Hospital's procedures are in accordance with applicable federal and state statutes, regulations, guidelines and policies. In addition, such a review should ensure that the Hospital has appropriate and reasonable mechanisms in place regarding beneficiary deductible or co-payment collection efforts, and has not claimed as bad debts any routinely waived Medicare copayments or deductibles (waiver also constitutes a violation of the anti-kickback statute that is discussed in detail below). Further, the Hospital may consult with the appropriate fiscal intermediary as to bad debt reporting requirements, if questions arise.

(r) Credit Balances. The Hospital shall institute procedures to refund all credit balances as required by law, and timely and accurately report Medicare and other federal health care program credit balances. To do this, the Hospital may do one or all of the following:

- redesignate segments of its information system to allow for the segregation of patient accounts reflecting credit balances. Then, remove these accounts from the active accounts and place them in a holding account pending the processing of a reimbursement claim to the appropriate program.
- regularly review the Hospital's information system to ensure that it has the ability to print out the individual patient accounts that reflect a credit balance in order to permit simplified tracking of credit balances.
- designate at least one person in the Patient Accounts Department as having the responsibility for tracking, recording and reporting credit balances, and require the Hospital's Business Office to review reports of credit balances and reimbursements or adjustments on a monthly basis.

(s) Service to HMO Members. The OIG has expressed concern regarding "knowing" failure to provide covered services or necessary care to members of a health maintenance organization. It is Hospital policy to avoid discrimination based on membership in certain health maintenance organizations.

Hospital employees and agents who prepare or submit claims should be alert for these and other errors. It is important to remember that outside consultants only advise the Hospital. The final decision on billing questions rests with the Hospital, and the Hospital remains ultimately responsible for all billing claims submitted. The Hospital does not permit charging for any Medicaid service at a rate higher than that approved by the state or accepting any payment as a precondition of admitting a Medicaid patient to the Hospital.

It is the Hospital's policy that the Compliance Committee, the Compliance Officer and Hospital employees and professional staff members strive to ensure that:

- the Hospital, Personnel and Affiliates provide for proper and timely documentation of all physician and other professional services prior to billing to so that only accurate and properly documented services are billed;
- the Hospital utilizes its unique position to deliver information to health providers as to what constitutes reasonable and necessary services; in this regard, the Hospital may provide Personnel and Affiliates with a comprehensive summary of the "medical necessity" definitions and rules of the various government and private plans;
- consistent with appropriate guidance from medical staff, physician and hospital records and medical notes used as a basis for a claim submission are appropriately organized in a legible form so they can be audited and reviewed;
- the diagnosis and procedures reported on reimbursement claims are based on the medical record and other documentation, and the documentation necessary for accurate code assignment is available to coding staff;
- compensation for billing department coders and billing consultants does not provide any financial incentive to improperly upcode claims;
- the Hospital carefully follows the Medicare rules on assignment and reassignment of billing rights. If there is any question whether the Hospital may bill for a particular service, either on behalf of a physician or on its own behalf, the question should be directed to the Compliance Officer for review; and
- Hospital employees understand that they should not submit claims for other entities, or claims prepared by other entities, including outside consultants, without approval from the Compliance Officer. Special care should be taken in reviewing these claims, and Hospital personnel should request documentation from outside entities if necessary to verify the accuracy of the claims.

### 2.2.3 Penalties

A provider or supplier who violates the false claims rules is guilty of a felony, and may be subject to fines of up to \$25,000 per offense, imprisonment for up to five years, or both. Other persons guilty of false claims may face fines of up to \$10,000 per offense, imprisonment

for up to one year, or both. In addition to the criminal penalties, the Federal False Claims Act permits substantial civil monetary penalties against any person who submits false claims. The Act provides a penalty of triple damages as well as fines up to \$10,000 for each false claim submitted. The person (as well as the Hospital) may be excluded from participating in the Medicare and Medicaid programs. Violations of the assignment and reassignment rules are misdemeanors carrying fines of up to \$2,000 and imprisonment of up to six months, or both.

In addition to these federal penalties, state statutes and regulations also impose both civil and criminal penalties for fraudulent Medicaid billing. There is a wide range of prohibited conduct set forth in the Texas Department of Health rules as grounds for fraud referral and administrative sanctions. These include not only fraudulent billing activities, but also such activities as providing false information with respect to a patient's eligibility for coverage under the Medicaid program, failure to provide and maintain quality services to Medicaid recipients, and many other prohibited activities. Civil monetary penalties for violations of these regulations can be substantial, as each fraudulently billed item is considered a separate violation.

In addition to civil monetary penalties, criminal sanctions can be imposed on fraudulent activity within the Medicaid program. Violations of the illegal remuneration and patient referral act is a Class A misdemeanor. If a person has previously been convicted of such an offense, a subsequent offense is a felony of the third degree. Additionally, general fraud provisions of the Texas Penal Code may have application to alleged fraudulent billing under the Medicaid program. Finally, the Texas Penal Code contains a chapter relating specifically to fraudulent billing activities to health care insurance companies. An offense under that chapter ranges from a Class C misdemeanor if the value of the claim is less than \$20 to a felony of the first degree if the value of the claim is \$200,000 or more. Additionally, when separate fraudulent claims are communicated to a health insurance company, the conduct may be considered as one offense and the value of the claims aggregated in determine the classification of offense, thus rendering it a more serious offense.

Numerous other federal laws prohibit false statements or inadequate disclosure to the government and mandate exclusion from the Medicare and Medicaid programs. For instance, neither the Hospital nor its agents are permitted to make, or induce others to make, false statements in connection with the Hospital's Medicare certification. Persons doing so are guilty of a felony and may be subject to fines of up to \$25,000 and imprisonment for up to five years. The Hospital or individual health care providers will be excluded from the Medicare and Medicaid programs for at least five years if convicted of a Medicare or Medicaid-related crime or any crime relating to patient abuse. Medicare and Medicaid exclusion may result if the Hospital or a provider is convicted of fraud, theft, embezzlement, or other financial misconduct in connection with any government-financed program.

The Hospital promotes full compliance with each of the relevant laws by maintaining a strict policy of integrity and accuracy in all its financial dealings. Each employee and professional, including outside consultants, who is involved in submitting charges, preparing claims, billing, and documenting services is expected to maintain the highest standards of personal, professional, and institutional responsibility.

## **2.3 *Payments and Illegal Remuneration***

The Hospital participates in the Medicare and the Medicaid programs. Federal law makes it illegal for the Hospital to provide or accept "remuneration" in exchange for referrals of patients covered by Medicare or Medicaid. The law also bars the payment or receipt of such remuneration in return for directly purchasing, leasing, ordering, or recommending the purchase, lease, or ordering of any goods, facilities, services, or items covered under the benefits of Medicare or Medicaid. In Texas, a parallel state statute applies these same prohibitions to all patients, regardless of payor source.

The so-called "fraud and abuse" and "anti-kickback" laws are designed to prevent fraud in the Medicare and Medicaid programs and abuse of the public funds supporting the programs. The Hospital is committed to carefully observing the anti-kickback rules and avoiding any practice that may be interpreted as abusive or violative of these provisions. Employees in the Business Office, Hospital Administration, Laboratory, Pharmacy, and Central Supply are expected to be vigilant in identifying potential anti-kickback violations and bringing them to the attention of the Compliance Officer.

