OSF HealthCare

Compliance Plan

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OSF HealthCare Compliance Plan

INTRODUCTION

This Compliance Plan establishes enterprise-wide standards and is in effect for all OSF facilities and operating divisions. This Plan applies to the following corporations:

- OSF Healthcare System (OSFHCS)
- OSF Saint Francis, Inc. (SFI)
- HeartCare Midwest (HCM)
- The member-managed limited liability companies in which OSFHCS is the sole member
- Ottawa Regional Hospital and Healthcare Center (ORHHC)/Saint Elizabeth Medical Center (SEMC), by virtue of Section 2.4 of the bylaws of ORHHC/SEMC and Sections 12.7.4, 17.1.23 and 16.19 of the affiliation agreement between OSFHCS and ORHHC/SEMC
- Ottawa Regional Medical Center (ORMC), by virtue of Section 2.4 of the bylaws of ORMC and Sections 12.7.4, 17.1.23 and 16.19 of the affiliation agreement between OSFHCS and ORMC
- Ottawa Regional Cardinal Sleep Center (ORCSC), by virtue of Sections 12.7.4, 17.1.23 and 16.19 of the affiliation agreement between OSFHCS and ORCSC

Throughout this Compliance Plan, these corporations are referred to, collectively, as "OSF."

OSF has established and maintains this Compliance Plan. The purpose of this Plan is to provide guidance to Board members, officers, managers and employees, including physicians and other providers, in the management and operation of OSF. This Plan assists all the facilities and operating divisions of OSF in implementing effective internal controls that promote adherence to Federal and State laws and regulations and to the program requirements of Federal, State and private health plans; safeguards OSF assets from financial penalties; and protects OSF executives against sanctions.

It is incumbent upon the officers and managers of OSF to provide ethical leadership to the organization and to assure that adequate systems and controls are in place to facilitate ethical and legal conduct. This Compliance Plan, together with the Philosophy and Values, and Mission and Vision of The Sisters of the Third Order of St. Francis, articulates the commitment of OSF to maintain high ethical standards, to improve quality of care, to reduce waste and to provide a central coordinating mechanism for disseminating information and guidance on Federal and State laws and regulations and on the program requirements of Federal, State and private health plans.

Compliance efforts are designed to establish a culture within OSF that promotes the prevention, detection and resolution of instances of conduct that do not conform to Federal or State law or to the program requirements of Federal, State or private health plans or to OSF policies. The establishment of this Compliance Plan significantly advances the prevention of fraud, waste and abuse in OSF facilities and operating divisions, while, at the same time, furthering the fundamental Philosophy and Values, and Mission and Vision of The Sisters of the Third Order of St. Francis.

COMPLIANCE PROGRAM BENEFITS

In addition to fulfilling the legal duty of OSF to ensure that the organization is not submitting false or inaccurate claims to government or private payers, OSF enjoys various additional benefits by maintaining an effective Compliance Program. This Program makes good business sense in that it helps fulfill the fundamental caregiving mission of OSF to patients and the community and assists the organization in identifying weaknesses in internal systems and controls. Other important benefits of this Program include the ability to:

- 1. Demonstrate in a concrete way to employees, to patients and to the communities that OSF serves the organization's strong commitment to honest and responsible provider and corporate conduct
- 2. Enhance the organization's reputation for integrity and quality, increasing the standing of OSF in the community and market competitiveness
- 3. Improve the quality, safety, consistency and efficiency of patient care through improved accuracy and completeness of documentation
- 4. Increase the likelihood of identifying and preventing illegal or unethical conduct and, when detected, initiate immediate and appropriate corrective action
- 5. Minimize the loss to the government and to taxpayers from any false claims through early detection and reporting
- 6. Reduce the risk to OSF of exposure to civil damages and penalties, criminal sanctions and administrative remedies, such as program exclusion
- 7. Satisfy the demands of private payers and other business partners with respect to compliance policies and controls
- 8. Provide a more accurate view of employee and contractor behavior relating to fraud, waste and abuse
- 9. Encourage employees to report potential problems and improve internal communication
- 10. React quickly to employees' compliance concerns and effectively target resources to address their concerns
- 11. Provide policies and procedures for the prompt and thorough investigation of alleged misconduct by corporate officers, managers, employees, physicians and other providers and independent contractors and consultants
- 12. Create a centralized source for distributing information on health care laws and regulations and the program requirements of Federal, State and private health plans with respect to fraud, waste and abuse and other issues

OSF recognizes that this Compliance Plan does not in itself eliminate fraud, waste and abuse from the organization. However, a strong internal culture, a commitment to abide by this Plan and a sincere effort to comply with Federal and State laws and regulations and with the program requirements of Federal, State and private health plans significantly reduce the risk of unlawful or improper conduct.

ELEMENTS OF A COMPLIANCE PROGRAM

The Federal Sentencing Guidelines produced by the United States Sentencing Commission, established by the Sentencing Reform Act of 1984, provide a uniform approach to sentencing defendants in Federal court. In 1991, the Federal Sentencing Guidelines were extended to organizations found guilty of violating Federal law and to specify the steps that organizations should take both before and after a criminal offense has occurred, measures that may serve to reduce the organization's culpability and, therefore, the fines or other penalties imposed.

These steps, which are designed to prevent, detect and remedy violations of law, are the hallmarks of an effective compliance program. Since 1998, the Office of Inspector General (OIG) of the Federal Department of Health and Human Services (HHS) has issued Compliance Program Guidance, based, in part, on the Federal Sentencing Guidelines, with respect to the elements of a compliance program for use by various types of providers.