### **2.3.1 Anti-Kickback Laws**

The federal and state anti-kickback laws are broadly written to prohibit the Hospital and its representatives from knowingly and willfully offering, paying, asking, or receiving any money or other benefit, directly or indirectly, in return for obtaining or rewarding favorable treatment in connection with the award of a government contract. The anti-kickback laws must be considered whenever something of value is given or received by the Hospital or its representatives or affiliates that is in any way connected to patient services. This is particularly true when the arrangement could result in over-utilization of services or a reduction in patient choice. Even if only one purpose of a payment scheme is to influence referrals, and otherwise it appears to be a legitimate, appropriate business arrangement, the payment may be unlawful.

There are many transactions that may violate the anti-kickback rules. For example, no one acting on behalf of the Hospital may offer gifts, loans, rebates, services, or payment of any kind to a physician who refers patients to the Hospital, or to a patient, without consulting the Compliance Officer. The Compliance Officer should review any discounts offered to the Hospital by suppliers and vendors, as well as discounts offered by the Hospital to insurance companies or other third party payors. Patient deductibles and co-payments may not be waived without the prior authorization of the Compliance Officer. Rentals of space and equipment must be at fair market value, without regard to the volume or value of referrals that may be received by the Hospital in connection with the space or equipment. Fair market value should be determined through an independent appraisal.

Agreements for professional services, management services, and consulting services must be in writing, have at least a one-year term, and specify the compensation in advance. Payment based on a percentage of revenue should be avoided in many circumstances. Any questions about these agreements should be directed to the Compliance Officer. Joint ventures with physicians or other health care providers, or investment in other health care entities, must be

reviewed by the Compliance Officer.

The U.S. Department of Health and Human Services has described a number of payment practices that will not be subject to criminal prosecution under the anti-kickback laws, commonly known as the "safe harbors." If an arrangement fits within a safe harbor and all of the elements of the safe harbor are satisfied, the arrangement will not create a risk of criminal penalties and exclusion from the Medicare and Medicaid programs. However, the failure to satisfy every element of a safe harbor does not in itself make an arrangement illegal. Analysis of a payment practice under the anti-kickback laws and the safe harbors is complex, and depends upon the specific facts and circumstance of each case. Employees should not make unilateral judgments on the availability of a safe harbor for a payment practice, investment, discount, or other arrangement. These situations must be brought to the attention of the Compliance Officer for review with legal counsel.

Contrary to common belief, violations of the anti-kickback statute are not subject to civil monetary penalties but rather criminal sanctions. A violation of the anti-kickback laws is a felony, punishable by a \$25,000 fine or imprisonment for up to five years, or both. Violation of the law could also mean that the Hospital and/or a physician is excluded from participating in the Medicare and Medicaid programs for up to five years.

In addition to the federal criminal penalties, Texas state law also provides for prohibitions on illegal remuneration. A violation of the state law is a Class A misdemeanor, unless it is shown that the person has previously been convicted of an offense or the person was employed by a federal, state, or local government at the time of the offense. In that case, a violation is a third degree felony. The state statute also provides for civil penalties of up to \$10,000 for each act of a violation. The state law, however, contains a provision indicating that if the act or course of action is not a violation of the federal laws, it will not be considered a violation of state law.

### 2.3.2 Entertainment and Gifts

The Hospital recognizes that business dealings may include a shared meal or other similar social occasion, which may be proper business expenses and activities. However, Hospital employees may not receive any gift under circumstances that could be construed as an improper attempt to influence the Hospital's or an employee's decisions or actions. When an employee receives a gift that may violate this policy, the gift should be returned to the donor and reported to the Compliance Officer. Gifts may only be received by Hospital employees when they are of such limited value that they could not reasonably be perceived by anyone as an attempt to affect the judgment of the recipient, such as token promotional gratuities from suppliers. A gift must be reported to the Compliance Officer upon its receipt any time an employee is not sure whether a gift is prohibited by this policy.

### 2.3.3 Discounts to Uninsured Patients

Federal regulations do not prohibit or restrict the Hospital's ability to offer discounts to uninsured patients who are unable to pay their hospital bills. Discounts offered to underinsured

patients potentially raise a more significant concern under the anti-kickback statute, and the Hospital should exercise care to ensure that such discounts are not tied directly or indirectly to the furnishing of items or services payable by a Federal health care program.

#### 2.3.4 Professional Courtesy Discounts

“Professional courtesy” refers to various programs that offer free or discounted hospital services to medical staff, employees, community physicians, and their families and staff. Although many professional courtesy programs are unlikely to pose a significant risk of abuse (and many may be legitimate employee benefits programs eligible for the employee safe harbor), some programs may implicate the fraud and abuse statutes.

In general, whether a professional courtesy program runs afoul of the anti-kickback statute turns on whether the recipients of the professional courtesy are selected in a manner that takes into account, directly or indirectly, any recipient's ability to refer to, or otherwise generate business for, the hospital. Also relevant is whether the physicians have solicited the professional courtesy in return for referrals. With respect to the Stark law, the key inquiry is whether the arrangement fits in the exception for professional courtesy at 42 CFR § 411.357(s). The Hospital should evaluate the method by which the courtesy is granted. The Stark law exception for professional courtesy requires that insurers be notified if “professional courtesy” includes “insurance only” billing.

### **2.4 Patient Referrals**

Patient referrals are important to the delivery of appropriate health care services. The Hospital's policy is that patients are free to select their health care providers and suppliers, subject only to the requirements of their health insurance plans. The choice of a hospital, a diagnostic facility, or a supplier should be made by the patient, with guidance from his or her physician as to which providers are qualified and medically appropriate.

Physicians and other health care providers may have financial relationships with the Hospital or its affiliates. These relationships may include compensation for administrative or management services, income guarantees, loans of certain types, or free or subsidized administrative services. In some cases, a physician may have invested as a part-owner in a piece of diagnostic equipment or a health care facility.

A federal law known as the "Stark law" applies to any physician who has, or whose immediate family member has a "financial relationship" with an entity such as the Hospital, and prohibits referrals by that physician to the Hospital for the provision of certain designated health services reimbursed by Medicare and Medicaid. If a financial relationship exists, referrals are prohibited unless a specific exception is met. The Hospital requires that each financial relationship with a referring physician or his or her family member fit within one of the exceptions to the Stark law. Although responsibility for evaluating financial relationships with physicians lies with the Compliance Officer, the chief of staff, the medical staff administration, and the payroll department are expected to monitor financial relationships and report any

irregularities to the Compliance Officer.

The Stark law applies to the clinical laboratory services, physical therapy, occupational therapy, radiology (including MRI, CT, ultrasound, and mammography), durable medical equipment, parenteral and enteral nutrients, equipment and supplies, prosthetics and orthotics, home health services, outpatient prescription drugs, inpatient and outpatient hospital services, and radiation therapy services and supplies.

The exceptions under the Stark law are complex, and several general rules must be followed. Both leases for physician office space and personal services contracts with physicians must be in writing and signed by the parties. Any premises leased must be specified and must not exceed the space reasonably needed for the physician's legitimate purposes. Rental charges must be set in advance at fair market value without regard to the volume or value of referrals by the physician. A lease must be commercially reasonable even if no referrals were made between the parties. Similarly, a personal service contract must specify the services to be provided by the physician to the Hospital, which must be reasonable and necessary, for legitimate purposes, and must be for at least one year. Compensation paid to physicians must also be set in advance at fair market value, be unrelated to the volume or value of referrals, and be commercially reasonable. Contract services may not involve the counseling or promotion of an illegal business arrangement. Physician incentive plans, which may include volume-based compensation, will be acceptable if certain requirements are met.

Physicians purchasing clinical laboratory services or other items or services from the Hospital must pay fair market value. An arrangement whereby the Hospital bills for a group practice may be acceptable if it was in place prior to December 19, 1989 and meets certain other requirements. A pathologist, radiologist, or radiation oncologist may provide Hospital laboratory, pathology, diagnostic radiology, or radiation oncology services on his own order or on a consultation request from another physician.

Penalties for violating the Stark law include (i) no Medicare or Medicaid payment for the service referred illegally; (ii) a refund to the beneficiary of any amounts collected; (iii) fines of up to \$15,000 levied on both the physician and the entity for each service referred illegally, plus additional fines based on the amounts billed; (iv) civil monetary penalties of up to \$100,000 plus other assessments; and (v) exclusion from the Medicare or Medicaid programs.

## ***2.5 Physician Recruitment***

The recruitment and retention of physicians require special care to comply with Hospital policy and applicable law. Physician recruitment has implications under the anti-kickback laws and the Stark law. Each recruitment package or commitment should be in writing, consistent with guidelines established with the Hospital. New or unique recruitment arrangements must be reviewed by the Compliance Officer, who may require legal counsel review and approval. In general, support provided to a new physician is most likely to be acceptable if it is provided in order to persuade the physician to relocate to the Hospital's geographic service area in order to become a member of the professional staff or if it is provided to a new physician completing his or her training. Support should be of limited duration. The physician cannot be required to refer

patients to the Hospital, and the amount of compensation or support cannot be related to the volume or value of referrals. Income guarantees present special issues and should be reviewed by the Compliance Officer and counsel on a case-by-case basis.

In the case of an income guarantee made to a recruited physician who joins a physician or physician practice, the costs allocated by the physician or physician practice to the recruited physician cannot exceed the actual additional incremental costs attributable to the recruited physician. Additionally, the physician or physician practice cannot impose additional practice restrictions (such as a covenant not to compete) on the recruited physician other than conditions related to quality of care.

## ***2.6 Competition and Antitrust Issues***

The Hospital is committed to complying with all state and federal antitrust laws. The purpose of the antitrust laws is to preserve the competitive free enterprise system. The antitrust laws in the United States are founded on the belief that the public interest is best served by competition, free from collusive agreements among competitors on price or service terms. The antitrust laws apply to health care services provided by hospitals and physicians, and the Hospital is firmly committed to the philosophy underlying those laws.

While the antitrust laws clearly prohibit most agreements to fix prices, divide markets, and boycott competitors-- which are addressed below-- they also proscribe conduct that is found to restrain competition unreasonably. This can include, depending on the facts and circumstances involved, certain attempts to tie or bundle services together, certain exclusionary activities, and certain agreements that have the effect of harming a competitor or unlawfully raising prices. Any questions that might arise should be addressed to the Compliance Officer.

### **2.6.1 Discussion With Competitors**

Hospital policy requires that the rates it charges for Hospital care and related items and services, and the terms of its third party payor contracts, must be determined solely by the Hospital. In independently determining prices and terms, the Hospital may take into account all relevant factors, including costs, market conditions, widely used reimbursement schedules, and prevailing competitive prices, to the extent these can be determined in the marketplace. There can be, however, no oral or written understanding with any competitor concerning prices, pricing policies, pricing formulas, bids, or bid formulas, or concerning discounts, credit arrangements, or related terms of sale or service. To avoid the possibility of misunderstanding or misinterpretation, Hospital policy prohibits any consultation or discussion with competitors relating to prices or terms which the Hospital or any competitor charges or intends to charge. Joint ventures and affiliations that may require pricing discussions must be individually reviewed for antitrust compliance. Discussions with competitors concerning rationalization of markets, down-sizing, or elimination of duplication ordinarily implicate market division and must be avoided.

Hospitals are often asked to share information concerning employee compensation. Hospital policy prohibits the sharing with competing hospitals of current information or future

plans regarding individual salaries or salary levels. The Hospital may participate in and receive the results of general surveys, but these must conform to the guidelines for participation in surveys provided under Trade Associations below.

Similarly, Hospital policy prohibits consultation or discussion with competitors with respect to its services, selection of markets, territories, bids, or customers. Any agreement or understanding with a competitor to divide markets is prohibited. This includes an agreement allocating shares of a market among competitors, dividing territories, or dividing product lines or customers.

### 2.6.2 Trade Associations

The Hospital and its health care providers are involved in trade and professional associations. These organizations promote quality patient care by allowing the Hospital and providers to learn new skills, develop policies and, where appropriate, speak with one voice on public issues. However, it is not always appropriate to share business information with trade associations and their members. Sharing information is appropriate if it is used to better inform consumers or to promote efficiency and competition.

The Hospital may participate in surveys of price, cost, and wage information if the survey is conducted by a third party and involves at least five comparably sized hospitals. Any price, cost, or wage information released by the Hospital must be at least three months old. If an employee is asked to provide a trade association with information about the Hospital's charges, costs, salaries, or other business matters, he or she should consult the Compliance Officer. Joint purchasing through a trade association is probably acceptable but any joint purchasing plan should be reviewed in advance by the Compliance Officer. If an employee or professional staff member has any question or concern about an activity of a trade association, he or she may ask the Compliance Officer to seek guidance from counsel.

### 2.6.3 Boycotts

Hospital policy prohibits any agreement with competitors to boycott or refuse to deal with a particular person or persons, such as a vendor, payor, or other provider. These agreements need not be written to be illegal; any understanding reached with a competitor (directly or indirectly) on such matters is prohibited. All negotiations by Hospital agents and employees must be conducted in good faith. Exclusive arrangements with payors, vendors, and providers must be approved by a Hospital Officer or by the Compliance Officer based on an analysis of the relevant market.

### 2.6.4 Physician Services

Hospital credentialing and peer review activities also may carry antitrust implications. Because of the special training and experience of physicians, their skills may best be evaluated by other physicians. It is appropriate for physicians to review the work of their peers. Because the physicians reviewing a particular physician may, by virtue of their medical specialties, be the physician's competitors, special care must be taken to ensure that free and open competition is

maintained. As a result, credentialing, peer review and physician discipline at the Hospital are conducted only through properly constituted committees. Physicians participating in these activities are expected to use objective medical judgment.

If any Hospital employee is involved in negotiating a contract of employment or a personal services contract with a physician or other health care provider, it is important to review with care any non-competition provisions incorporated in the agreement. The appropriate geographic scope and duration of a non-competition agreement may vary from case to case. Questions about the appropriateness of a non-competition provision should be directed to the Compliance Officer for review with legal counsel.