The Board of Directors has established and maintains the OSF Compliance Program, which is built on the original seven elements of the Federal Sentencing Guidelines, with the addition of Risk Assessment as a widely recognized eighth element. According to the Office of Inspector General (OIG), the elements of an effective compliance program are:

- 1. Developing and distributing written standards of conduct, as well as new and revised written policies and procedures that reflect the commitment of OSF to compliance
- 2. Designating a Chief Compliance Officer and the members of the Board Compliance Committee, the Compliance Oversight Committee, the OSF Compliance Committee and the OSF Physician Practice Compliance Committee
- 3. Developing and implementing effective compliance education programs for all employees, as well as focused training for employees in various functional areas
- 4. Maintaining a compliance hotline—the OSF Integrity Line—to receive reports of possible non-compliance and adopting procedures to protect the anonymity of complainants and to protect whistleblowers from retaliation
- 5. Developing processes to respond to allegations of illegal or improper conduct and to enforce appropriate disciplinary action against employees who have violated internal compliance policies, Federal or State laws or regulations or the program requirements of Federal, State or private health plans
- 6. Using audits and other evaluation techniques to monitor compliance, especially in identified problem areas
- 7. Investigating and taking reasonable steps to prevent criminal conduct—steps that may include self-reporting, cooperating with authorities and making restitution to identified victims
- 8. Conducting a review of the major compliance risks facing the organization and an assessment of the effectiveness of the Compliance Program in addressing these risks, and make modifications to the Program, as needed

1. Written Standards of Conduct and Policies and Procedures

A. Standards of Conduct

It is the obligation of each OSF employee to abide by and to conform his or her conduct to the Philosophy and Values, Mission and Vision of The Sisters of the Third Order of St. Francis, to this Compliance Plan and to the OSF Standards of Performance. These foundational documents provide a framework for the ethical performance of job duties by OSF employees. Adherence to these standards of conduct will result in conduct that complies with Federal and State laws and regulations and with the program requirements of Federal, State and private health plans.

OSF is committed to operating in accordance with this Compliance Plan, with an emphasis on preventing fraud, waste and abuse. OSF expects Board members, officers, managers, employees, physicians and other providers, and agents and vendors to function in accordance with this Plan. The organization is committed to disseminating this Plan, providing education on its standards and directives, updating the content, as necessary, and maintaining a vehicle for the reporting of activities found not to be in compliance with this Plan.

B. Written Policies and Procedures

The written compliance policies and procedures of OSF communicate the commitment of the organization to comply with Federal and State laws and regulations and with the program requirements of Federal, State and private health plans, with an emphasis on preventing fraud, waste and abuse.

Organization-wide compliance policies and procedures are developed and revised at the direction of the Chief Compliance Officer and are reviewed by the OSF Compliance Committee, the OSF Physician Practice Compliance Committee and the Board Compliance Committee, after which the policies and procedures are approved by the Board. Compliance policies and procedures are reviewed at least once every three years and revised, as needed.

Many of the provisions in this Compliance Plan are detailed in the compliance policies and procedures, which may be accessed at <u>Compliance Policies</u>.

2. Designation of Compliance Officer and Compliance Committees

A. Compliance Officer

By action of the Board of Directors on May 5, 1997, the corporate position of Director of Compliance (now called the Chief Compliance Officer) was created. The primary responsibilities of the Chief Compliance Officer include:

- 1. Directing and monitoring the OSF Compliance Program and maintaining this Compliance Plan
- 2. Providing reasonable assurance to the Board that all facilities and operating divisions are functioning in compliance with Federal and State laws and regulations, with the program requirements of Federal, State and private health plans and with OSF compliance policies and standards
- 3. Advising Board members, officers, managers or employees with respect to compliance issues
- 4. Directing the development, implementation and revision of compliance policies and procedures
- 5. Directing the development and implementation of ongoing education programs that focus on the elements of the OSF Compliance Program and that promote an understanding of and compliance with Federal and State laws and regulations and with the program requirements of Federal, State and private health plans
- 6. Administering and promoting awareness and appropriate use of a compliance hotline the OSF Integrity Line—for the reporting of illegal or improper behavior or other compliance issues
- 7. Establishing mechanisms to protect qui tam relators or whistleblowers, that is, private individuals who bring civil actions in the name of the Federal or State government and who may be entitled to a percentage of any recoveries
- 8. Directing internal compliance risk assessments, audits and other reviews to monitor and report on the effectiveness of compliance controls organization-wide or at a facility, operating division or work unit level
- 9. Engaging consultants to conduct compliance risk assessments, audits and other reviews, establishing standards for these consultants, monitoring the quality of their work, analyzing their findings and taking corrective action in response, as needed
- 10. Overseeing compliance audits and reviews conducted by government agencies or contractors, including the Office of Inspector General (OIG) of a Federal or State agency, a United States Attorney, Center for Medicare and Medicaid Services (CMS) contractors or State payment agencies, and the Internal Revenue Service (IRS)

The Chief Compliance Officer reports directly to the Board of Directors and has express authority to communicate personally with the Board and with the Board Compliance Committee, as necessary. The Chief Compliance Officer is authorized to engage external consultants, including outside legal counsel, as warranted, and to review all documents, records and other information that are relevant to compliance activities.

B. Compliance Committees

The Board of Directors has established a Board Compliance Committee. The Committee meets quarterly and is composed of voting Board members and a lesser number of non-voting members with compliance expertise. The Board Compliance Committee is charged with overseeing all aspects of the Compliance Program.