#### 2.6.5 Penalties

Penalties for antitrust violations are substantial. Individuals and corporations can be fined \$350,000 and \$10,000,000 respectively, for each antitrust violation, and individuals can be sentenced for up to three years in prison for each offense. In addition, actions giving rise to antitrust violations may violate other federal criminal statutes, such as mail fraud or wire fraud, under which substantial fines and even longer prison sentences can be imposed. Antitrust violations also create civil liability. Private individuals or companies may bring actions to enjoin antitrust violations and to recover damages for injuries caused by violations. If successful, private claimants are entitled to receive three times the amount of damages suffered, plus attorneys fees. Moreover, if the antitrust violation was a conspiracy, each member of that conspiracy may be liable for the entire damage caused by the conspiracy.

#### 2.6.6 Unfair or Deceptive Practices

In addition to the antitrust laws, the Hospital is committed to complying with other federal and state laws governing market competition. Federal law, particularly the Federal Trade Commission Act, and state law, including the Deceptive Trade Practices - Consumer Protection Act, prohibit the use of "unfair or deceptive acts and practices," including the distribution of labeling, advertising, and marketing materials that are false or misleading. Hospital employees responsible for preparing and distributing such materials must be familiar with these laws. Questions about specific materials should be directed to the Compliance Officer before distribution.

Under state law, a private cause of action is provided for under the Deceptive Trade Practices - Consumer Protection Act. In many cases, treble damages may be obtained by the aggrieved party and attorneys fees are also recoverable. Great care should be utilized when making representations about the services and functions of the Hospital to ensure that false or misleading information is not provided with respect to the Hospital or its services.

### **2.7 *Physician Practice Acquisition***

To improve the delivery of health care services, the Hospital may, from time to time, acquire physician practices. These acquisitions require special care to comply with applicable

law because they have implications under the anti-kickback laws and the Stark law.

### 2.7.1 Anti-Kickback Laws

As discussed above, federal law makes it illegal for the Hospital to provide or accept "remuneration" in exchange for referrals of patients covered by Medicare or Medicaid. Acquisitions of physician practices may implicate the anti-kickback laws because they may constitute illegal payments to induce the referral of Medicare or Medicaid patients.

Generally, acquisitions will comply with federal law when the amounts paid by the Hospital reflect the fair market value of the acquired practice. Fair market value should be determined through an independent appraisal. Payments in excess of fair market value may violate the anti-kickback laws, particularly when there is an ongoing relationship between the Hospital and the acquired practice. Several specific types of payment are subject to scrutiny, including payment for good will, payment for value of ongoing business unit, payment for covenants not to compete, payment for exclusive dealing agreements, payment for patient lists, and payment for patient records.

The "safe harbor" protections discussed above may also apply to a particular acquisition. Employees should not, however, make unilateral judgments on the availability of a safe harbor. These situations must be brought to the attention of the Compliance Officer for review with legal counsel. Any questions should be directed to the Compliance Officer, and any proposed acquisition of a physician practice must be reviewed by the Compliance Officer.

### 2.7.2 Stark Law

Physician practice acquisitions also implicate the Stark law discussed earlier. Because the law is particularly complex, all transactions must be reviewed by the Compliance Officer and legal counsel to ensure compliance.

## **2.8 Gainsharing Arrangements**

The civil monetary penalties (CMPs) set forth in Section 1128A(b)(1) of the Social Security Act prohibit the Hospital from knowingly making a payment directly or indirectly to a physician as an inducement to reduce or limit items or services furnished to Medicare or Medicaid beneficiaries under the physician's direct care. The Hospital, and the physicians involved in the arrangement, are liable for CMPs of up to \$2,000 per patient covered by the payments.

The statutory prohibition on these types of payments is very broad. For example, the payment need not be tied to an actual reduction in services, so long as the hospital knows that the payment may influence the physician to reduce or limit services to his or her patients. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. In short, an incentive plan implemented by the Hospital that encourages physicians through payments to reduce or limit clinical services, directly or indirectly violates the statute.

The Hospital may be engaged in, or consider entering into, incentive arrangements with physicians, commonly called “gainsharing.” Gainsharing arrangements would involve the Hospital giving physicians a percentage share of any reduction in the Hospital’s costs for patient care attributable in part to the physicians’ efforts. The plain language of Section 1128A(b)(1) of the Social Security Act prohibits tying the physicians’ compensation for services to reductions or limitations in items or services provided to patients under the physicians’ care.

Additionally, gainsharing arrangements can also implicate the anti-kickback statute if the cost-savings payments are used to influence referrals. For example, the statute is potentially implicated if a gainsharing arrangement is intended to influence physicians to attract healthy patients to the Hospital and steer sicker (and more costly) patients to a hospital that does not offer gainsharing payments. Similarly, the statute may be implicated if the Hospital offers a cost-sharing program with the intent to foster physician loyalty and attract more referrals. Wherever possible, the Hospital should consider structuring cost-saving arrangements to fit in the personal services safe harbor. For many of the reasons outlined above, gainsharing arrangements may also implicate the Stark law.

Properly structured, gainsharing arrangements can serve the legitimate business and medical purposes of the Hospital, such as increasing efficiency, reducing waste, and, thereby, potentially increasing the Hospital's profitability. However, given the potential problems with gainsharing arrangements, Hospital staff should consult with legal counsel before implementing any such arrangements.

## **2.9 Patient Transfers**

Operation of the emergency department is an important part of the Hospital's service to the community and is a place where any sick or injured person may come for care regardless of his or her ability to pay. An "anti-dumping" law has been enacted to ensure that patients are not transferred from a hospital emergency room to another facility unless it is medically appropriate. Under that law, prompt and effective emergency care may not be delayed in order to determine a patient's insurance or financial status. Each patient who presents at the emergency department must receive an appropriate medical screening examination. Patients with emergency medical conditions, and patients in active labor, must be cared for in the Hospital's emergency department until their condition has stabilized. An emergency may include psychiatric disturbances, symptoms of substance abuse, or contractions experienced by pregnant women.

If necessary, the stabilized patient may be transferred to another hospital that is qualified to care for the patient, has space available, and has agreed to accept the transfer. Before transfer, Hospital staff shall provide the medical treatment which minimizes the risks to the patient's health and, in the case of a woman in labor, the health of the unborn child. A physician must sign a certification that the medical benefits reasonably expected from treatment at another medical facility outweigh the increased risks to the patient (and, if appropriate, the unborn child). No physician will be penalized for refusing to authorize the transfer of an individual with an emergency condition that has not been stabilized. The transfer must be performed by qualified personnel and transportation equipment, including life support measures during transfer if

medically appropriate. A copy of the patient's record, including complete records of the emergency department encounter and any other records that are available, must be sent to the receiving hospital.

The "anti-dumping" law carries reporting obligations. Any employee who believes that an emergency patient has been transferred improperly must report the incident to the Compliance Officer. No employee will be penalized for reporting a suspected violation of the patient transfer law. If an employee or professional staff member believes that an emergency patient has been transferred to the Hospital improperly, the suspected violation must be reported to the Compliance Officer and to proper authorities within seventy-two (72) hours of its occurrence. The name and address of any on-call physician who refuses or fails to appear within a reasonable time to provide necessary stabilizing treatment of an emergency medical condition or active labor is to be reported immediately to the Compliance Officer.