The Board of Directors has also established a Compliance Oversight Committee, which consists of a small number of Corporate Office leaders, who conduct meetings, as needed, to advise and assist the Chief Compliance Officer, with respect to audits and investigations.

The CEO of each facility and operating division appoints a Compliance Officer for the facility or division. The Compliance Officer is accountable, at his or her facility or division, for the oversight of the Compliance Program. In turn, the Compliance Officer appoints a Compliance Coordinator, who is responsible, at his or her facility or division, for day-to-day compliance activities and initiatives.

The Chief Compliance Officer has established the OSF Compliance Committee, a management committee composed of the facility and operating division Compliance Officers and Compliance Coordinators and others with compliance expertise, and the OSF Physician Practice Compliance Committee, a management committee comprised of the Physician Practice Compliance Officer, the Physician Practice Compliance Coordinators and others with compliance Coordinators and others with compliance Coordinators and others of the Physician Practice Compliance Officer, the Physician Practice Compliance Coordinators and others of the Compliance Program. The functions of committee members include:

- 1. Reviewing the Compliance Program to determine the extent to which the Program is meeting the needs of OSF
- 2. Reviewing the Compliance Plan and revisions to the Plan
- 3. Actively participating in quarterly committee meetings
- 4. Analyzing Federal and State laws and regulations applicable to OSF and its clinical and business operations
- 5. Assessing existing compliance policies and procedures and reviewing new and revised compliance policies and procedures

- 6. Participating in training on the elements of an effective compliance program and on compliance developments in the healthcare industry and trends in enforcement
- 7. Reviewing compliance education materials
- 8. Reviewing reports on the number and nature of calls and e-mail contacts to the OSF Integrity Line and other reported compliance matters
- 9. Communicating possible compliance matters to the committee and collaborating with committee members on the resolution of the issues
- 10. Monitoring the effectiveness of existing internal controls and recommending the development of new systems and controls
- 11. Uncovering, assessing and addressing specific areas of compliance risk
- 12. Reviewing the annual Compliance Audit Plan
- 13. Analyzing the findings of compliance audits and monitoring activities
- 14. Assessing the effectiveness of the remedial steps taken in response to compliance audits
- 15. Considering measures to implement standards of conduct that promote compliance with Federal and State law, this Compliance Plan and OSF policies and procedures

3. Training and Education

Inherent in maintaining a culture of compliance is a broad-based understanding of specific compliance requirements, instructions, processes and outcomes. OSF provides compliance education to Board members, officers, managers and employees, including physicians and other providers. This compliance education embodies the Philosophy and Values, and Mission and Vision of The Sisters of the Third Order of St. Francis, and emphasizes the need for compliance with Federal and State laws and regulations and with the program requirements of Federal, State and private health plans. This compliance education falls into two broad categories: general training aimed at raising awareness of the OSF Compliance Program and training focused on the impact of particular Federal and State requirements on certain job functions.

With respect to general compliance education, employees are trained on the elements of the Compliance Program, including compliance policies and procedures that are broadly applicable. An important aim of this general education is to provide useful information about the Federal and State False Claims Acts, including penalties for any violations and the whistleblower protections under these laws. This general education covers both the major areas of compliance risk, including fraud, waste and abuse, marketing practices, coding, claim development and submission, and the steps that need to be taken to prevent or mitigate the risks. The training emphasizes the affirmative duty of employees to report compliance risks and concerns and illegal or improper conduct.

In addition, employees receive specific compliance education on the ways in which Federal and State laws and regulations and the program requirements of Federal, State and private health plans affect their work. For example, although all employees should understand the importance of properly billing Federal, State and private health plans, it is essential that indepth training on correct coding and billing be presented regularly to employees in these roles and that ongoing education on appropriate documentation be provided to physicians and other providers. Employees who are directly responsible for any part of the process that results in claim or cost report filing are to receive compliance training prior to their performing any work that results in the production of a claim or cost report.

Employees receive compliance education during new employee orientation and on an ongoing basis. While the Chief Compliance Officer has overall responsibility for compliance education and provides internal and external training resources, maintaining an understanding of specific coverage, documentation, coding and billing and cost reporting requirements extends throughout the organization.

OSF facilities and operating divisions are expected to provide employees with appropriate training on the importance of compliance with the Federal and State laws and regulations and the program requirements of Federal, State and private health plans that apply to their responsibilities. Managers of specific departments or work units are expected to identify areas that require compliance education and to assist in the delivery of training. Also, periodic professional education courses that may be required for certain providers are considered a part of compliance training.

Participation in compliance training on the part of Board members, officers, managers and employees, including physicians and other providers, is to be logged, and the documentation is to be maintained and, on request, provided to the Chief Compliance Officer. Failure to comply with compliance training requirements may result in disciplinary action, including possible termination of employment, in accordance with the Human Resources policy on Positive Discipline.

4. Lines of Communication

A. Access to the Compliance Officer

In order to promote open lines of communication between the Chief Compliance Officer and OSF employees, the organization maintains, to the extent possible, the anonymity of individuals who contact the Chief Compliance Officer. Employees are assured that no retaliation is permitted.

Employees are encouraged to follow the chain of command when reporting issues or problems. They should first report issues or problems to their immediate supervisor, manager or director. Employees should report personnel matters to their supervisor or to the Human Resources Department of their facility or operating division.

Employees may contact the Chief Compliance Officer when they have exhausted other avenues or when they feel uncomfortable going through the normal chain of command. In some situations, following the chain of command may not be appropriate or workable. Communications to the Chief Compliance Officer are not limited to matters of compliance with Federal or State laws and regulations or to concerns about fraud, waste and abuse.