In addition to the Hospital's medical records, the emergency department will maintain an on-call duty roster and a log documenting each individual who comes to the emergency department seeking assistance. The log must document whether the patient refused treatment or was refused treatment, transferred, was admitted and treated, stabilized and transferred, or discharged. When a patient or a patient's legal representative requests a transfer or refuses a transfer, the informed consent or refusal must be documented in writing. If there are questions about the records required under the patient transfer law, the Compliance Officer will answer them or refer them to counsel.

The federal "anti-dumping" law is enforced through civil monetary penalties and through damages in private civil actions. If a hospital violates the statute, it can be fined up to \$50,000 for each violation. A physician, including an on-call physician, who is responsible for the examination, treatment, or transfer of an emergency patient and who negligently violates the law may be fined up to \$50,000 for each violation. If the violation is gross and flagrant or repeated, the physician may be excluded from participation in the Medicare and Medicaid programs.

Texas statutes and regulations of the Texas Department of State Health Services also provide for minimum standards in patient transfers. Personnel involved in the transfer of a patient shall ensure that all provisions of any governing transfer agreements are strictly followed, and in the absence of a transfer agreement, that all rules and regulations of the Texas Department of State Health services are strictly followed.

## **2.10 Substandard Care**

The OIG has authority to exclude any individual or entity from participation in Federal health care programs if the individual or entity provides unnecessary items or services, or substandard items or services.<sup>25</sup> Neither knowledge nor intent is required for exclusion under this provision. The exclusion can be based upon unnecessary or substandard items or services provided to any patient, even if that patient is not a Medicare or Medicaid beneficiary.

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<sup>25</sup> Social Security Act, Section 1128(b)(6)(B)

The Hospital is fully committed to providing quality care to its patients. To achieve its quality-related goals, the Hospital shall continually measure its performance against comprehensive standards. The Hospital is aware it must meet all of the Medicare hospital conditions of participation (COPs), including without limitation, the COP pertaining to a quality assessment and performance improvement program at 42 CFR § 482.21 and the hospital COP pertaining to the medical staff at 42 CFR § 482.22. In addition, the Hospital shall develop quality of care protocols and implement mechanisms for evaluating compliance with those protocols. The Hospital shall review the quality of nursing and other ancillary services. Medical services provided at the Hospital shall be reviewed by appropriately overseeing the credentialing and peer review of the medical staff.

## ***2.11 Relationships with Beneficiaries***

The Hospital's relationship with Federal health care beneficiaries may also implicate the fraud and abuse laws. The Hospital may not offer valuable items or services to Medicare or Medicaid beneficiaries to attract their business. In this regard, the Hospital shall comply with the OIG's August 2002 Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries.<sup>26</sup>

### **2.11.1 Gifts and Gratuities**

The Hospital shall scrutinize any offers of gifts or gratuities to beneficiaries for compliance with the CMP provision prohibiting inducements to Medicare and Medicaid beneficiaries. The most key factor to be considered is whether the remuneration is something that the hospital knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier for Medicare or Medicaid payable services.

### **2.11.2 Cost-Sharing Waivers**

In general, the Hospital is obligated to collect cost-sharing amounts owed by Federal health care program beneficiaries. Waiving owed amounts may constitute prohibited remuneration to beneficiaries under Section 1128A(a)(5) of the Social Security Act or the anti-kickback statute. Certain waivers of Part A inpatient cost-sharing amounts may be protected by structuring them to fit in the safe harbor for waivers of beneficiary inpatient coinsurance and deductible amounts at 42 CFR § 1001.952(k). Under the safe harbor, waived amounts may not be claimed as bad debt; the waivers must be offered uniformly across the board without regard to the reason for admission, length of stay, or DRG; and waivers may not be made as part of any agreement with a third party payer, unless the third party payer is a Medicare SELECT plan under Section 1882(t)(1) of the Act.<sup>27</sup>

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<sup>26</sup> Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries, 67 Fed. Reg. 55855 (August 30, 2002)

<sup>27</sup> The OIG has proposed a rule to extend this safe harbor to protect waivers of Part B cost-sharing amounts pursuant to agreements with Medicare SELECT plans. See 67 FR 60202

In addition, the Hospital may waive cost-sharing amounts on the basis of a beneficiary's financial need, so long as the waiver is not routine, not advertised, and made based on a good faith, individualized assessment of the beneficiary's financial need or after reasonable collection efforts have failed.<sup>28</sup> Because a good faith determination of “financial need” may vary depending on the individual patient's circumstances, the OIG allows the following factors to be considered when making the determination: (1) the local cost of living; (2) a patient's income, assets, and expenses; (3) a patient's family size; and (4) the scope and extent of a patient's medical bills.

The Hospital shall use a reasonable set of financial need guidelines that are based on objective criteria and appropriate for community. The guidelines shall be applied uniformly in all cases. The Hospital shall also consider that the financial status of a patient may change over time and will recheck a patient's eligibility at reasonable intervals sufficient to ensure that the patient remains in financial need. The Hospital shall take reasonable measures to document determinations of Medicare beneficiaries' financial need.<sup>29</sup>

### 2.11.3 Free Transportation

The plain language of the CMP prohibits offering free transportation to Medicare or Medicaid beneficiaries to influence their selection of a particular provider, practitioner, or supplier. The Hospital can offer free local transportation of low value (i.e., within the \$10 per item and \$50 annual limits).<sup>30</sup> However, specialized transportation, such as ambulances, would exceed the low value threshold and are problematic, as are arrangements tied in any manner to the volume or value of referrals and arrangements tied to particularly lucrative treatments or medical conditions. In the absence of a final rule on this subject, the OIG will not impose CMPs if the Hospital's transportation program(s) meets the following criteria:

- The program was in existence prior to August 30, 2002, the date of publication of the Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries.

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(September 25, 2002). However, the OIG is still considering comments on this rule, and it has not been finalized.

<sup>28</sup> Social Security Act, Section 1128A(i)(6)(A)

<sup>29</sup> OIG Fraud Alert, “Hospital Discounts Offered To Patients Who Cannot Afford To Pay Their Hospital Bills,” February 19, 2004

<sup>30</sup> The OIG's position on local transportation of nominal value is more fully set forth in the preamble to the final rule enacting 42 CFR 1003.102(b)(13). See 65 FR 24400, 24411 (April 26, 2000)

- Transportation is offered uniformly and without charge or at reduced charge to all patients of the Hospital or Hospital-owned ambulatory surgical center (and may also be made available to their families).
- The transportation is only provided to and from the Hospital or a hospital-owned ambulatory surgical center and is for the purpose of receiving hospital or ambulatory surgical center services (or, in the case of family members, accompanying or visiting hospital or ambulatory surgical center patients).
- The transportation is provided only within the Hospital's or ambulatory surgical center's primary service area.
- The costs of the transportation are not claimed directly or indirectly by any Federal health care program cost report or claim and are not otherwise shifted to any Federal health care program.
- The transportation does not include ambulance transportation.