Employees have an affirmative duty to report illegal or improper conduct and other compliance issues. In the event that employees have questions or are uncertain or confused about the requirements of OSF policies and procedures, Federal or State laws and regulations or the program requirements of Federal, State and private health plans, they are encouraged to seek clarification from the Compliance Officer in their facility or operating division or from the Corporate Compliance Division.

B. OSF Integrity Line and Other Forms of Communication

OSF contracts with an outside vendor to staff the OSF Integrity Line, a vehicle for employees to report illegal or improper behavior or other compliance issues, including concerns about possible fraud, waste or abuse, HIPAA violations, conflicts of interest, theft of OSF property, and workplace violence, harassment or discrimination. The OSF Integrity Line is not intended to be a substitute for communication between employees and their supervisors. Employees with questions, concerns or suggestions about normal operating procedures should typically raise them directly with their supervisors.

The OSF Integrity Line may be accessed by calling 800-547-2822 or by logging-on to <u>www.OSFIntegrityLine.alertline.com</u>. This service is available twenty-four hours a day, seven days a week. Employees who contact the OSF Integrity Line are assigned a report number, a personal identification number (PIN) and a contact date. Employees may call back or log-on again on the contact date for information about the investigation and resolution of the matter that they reported.

Employees who contact the OSF Integrity Line may choose to remain anonymous. Reports are relayed confidentially to the Chief Compliance Officer or designee, who strives to maintain the anonymity of employees who contact the OSF Integrity Line. However, a caller's identity may become known or may need to be revealed in the course of investigating a reported concern or in certain instances when government officials become involved. Retaliation against employees who contact the OSF Integrity Line is not tolerated. Any reported retaliation is handled through the OSF Positive Discipline process.

Details about the OSF Integrity Line are provided to new employees during orientation or in the packet of information provided to them by the Human Resources Department of their facility or operating division. The packet of information includes a brochure explaining the use of the OSF Integrity Line and a wallet card with instructions on how to call or log-on to the OSF Integrity Line.

Matters reported to the OSF Integrity Line or through other means are recorded by the Corporate Compliance Division and are investigated promptly. The nature of a reported concern, the steps taken to investigate the matter and the results of the investigation are tracked. A report that shows the number and types of issues reported to the OSF Integrity Line is presented periodically to the Board Compliance Committee.

Assertions of fraud, waste and abuse by employees who may have participated in illegal conduct or who may have committed other misconduct raise numerous complex legal and management issues that are examined on a case-by-case basis.

5. Disciplinary Guidelines

A. Discipline Policy and Actions

Board members, officers, managers and employees, including physicians and other providers, are expected to comply with the requirements in the Human Resources Handbook, the OSF Standards of Performance and the Rules of Conduct in the Human Resources policy on Positive Discipline. Employees receive copies of the Handbook and the Standards of Performance and are required to familiarize themselves with the content and to sign an acknowledgement that they have received and understand the requirements and standards. Violations of any requirement or standard may result in disciplinary action, including termination of employment, at the discretion of OSF.

B. Hiring and Background Investigations

The Office of Inspector General (OIG) of the Federal Department of Health and Human Services (HHS) has the authority to exclude from participation in Medicare, Medicaid and other Federal health care programs individuals and entities who have engaged in fraud or abuse or other financial misconduct. The OIG and other government agencies maintain lists of individuals and entities that have been excluded from participation in a Federal or State health care program.

OSF does not knowingly employ or engage in business with any individual and entity that has been convicted of a criminal offense related to health care or is listed as debarred, excluded or otherwise ineligible for participation in a Federal or State health care program.

The Human Resources department in OSF facilities and operating divisions conduct a reasonable and prudent background investigation, including a reference check, for all employees as part of the hiring process. Applicants must disclose any criminal conviction or exclusion action. Other background investigations are performed as part of the credentialing process for physicians and other providers. The Corporate Finance and Accounting Division screens all new business vendors prior to completing a contract for services.

OSF contracts with a third-party provider of comprehensive exclusion list checking services (referred to in this Compliance Plan as the "Screening Services Provider"). On an annual basis, the Screening Services Provider screens all current employees, business vendors and independent contractors against the entire Federal and State government exclusion databases listed below, and, on a monthly basis, screens against any new additions to the information in these databases.

- 1. **LEIE** The OIG of HHS maintains the List of Excluded Individuals/Entities. http://exclusions.oig.hhs.gov/
- 2. **EPLS/SAM** The System for Award Management maintains the Excluded Parties List System.

https://www.sam.gov/portal/public/SAM/

- SDN/OFAC The Federal Office of Foreign Assets Control maintains the Specially Designated Nationals List. <u>http://www.treasury.gov/ofac/downloads/t11sdn.pdf</u>
- 4. Illinois HFS The Illinois Department of Healthcare and Family Services Office of Inspector General maintains a list of providers who have been terminated, suspended or barred, or have voluntarily withdrawn or have otherwise been excluded from participation in the Illinois Medical Assistance Program. <u>http://www.hfs.illinois.gov/all/062609n.html</u> <u>https://www.idfpr.com/dpr/licenselookup/default.asp</u>
- 5. Michigan MDCH The Michigan Department of Community Health maintains a list of sanctioned providers. <u>http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-16459--,00.html</u>

If a current employee is identified as an excluded individual through the annual or monthly verification process, then the employee is suspended without pay for up to thirty days. If the employee, while on suspension, submits documentation that the information in the Screening Services Provider report is inaccurate or is no longer valid and that he or she is not an excluded individual, then the employee is reinstated and receives back pay for the period of suspension. If the employee is unable to provide documentation to the Corporate Human Resources Division that he or she is not an excluded individual, then his or her employment is terminated at the end of the thirty-day suspension.