## ***2.12 Response to Investigations***

State and federal agencies have broad legal authority to investigate the Hospital and review its records. The Hospital will comply with subpoenas and cooperate with governmental investigations to the full extent required by law. The Compliance Officer is responsible for coordinating the Hospital's response to investigations and the release of any information.

If a department, an employee, or a professional staff member receives an investigative demand, subpoena, or search warrant involving the Hospital, it should be brought immediately to the Compliance Officer. Do not release or copy any documents without authorization from the Compliance Officer or Hospital counsel. If an investigator, agent, or government auditor comes to the Hospital, contact the Compliance Officer immediately. In the Compliance Officer's absence, contact the Hospital's Chief Executive Officer or a member of the Compliance Committee. Ask the investigator to wait until the Compliance Officer or his designee arrives before reviewing any documents or conducting any interviews. The Compliance Officer, his designee, or Hospital counsel is responsible for assisting with any interviews, and the Hospital will provide counsel to employees, where appropriate. If Hospital employees are approached by government investigators and agents, the employee has the right to insist on being interviewed only at the Hospital, during business hours or with counsel present.

If a professional staff member receives an investigative demand at his or her private office and the investigation may involve the Hospital, the staff member is asked to notify the Compliance Officer immediately.

Hospital employees are not permitted to alter, remove, or destroy documents or records of the Hospital. This includes paper, tape, and computer records.

Subject to coordination by the Compliance Officer, the Hospital and its employees will

disclose information required by government officials, supply payment information, provide information on subcontractors, and grant authorized federal and state authorities with immediate access to the Hospital and its personnel. Failure to comply with these requirements could mean that the Hospital will be excluded from participating in the Medicare and Medicaid programs.

Subcontractors of the Hospital who provide items or services in connection with the Medicare and/or Medicaid programs are required to comply with the Hospital's policies on responding to investigations. Subcontractors must immediately furnish the Compliance Officer, Hospital counsel, or authorized government officials with information required in an investigation.

### ***2.13 Governmental Organizations***

As a municipal hospital authority and a governmental entity, the Hospital is governed by Texas constitutional and statutory restrictions on the expenditure of public funds. The Hospital, and all funds expended by the Hospital, must provide a community benefit and serve the legitimate purposes of the Hospital. Similar to tax-exempt organizations, none of the Hospital's earnings may inure to the benefit of any private individual without a commensurate public return. Such "private inurement" would violate the restrictions on public spending. Thus, a private person may not receive more than an incidental benefit from hospital assets, measured against the overall community benefit provided by the Hospital.

Because the Hospital is a governmental entity, all contracts and agreements must be negotiated at arms length. Compensation provided to health professionals for recruitment, retention, employment, and personal services must be reasonable in the context of the services provided and the need for them. Reasonableness must be analyzed based on an overall compensation and benefits. Areas of particular concern are below market rents, compensation tied to Hospital or department revenues, income guarantees (especially where there is no obligation to repay), any loans or guarantees, and compensation which is not commensurate with fair market value. Gifts and bonuses which are not budgeted for as compensation to an individual employee are also problematic, as this gives the appearance of imparting a private benefit to the individual employee and may be an improper use of public funds.

If an employee is aware of payments by the Hospital to a private individual or organization that may be unrelated to the Hospital's purpose or in excess of fair market value, or which is not tied to a direct benefit to the Hospital or the community, these circumstances should be disclosed to the employee's supervisor or to the Compliance Officer.

### ***2.14 Confidentiality and Security of Health Information***

Hospital employees and health care professionals possess sensitive, privileged information about patients and their care. Patients properly expect that this information will be kept confidential. The Hospital takes very seriously any violation of a patient's confidentiality. Discussing a patient's medical condition, or providing any information about patients to anyone other than Hospital personnel who need the information and other authorized persons, will have serious consequences for an employee. Employees should not discuss patients outside the

Hospital or with their families, including the identity, history, diagnosis, prognosis, treatment, or any other information about the patient. Employees must take due care not discuss confidential patient information in places where we can be overheard by others -- such as corridors, elevators, the cafeteria, other restaurants, and on cellular phones.

The Hospital is the owner of the medical record which documents a patient's condition and the services received by the patient at the Hospital. Medical records are strictly confidential, which means that they may not be released except with the consent of the patient or in other limited circumstances. Special protections apply to mental health records, records of drug and alcohol abuse treatment, and records relating to HIV infection. Medical records should not be physically removed from the Hospital, altered, or destroyed. Employees who have access to medical records must preserve their confidentiality and integrity, and no employee is permitted access to the medical record of any patient without a legitimate, Hospital-related reason for so doing. Any unauthorized release of or access to medical records should be reported to a supervisor.

From time to time, personnel involved in the maintenance of Hospital medical records may be requested to provide copies of such records through various means, including requests directly from the patient, a family member, an attorney or by subpoena. Texas law has very strict requirements for the release of such information. Failure to adhere to these requirements or releasing such information in the absence of proper authorization or statutory exception could subject the Hospital and the individual employee to civil liability to the patient. Any employee who releases information from any Hospital record must familiarize themselves with the statutory requirements for release of information and the general confidentiality provisions under state law. Any questionable circumstance must be brought to the attention of the Compliance Officer for review and consultation with legal counsel.

The HIPAA Privacy Rule addresses the use and disclosure of individuals' identifiable health information (protected health information or PHI) by the Hospital as well as standards for individuals' privacy rights to understand and control how their health information is used.<sup>31</sup> The Privacy Rule gives the Hospital some flexibility to create its own privacy procedures. The Hospital shall make sure that it is compliant with all applicable provisions of the Privacy Rule, including provisions pertaining to required disclosures (such as required disclosures to the Department of Health and Human Services when it is undertaking a Privacy Rule investigation or compliance review) by developing appropriate privacy procedures that are tailored to fit its particular size and needs.

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<sup>31</sup> The Privacy Rule (45 CFR parts 160 and 164, subparts A and E) and other helpful information about how it applies, including frequently asked questions, can be found on the Web page of the Department's Office for Civil Rights (OCR) at <http://www.hhs.gov/ocr/hipaa/>. Questions about the privacy rule should be submitted to OCR. The Hospital can contact OCR by following the instructions on its Web page, <http://www.hhs.gov/ocr/contact.html>, or by calling the HIPAA toll-free number, (866) 627-7748.

The final HIPAA Security Rule<sup>32</sup> specifies a series of administrative, technical, and physical security safeguards for the Hospital to use to assure, among other provisions, the confidentiality of electronic PHI. The Security Rule requirements are flexible and scalable, which allows the Hospital to tailor its approach to compliance, taking into consideration the Hospital's organization and capabilities, as well as costs, in designing its security plans and procedures.

The Texas Penal Code also contains provisions prohibiting the unauthorized access of computer systems, which is designed to punish and deter computer crime. In compliance with the law, the Hospital prohibits unauthorized access to its computer system, either directly or by network or telephone. An individual who does not have a legitimate password will be held to know that access is unauthorized. The Hospital prohibits the destruction or corruption of electronically stored or processed data. Persons who violate these rules will be prosecuted to the full extent of the law.

## **2.11 Discrimination**

The Hospital and its affiliates are committed to a policy of nondiscrimination and equal opportunity for all qualified applicants and employees, without regard to race, color, sex, religion, age, national origin, ancestry, disability, veteran status or any other illegal criteria. Our policy of non-discrimination extends to the care of patients. Discrimination may also violate state and/or federal anti-discrimination laws and trigger substantial civil penalties. If an employee feels he or she or any patient has been discriminated against or harassed on the basis of his or her race, color, sex, or other protected category, he or she should contact the Hospital Administrator or the Director of Human Resources so that an investigation may be initiated in accordance with Hospital policies and procedures. A patient who feels he or she has been the subject of unlawful discrimination or harassment is encouraged to contact the Patient Representative, who will refer the matter to the appropriate Hospital personnel for investigation.

The Hospital is also strongly committed to complying with other federal and state laws governing employment. These laws include: the Americans with Disabilities Act, the Employee Retiree Income Security Act, the Labor Management Relations Act, the Age Discrimination in Employment Act, the Fair Labor Standards Act, and the Immigration Reform and Control Act. The Hospital's Personnel Policies, including its Sexual Harassment Policy and its Discrimination Policy, also address discrimination and all employees are charged with familiarizing themselves with and adhering to these policies. The human resources department can provide employees with information on the applicable laws and policies and can direct questions to the proper person.

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<sup>32</sup> The Security Rule (45 CFR parts 160 and 164, subparts A and C) was published in the Federal Register on February 20, 2003. It is available on CMS's Web page at <http://www.cms.gov/hipaa/hipaa2>. Questions about the HIPAA Security Rule should be submitted to CMS. The Hospital can contact CMS by following the instructions on its Web page, <http://www.cms.gov/hipaa/hipaa2/contact>, or by calling the HIPAA toll-free number, (866) 627-7748.

## **2.12 Political Contributions**

Direct political activities on behalf of the Hospital are prohibited by law. The Hospital may not make any contributions -- whether direct or indirect -- to candidates for federal, state or local office. Thus, the Hospital may not contribute any money, or lend the use of facilities or other hospital equipment to candidates for federal, state or local office. Nor may the Hospital make contributions to political action committees that make contributions to candidates for federal, state or local office. The Hospital may not require any employees or professional staff members to make any such contribution. Finally, the Hospital cannot reimburse its employees or professional staff members for any money they contribute to federal, state or local candidates or campaigns.

Violation of federal election laws carries potential criminal penalties of up to one year in jail and a fine of \$25,000 or three times the amount of the illegal contribution, whichever is greater. Civil penalties also may be assessed. State law also contains similar penalties.

Consistent with its governmental status, the Hospital does not carry on "propaganda" or attempt to "influence legislation." The Hospital and its representatives may not participate in or intervene in any political campaign for or against any candidate.

## **2.13 Purchasing**

Purchasing decisions must be made in accordance with applicable Hospital policy. In addition, the prohibitions discussed elsewhere in this Manual relating "Payments, Discounts, and Gifts" apply to purchasing decisions made on behalf of the Hospital. Purchasing decisions must in all instances be made free from any conflicts of interest that could affect the outcome. The Hospital is committed to a fair and objective procurement system which results in the acquisition of quality goods and services for the Hospital at a fair price.

## **2.14 Controlled Substances**

The Hospital, through its pharmacy, is registered to compound and dispense narcotics and other controlled substances. Improper use of these substances is illegal and extremely dangerous.

The Hospital requires that its employees comply with the terms of the Hospital's controlled substances registration and with federal and state laws regulating controlled substances. Under Hospital policy, access to controlled substances is limited to persons who are properly licensed and who have express authority to handle them. No health care practitioner may dispense controlled substances except in conformity with state and federal laws and the terms of the practitioner's license. Employees should carefully follow record-keeping procedures established by their departments and the pharmacy. Unauthorized manufacture, distribution, use, or possession of controlled substances by Hospital employees is strictly prohibited, and will be prosecuted to the full extent of the law. Any employee who knows of unauthorized handling of

controlled substances is to provide the information immediately to his or her supervisor or the Compliance Officer.

The Texas Pharmacy Act and the Texas Controlled Substances Act, as well as regulations promulgated by the Texas State Board of Pharmacy, also govern the management, handling, classification, and other issues pertaining to controlled substances, and all personnel working with or handling controlled substances shall familiarize themselves with any such provisions which may apply to them. Any questions concerning these statutes or regulations should be directed to the pharmacist-in-charge or the Compliance Officer.

Federal law may impose sentences of up to twenty years in prison and fines of up to \$1,000,000. If the Hospital or its employee is convicted under federal or state law of unlawfully manufacturing, distributing, prescribing, or dispensing a controlled substance, the Hospital can be excluded from the Medicare and Medicaid programs.

### ***2.15 Reporting Requirements***

Texas law contains various reporting requirements, some of which apply specifically to Hospital personnel and some of which are applicable to the public at large. This section is intended to increase awareness of some of these reporting requirements. Specific questions about reporting requirements must be addressed to the Compliance Officer, who shall consult with legal counsel in order to determine whether a report should be made in specific circumstance. Individual personnel must make themselves aware of the specific provisions governing these reporting requirements, as many of these statutes contained immunities for making such reports. Failure to comply with the provisions of the statute could result in a waiver of such immunities, and by the very nature of some reporting requirements, may result in a breach of patient confidentiality which could expose the individual and the Hospital liable for damages.

Texas statutes contain provisions relating to required reporting of suspected abuse and neglect cases. State law requires any person who has reason to believe that a child or minor has been subjected to abuse or neglect to report this to the appropriate authorities. Additionally, "professionals" who have such a suspicion must make such a report or be subject to criminal liability. There are also similar reporting requirements for suspected cases of abuse or neglect involving an elderly person. The statutory requirements must be rigidly adhered to in order to ensure that the full extent of the immunities provided in this statute apply to the report and the person making the report.

State law also imposes certain requirements for reporting cases of communicable diseases. A list of reportable communicable diseases should be maintained by the Hospital in order to address questions regarding these reporting requirements. Reports of HIV/AIDS cases have very specific confidentiality and reporting requirements under state law and must be rigidly adhered to in order to minimize exposure to potential liability in such cases.

Hospital personnel and other professionals are also required to report gunshot wounds to appropriate law enforcement personnel.

Finally, many health care professionals employed by or on staff at the Hospital are governed by their own licensing acts. Often, these acts contain reporting requirements for individual licensees whose conduct may not be in accordance with the standards provided for in the licensing act or in agency rules and regulations. Individual licensed personnel should familiarize themselves with these requirements to ensure that they will be in compliance with their licensing acts and not subject to disciplinary action for failing to make a required report.

## ***2.16 Waste Disposal and Environmental Issues***

A hospital produces waste of various types. The Hospital is committed to safe and responsible disposal of biomedical waste and other waste products. Compliance with applicable federal and state environmental regulations requires ongoing monitoring and care. The Hospital uses biohazard labels and biohazard containers for the disposal of infectious or physically dangerous medical or biological waste. Failure to properly dispose of this waste could result in significant penalties to the Hospital. Employees who come into contact with biological waste should be familiar with the Hospital's medical waste policy and procedures, and should report any deviations from the policy to their supervisor or the Compliance Officer.