With respect to non-OSF-employed physicians and other providers, medical staff privileges are granted and revoked in accord with the medical staff bylaws for each facility. The Procedures for Appointment and Reappointment describe the process for verifying the credentials of physicians and other providers to whom privileges are extended.

If a current vendor is identified as an excluded entity through the annual or monthly verification process, then the contract with the vendor is suspended for up to thirty days. If the vendor submits documentation that the information in the Screening Services Provider report is inaccurate or is no longer valid and that they are not an excluded entity, then the contract is reinstated. If the vendor is unable to provide documentation to the Corporate Finance and Accounting Division that it is not an excluded entity, then the contract is terminated at the end of the thirty-day suspension.

6. Auditing and Monitoring

OSF recognizes that, in order for the Compliance Program to be successful and effective, auditing and monitoring are necessary to test and verify compliance with Federal and State laws and regulations, with the program requirements of Federal, State and private health plans, with this Compliance Plan and with organization-wide compliance standards, policies and procedures and the compliance standards, policies and procedures specific to a facility, operating division or work unit.

An audit is typically a more formal review of compliance with a particular set of internal (OSF compliance policies, for example) or external (Federal and State laws and regulations) standards or requirements. Audits are typically conducted by individuals who are independent from the area being audited. Monitoring refers to reviews that are repeated on a regular basis during the normal course of operations. Monitoring activities may be part of a corrective action plan to demonstrate that remedial steps continue to be effective. Monitoring may also be initiated to confirm and document ongoing compliance when no specific problems have been identified.

The Corporate Compliance Division maintains a Compliance Audit Program, which is coordinated by Compliance, Reimbursement and Clinical Auditors. The Corporate Compliance Division contracts, as needed, with external auditors who have expertise in Federal and State laws and regulations and in the program requirements of Federal, State and private health plans. Internal and external compliance audits may focus on the effectiveness of the Compliance Program, in general, or may target specific compliance issues or particular clinical or business operations.

The auditing and monitoring and other activities of the Compliance Audit Program are designed to verify that:

- 1. Compliance and other risks are appropriately identified and managed, proactively, when possible
- 2. Effective controls are in place with respect to clinical and business operations
- 3. Appropriate follow-up steps—undertaken in response to earlier auditing or monitoring and contained in a corrective action plan—have actually been taken and have had a demonstrable impact on improving operating procedures and results
- 4. The conduct of employees, independent contractors (including non-OSF-employed physicians and other providers who hold privileges at one or more OSF facilities) and business vendors is in compliance with Federal and State laws and regulations, with the program requirements of Federal, State and private health plans and with OSF standards, policies and procedures
- 5. Appropriate interaction occurs between regulatory authorities and the various OSF facilities and operating divisions

Specifically, the Corporate Compliance Division, with respect to the Compliance Audit Program, is responsible for:

- 1. Identifying compliance and other risks through compliance risk assessments
- 2. Developing and implementing an annual Compliance Audit Plan using appropriate riskbased methodology
- 3. Conducting or coordinating compliance audits in high-risk areas
- 4. Tracking any follow-up monitoring activities undertaken to verify that remedial steps have been taken to correct deficiencies identified through auditing and that the remedial measures have resulted in reduced error rates
- 5. Maintaining an organization-wide database of compliance audit activities and findings and monitoring the database for emerging trends
- 6. Developing appropriate compliance education programs based on audit results

The annual Compliance Audit Plan includes consideration of:

- 1. Federal and State laws and regulations, especially new legal or regulatory requirements
- 2. The annual work plan of the Office of Inspector General (OIG) of the Federal Department of Health and Human Services (HHS)
- 3. The enforcement priorities of regulatory authorities
- 4. The reimbursement policies of government contractors
- 5. The results of compliance risk assessments
- 6. The risks identified by the Board Compliance Committee, the OSF Compliance Committee, the OSF Physician Practice Compliance Committee and OSF leadership
- 7. The findings of earlier audits

The annual Compliance Audit Plan may call for a combination of the following types of audit activities:

- 1. Financial audits, including determinations of the accuracy and reliability of claim and other data developed within OSF
- 2. Operational audits focusing on improving the effectiveness and efficiency of clinical or business processes
- 3. Reviews of internal controls, including determinations of whether or not the controls are properly designed and functioning as intended
- 4. Reviews of compliance with Federal and State laws and regulations, including determinations of the effectiveness of the OSF Compliance Program
- 5. Reviews of compliance with OSF policies and procedures

The annual Compliance Audit Plan may call for the use of various approaches, including:

- 1. Structured audits by the Corporate Compliance Division, facility or operating division managers, or external auditors
- 2. Onsite visits
- 3. Interviews
- 4. Document reviews
- 5. Questionnaires
- 6. Exit interviews with departing employees
- 7. Ongoing monitoring

The annual Compliance Audit Plan and the results of audit and monitoring activity are reported to the Board Compliance Committee, the OSF Compliance Committee and the OSF Physician Practice Compliance Committee.

7. Responding to Detected Offenses and Developing Corrective Action Initiatives

A. Violations and Investigations

Violations of this Compliance Plan, failures to comply with Federal or State laws or regulations or with the program requirements of Federal, State and private health plans and other types of misconduct threaten the status of OSF as an honest, trustworthy and reliable provider eligible to participate in Federal, State and private health care programs. Detected but uncorrected misconduct may seriously endanger the Philosophy and Values, Mission and Vision of The Sisters of the Third Order of St. Francis, as well as the reputation and legal and financial status of the organization.