The Hospital complies with the Clean Air Act, the Clean Water Act, the Resource Conservation and Recovery Act, and other federal and state laws and regulations governing the discharge of Hospital waste. If any employee suspects noncompliance or violation of any of these requirements, the circumstances should be reported to a supervisor or to the Compliance Officer. Spills and releases of hazardous materials must be reported immediately, so that necessary reports can be made and cleanup can be initiated.

The Hospital supports ongoing legal and technical review to identify and correct environmental problems. The Hospital will initiate environmental assessments and compliance audits as appropriate. Failure to prevent, report, or correct environmental problems can result in criminal and civil penalties as high as \$50,000 per day per violation, imprisonment for up to two years, or both. Even merely negligent violations can result in imprisonment and substantial fines if they pose a serious threat to human health.

## ***2.17 Fund-Raising***

In furtherance of its purposes, the Hospital may from time-to-time conduct fund-raising activities through the Hospital Auxiliary (the "Auxiliary") or otherwise. Hospital policy requires that all solicitation of contributions for the Hospital or its affiliates must be duly authorized by the Administrator or the Board of Directors or conducted through the Auxiliary. The Hospital does not authorize any employee or other individual to use the Hospital's or the Auxiliary's name in any fund-raising activities not approved or authorized.

It is illegal for any employee or representative of the Hospital to make any false, deceptive, or misleading statement in connection with a solicitation of funds or a sale of goods or services to benefit the Hospital. It is against Hospital policy to use any sponsor or endorsement in connection with fund-raising activities unless the sponsor or endorsement has been verified.

## **2.18 Conflicts of Interest**

Hospital employees should avoid all potential conflicts of interest. Adherence to this policy ensures that the Hospital's employees act with total objectivity in carrying out their duties for the Hospital.

To this end, Hospital employees may not be employed by, act as a consultant to, or have an independent business relationship with any of the Hospital's service providers, competitors, or third party payors. Nor may employees invest in any payor, provider, supplier, or competitor (other than through mutual funds or through holdings of less than 0.5 percent of the outstanding shares of publicly traded securities) unless they first obtain written permission from the Compliance Officer.

Employees should not have other outside employment or business interests that place them in the position of appearing to represent the Hospital, providing goods or services substantially similar to those the Hospital provides or is considering making available, or lessening their efficiency, productivity, or dedication to the Hospital in performing their everyday duties.

Employees may not use Hospital assets for personal benefit or personal business purposes. Employees may not have an interest in or speculate in products or real estate the value of which may be affected by the Hospital's business. Employees may not divulge or use the Hospital confidential information -- such as financial data, payor information, computer programs, and patient information -- for their own personal or business purposes.

Any personal or business activities by an employee that may raise concerns along these lines must be reviewed with, and approved in advance, by the employee's immediate supervisor or the Compliance Officer.

In order for the Hospital to comply with requirements of the Medicare program, every employee must notify a human resources supervisor or the Compliance Officer if he or she was at any time during the year preceding his or her employment with the Hospital employed by the Medicare intermediary or carrier. An employee's failure to make this disclosure at the time of employment could cause the Hospital to lose its right to participate in Medicare.

## **2.19 *Independent Contractors & Vendors***

The Hospital purchases goods and services from many consultants, independent contractors, and vendors. The Hospital's policy is that all contractors and vendors who provide items or services to the Hospital must comply with all applicable laws and Hospital policies. Each consultant, vendor, contractor, or other agent furnishing items or services worth at least \$25,000 per year shall be given a copy of the Hospital's Compliance Program Policy and shall provide a written certification that it is aware of and will comply with the Hospital's Compliance

Program Policy Manual. Contractors should bring any questions or concerns about Hospital practice or their own operations to the Compliance Officer.

Hospital employees who work with consultants, contractors, and vendors or who process their invoices should be aware that the Hospital's compliance policies apply to those outside companies as well. Employees are encouraged to monitor carefully the activities of contractors in their areas. Any irregularities, questions, or concerns on those matters should be directed to the Compliance Officer.

## ***2.20 Federally Funded Grants***

The Hospital from time to time receives federal grants. Federal regulations impose duties and obligations upon the recipients of federal grants. As a recipient institution, the Hospital expects its personnel to abide by all applicable federal regulations, including but not limited to regulations relating to accurate reporting and appropriate expenditure of grant funds. Questions relating to matters concerning federal grants should be directed to Administrative Director of Fiscal Services to ensure that all regulations are observed.

## SUBCONTRACTOR CERTIFICATION AND AGREEMENT OF COMPLIANCE

I hereby certify that I am a duly authorized Officer of the independent contractor named below ("Contractor"). On behalf of Contractor and its Officers, directors, employees, and agents, I certify that I have received and read the "Compliance Program Policy Manual" of Wise Regional Health System (the "Hospital"), and fully understand the requirements set forth in that document. I certify that Contractor shall act in full accordance with all rules and policies of the Hospital. These rules and policies include the Hospital's commitment to comply with all applicable federal and state laws and the Hospital's commitment to conduct its business in compliance with the highest ethical standards.

To this end, Contractor expressly agrees that the Hospital's "Compliance Program Policy Manual" shall be incorporated within and made a part of Contractor's agreement with the Hospital and shall survive termination of that agreement for any reason. Any failure of Contractor to comply with the rules and policies set forth in the Hospital's Compliance Program Policy Manual, or to report violations of these rules and policies, may result in immediate termination by the Hospital of its agreement with Contractor.

Name of Contractor:

Signed:

Date:

EMPLOYEE CERTIFICATION AND AGREEMENT OF COMPLIANCE

I certify that I have read Wise Regional Health System's "Compliance Program Policy Manual," and fully understand the requirements set forth in that document. I agree specifically to act in accordance with the policies of Wise Regional Health System set forth in that document and understand that I will be subject to disciplinary action, including termination, for violating those policies or failing to report violations of these policies.

Signed:

Date:

**This Compliance Program Policy Manual was developed by the Texas Organization of Rural and Community Hospitals (“TORCH”) with the assistance of the law firm of DAVIS & WILKERSON, P.C. of Austin, Texas (“DAVIS & WILKERSON”). A compliance program, in order to be and remain effective, involves educating employees and staff members on the procedures embodied by the policy manual and the substantive compliance concepts. The specific educational tools required to implement the program and maintain legal compliance are beyond the scope of the policy manual, and must be developed under the auspices of the Compliance Committee, with or without the use of outside consultants or experts. An effective program also requires monitoring and updating the program as legal requirements or the Hospital’s circumstances change. Neither TORCH nor DAVIS & WILKERSON assumes or retains any responsibility for initial or continued assistance, monitoring, updating or providing advise or counsel to the Hospital with respect to implementing and/or maintaining its compliance program, and no attorney-client relationship has been established between Hospital and DAVIS & WILKERSON, P.C. by virtue of any aspect of DAVIS & WILKERSON’s involvement in the development of this Policy Manual.**

**For more information on compliance programs, please contact DAVIS & WILKERSON, P.C., 1801 South Mopac, Suite 300, Austin, Texas 78746, phone 512/482-0614, fax 512/482-0342.**