Employees have an affirmative duty to report illegal or improper conduct and other compliance issues. Facility and operating division Compliance Officers and managers must initiate prompt steps to investigate the conduct in question in order to determine whether or not a material violation of law or the requirements of this Compliance Plan has occurred, and if so, to take the steps necessary to correct the problem.

The Human Resources policy on Positive Discipline outlines the steps in the process of disciplining employees for violations of the Rules of Conduct, including violation of the Compliance Program. The Positive Discipline policy notes that, in addition to employment-related measures, criminal, civil or administrative sanctions (including exclusion from participation in a Federal or State health care program) may be imposed for violations of the Compliance Program.

B. Reporting

If a facility or operating division Compliance Officer, manager or legal counsel discovers credible evidence of misconduct on the part of any individual or entity and, after reasonable inquiry, has reason to believe that the misconduct may violate the Philosophy and Values, Mission and Vision of The Sisters of the Third Order of St. Francis, this Compliance Plan, the organization's compliance or other policies and procedures or criminal, civil or administrative law, then the facility or division Compliance Officer promptly notifies the Chief Compliance Officer and Corporate Legal Counsel.

If violations of law are found, then the Chief Compliance Officer and Corporate Legal Counsel determine the appropriateness of self-reporting to the relevant Federal or State government agency and the most suitable means of self-reporting available. Prompt reporting would demonstrate the good faith and willingness of OSF to work with government officials to correct and remedy a detected compliance problem. For example, self-reporting would be considered a mitigating factor by the Office of Inspector General (OIG) in determining administrative sanctions, including penalties, assessments and exclusion.

8. Compliance Risk Assessments

OSF analyzes the compliance risks that the organization, as a whole, and its facilities and operating divisions face. Compliance risk analysis is performed by the Corporate Compliance Division, by the facilities and operating divisions and by external parties engaged by OSF. It is incumbent on OSF Board members, officers, managers and employees, including physicians and other providers, to be vigilant and proactive in identifying and bringing compliance risks to the attention of the Corporate Compliance Division.

A risk assessment is a process utilized to identify, measure and prioritize opportunities for improvement following a risk analysis. Included in the risk assessment is a risk profile that outlines the most significant or most urgent compliance risks to the organization. Factors that are considered in developing the risk profile include:

- 1. The pervasiveness of the risk across OSF
- 2. The complexity of the risk
- 3. The impact on the culture, reputation, finances and clinical and business operations of OSF
- 4. The organization's previous experience
- 5. Industry trends
- 6. Government enforcement priorities

In addition to evaluating its compliance risks, OSF reviews its Compliance Program to determine the effectiveness of the Program in addressing the risks identified, and the organization makes modifications to the Program, as needed. Compliance auditing and monitoring priorities are determined based on the various risks.

OSF provides health care services through a variety of delivery systems. Given the structure of OSF, risk areas and levels vary, depending on the delivery mechanism. In the following section, general compliance risk areas that apply broadly to multiple OSF facilities and operating divisions are described. The specific compliance risks highlighted in guidance from the Office of Inspector General (OIG) are outlined at the end of this document.

GENERAL COMPLIANCE RISKS

1. Submission of Accurate Claims, Other Requests for Payment and Financial Reporting

OSF believes that the development and submission of complete and accurate claims, other requests for payment and financial reports to Federal, State and private health plans is inherent in the Philosophy and Values, Mission and Vision of The Sisters of the Third Order of St. Francis and is among the expectations of OSF patients. Claims must comply with Federal and State laws and regulations and with the program requirements of Federal, State and private health plans. A process must be in place for reviewing claims for accuracy and completeness on both a pre- and a post-submission basis.

Claims and the clinical documentation supporting the claims must be complete and accurate and must reflect reasonable and necessary services ordered by appropriately licensed medical professionals who are participating providers in the health care programs to which the claims are submitted. Professional services rendered to patients must be documented in an accurate and timely manner. Medical records and other clinical documentation must support the diagnoses and the procedures reported on the claims, and the documentation necessary for the accurate assignment of codes must be available to clinical, billing and coding staff members.

Compensation for billing and coding staff members (and for consultants involved in billing and coding functions) must not include incentives to submit improper claims, and compensation must not be tied to patient volume or the volume of work produced. Ongoing compliance education must be delivered to employees who perform activities or provide information that results in the development and submission of claims.

Billing for items or services not ordered, not documented or not rendered

Only certain screening tests, such as mammograms, may be covered in the absence of an order by a qualified medical professional. Even when ordered, a lack of documentation identifying the services provided may cause payers to conclude that the services are not covered. Covered services based on the types of providers rendering the service are outlined in the Medicare Benefit Policy Manual (Publication #100-02).

Upcoding, unbundling and failure to use coding modifiers properly

Upcoding, unbundling and the failure to use coding modifiers properly are the outcome of incorrect coding practices. Coding instructions are found throughout the CMS manual system. Direction of the use of codes and modifiers is found in Chapter 23 of the Medicare Claims Processing Manual (Publication #100-04). Virtually all the claims submitted to Federal, State and other payers use ICD-9-CM diagnosis and procedure codes or HCPCS/CPT codes as the basis of payment. ICD-9-CM codes are updated every year by CMS. CMS provides annual and quarterly updates to HCPCS/CPT codes. Notices of these coding changes are routinely provided by CMS in Federal Register issuances followed by manual transmittals describing the changes.

An understanding of the National Correct Coding Initiative (NCCI) is essential. CCI edits apply to Medicare Part B claims and describe various combinations of codes that are not acceptable or are acceptable only if modified.

Providing or billing non-covered or medically unnecessary services as covered, except at the request of patients

The Medicare Benefit Policy Manual defines non-covered services, and the limitation on beneficiaries' financial liability when Medicare claims are disallowed is outlined in Sections 1879(a)-(g) of the Act. It is inappropriate to submit claims as covered for services that are known to be non-covered or medically unnecessary, unless a patient requests that OSF does so. In most instances in which non-covered or medically unnecessary services are ordered, patients must be informed prior to treatment. The requirements with respect to informing patients are explained in Chapter 30 of the Medicare Claims Processing Manual (Publication #100-04).

Duplicate billing

Duplicate billing may occur for many reasons, some of which are considered simple errors. However, duplicate billing may also be indicative of a lack of controls in billing systems or of an attempt to submit claims for services that have already been processed to denial or for which payments have already been made by other payers. Billing separately for services that are included in claims for other services is also a form of duplicate billing.

False cost reports

Accurate reporting of costs is required of all institutional providers. Cost reporting instructions and forms are found in Parts 1 and 2 of the Medicare Provider Reimbursement Manual.

Credit balances

Credit balances occur on the basis of claims when providers collect amounts in excess of what is allowed by Medicare payment instructions. Medicare itself may be the payer of the excess amounts, or the credit balances may occur when payments are made by both Medicare and other payers for the same services. The requirements with respect to duplicate primary payments from Medicare and other payers are outlined in Chapter 3, Section 10.5 of the Medicare Secondary Payer Manual (Publication #100-05). Instructions for reporting credit balances are found in Chapter 12 of the Medicare Financial Management Manual (Publication #100-06).

2. Anti-Kickback Statute and Physician Self-Referral (Stark) Law

All items and services provided by or to—and all payments to or from—OSF according to arrangements with referral sources must be pursuant to a written contract signed by the parties, which has been approved through the corporate contract approval process.

OSF does not enter into financial arrangements—either ownership/investment or compensation arrangements—with physicians that are designed to provide inappropriate remuneration to OSF facilities or operating divisions in return for the physicians' providing services to Medicare beneficiaries at the facilities or operating divisions.

OSF does not submit or cause to be submitted to the Federal health care programs claims for patients who were referred to OSF hospitals pursuant to financial arrangements—either ownership/investment or compensation arrangements—designed to induce the referrals in violation of the Stark law, Federal or State anti-kickback statutes or other Federal or State laws or regulations.

Anti-Kickback Statute

The Federal anti-kickback statute provides criminal and administrative penalties for an individual or entity that knowingly and willfully offers, pays, solicits or receives remuneration in order to induce or reward the referral of items or services reimbursable under a Federal health care program. The types of remuneration covered include, specifically, kickbacks, bribes, and rebates, whether made directly or indirectly, overtly or covertly, in cash or in kind.

The anti-kickback statute establishes a number of "safe harbors," which are defined as transactions or relationships that meet all the standards of an applicable safe harbor and that, therefore, have immunity from any criminal or administrative penalties under the anti-kickback statute. Regulations related to the anti-kickback statute are found at 42 CFR Chapter V, Subchapter B. Section 1001.952 describes the safe harbors.

Claims resulting from referrals made in violation of the anti-kickback statute may constitute false or fraudulent claims under the False Claims Act. Violations of the anti-kickback statute are punishable by criminal penalties of up to \$25,000 in fines or up to five years in jail or both, by exclusion from the Federal health care programs and by civil money penalties of \$50,000 for each violation, plus three times the amount of each claim deemed fraudulent.

Stark Law

The Stark law prohibits Medicare payment for certain designated health services provided by a hospital and other entity based on a referral from a physician with whom (or with whose immediate family members) the entity has a financial relationship. For purposes of the Stark law, financial relationships consist of:

- Direct or indirect ownership or investment interests on the part of physicians or their immediate family members in entities to which the physicians refer, or
- Direct or indirect compensation arrangements between the physicians, or their immediate family member, and the entities.

The Stark law provides exceptions that are categorized as exceptions to ownership and investment interests, as exceptions to compensation arrangements or as exceptions to both.

Sanctions for violation of the Stark law include denial of payment, exclusion from the Federal health care programs, civil monetary penalties of up to \$15,000 per item or service, civil monetary penalties of up to \$100,000 for physicians or entities that engage in a circumvention scheme to provide referrals that would otherwise violate the Stark law and CMPs of up to \$10,000 per day for failure to meet a reporting requirement under the law.

Regulations under the Stark law are found at 42 CFR Chapter IV, Subchapter B, Sections 411.351-361. Exceptions to the prohibited self-referral practices are described in Sections 411.355-357. An explanation of the compliance risks associated with the anti-kickback statute and the Stark law is provided by the Office of Inspector General (OIG) compliance program guidance, especially the supplemental guidance for hospitals. Additional direction is provided by Chapter 4 of the Medicare Program Integrity Manual (Publication #100-15). The chapter is aimed primarily at the activities conducted by Medicare Contractors, but the content is also instructive for providers.

3. Emergency Medical Treatment and Active Labor Act (EMTALA)

EMTALA is the Federal law that requires a hospital to evaluate, treat or appropriately transfer an individual who comes to the hospital emergency department (ED). When the hospital is required to perform a medical screening examination (MSE) in order to determine whether or not the person is suffering from an emergency medical condition, the hospital may not delay the MSE or needed treatment in order to inquire about the individual's method of payment or insurance status. If an individual comes to the ED for evaluation or treatment while the hospital's ED is on diversion, then the hospital is required to provide the examination or treatment despite its status as on diversion.

Generally, a hospital ED may not transfer an individual with an unstable emergency medical condition, unless a physician certifies that the benefits of transfer outweigh the risks. In such circumstances, the hospital must provide stabilizing treatment to minimize the risks of transfer. Furthermore, the hospital must ensure that the receiving facility has the available space and qualified personnel to treat the individual and that the receiving facility has agreed to accept transfer of the individual. Certain medical records must accompany the individual. A hospital with specialized capabilities or facilities must accept an appropriate transfer of an individual who requires specialized services, if the hospital has the capacity to treat the individual.

A hospital must provide appropriate screening and treatment services within the full range of the capabilities of its facilities and staff, which includes access to specialists who are on call. Hospital policies and procedures must be clear as to the requirement to provide access to the complete scope of hospital services. All ED staff members, including on-call physicians, must be trained on their responsibilities under EMTALA, including the obligation to accept individuals who are appropriately transferred from other facilities.

EMTALA applies to the outpatient provider-based departments of a hospital that are held out to the public as sites that provide care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment.

EMTALA is found in Section 1867 of the Act:

<u>http://www.ssa.gov/OP_Home/ssact/title18/1867.htm</u>. CMS provides guidance at: <u>http://www.cms.hhs.gov/EMTALA/</u>. Additional guidance is offered by the OIG in its supplemental compliance program guidance for hospitals.

4. Conditions of Participation (CoPs) and Conditions for Coverage (CfCs)

CMS develops CoPs and CfCs that providers must meet in order to participate in the Medicare program. (Most other Federal health care programs include Medicare participation as a requirement for payment.) The CoPs and the CfCs, which apply to all patients, are intended to improve the quality of care and to protect the health and safety of beneficiaries. CMS also ensures that the standards of accrediting organizations recognized by CMS (through a process called "deeming") meet or exceed the requirements of the CoPs and CfCs.

The OIG may exclude an individual or entity from participation in the Federal health care programs if the individual or entity provides unnecessary or substandard items or services or fails to meet other program requirements.

Providers should be familiar with the CoPs and CfCs applicable to them. The CoPs and CfCs, as well as interpretive guidelines and other supporting references are found at: <u>http://www.cms.gov/CFCsAndCoPs/</u>.

5. Relationships with Federal Health Care Program Beneficiaries

It is inappropriate to offer or transfer remuneration to a Medicare Beneficiary (or Medicaid beneficiary) that the offering party knows or should know is likely to influence the beneficiary to order or receive items or services for which payment may be made under the Medicare (or Medicaid) programs. The definition of remuneration expressly includes the offer or transfer of items or services for free or for other than fair market value, including the waiver of all or part of a beneficiary's deductible or coinsurance. In other words, a provider may not offer items or services of value to a Medicare Beneficiary (or Medicaid beneficiary) to attract his or her business. This restriction applies to all types of providers. Violations of this restriction may result in the imposition of civil monetary penalties.

Three primary categories of gifts and inducements, along with limitations and exceptions, are outlined in the OIG supplemental compliance program guidance for hospitals:

- 1. Gifts and gratuities, including items or services valued at more than \$10 per item or service or at more than \$50 per patient in total on an annual basis
- 2. Cost-sharing waivers, including waivers of patient deductibles or coinsurance
- 3. Free transportation.

Providers should familiarize themselves with the August, 2002 OIG Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries.

6. Health Insurance Portability and Accountability Act (HIPAA) and other Privacy Laws

HIPAA is a sweeping law that includes anti-fraud provisions and rules that protect workers' health insurance coverage when they change or lose their job. The outline below provides an overview of the administrative simplification provision of HIPAA governing privacy, information security, electronic transaction and code sets (TCSs) and National Provider Identifiers (NPIs). The Federal Department of Health and Human Services (HHS) Office for Civil Rights (OCR) enforces the Privacy Rule and the Security Rule, and CMS administers the TCS and NPI standards.

Non-compliance with the administrative simplification rules and standards is subject to civil monetary penalties. The Privacy Rule also imposes criminal penalties on persons who knowingly obtain or disclose individually identifiable health information in violation of HIPAA. The criminal penalties increase if the wrongful conduct involves false pretenses, and increases further if the wrongful conduct involves the intent to sell, transfer or use individually identifiable health information for commercial advantage, personal gain or malicious harm.

Privacy

The Privacy Rule addresses the use and disclosure of protected health information (PHI) by providers and other covered entities. The Privacy Rule also provides certain rights to patients with respect to their PHI.

Risks in terms of the Privacy Rule include:

- 1. Inappropriate use and disclosures of PHI
- 2. Failure to provide a Notice of Privacy Practices (NPP) to patients at the first delivery of service to them
- 3. Failure to honor patients' rights, including:
 - Failure to allow patients to access their PHI
 - Failure to provide patients with a copy of their PHI
 - Failure to make agreed-to amendments to their PHI
 - Failure to honor restrictions on release of their PHI
 - Failure to abide by patients' reasonable requests for confidential communications
 - Failure to account for disclosures of their PHI
- 4. Failure to obtain or abide by patients' authorization for certain disclosures of their PHI
- 5. Failure to provide patients with an opportunity to object to disclosure of their PHI
- 6. Failure to provide timely breach notifications, as required, to patients, the media and HHS Secretary
- 7. Failure to execute the required agreements with Business Associates

- 8. Failure to meet the following administrative requirements of the Privacy Rule:
 - Designation of a privacy official
 - Workforce training
 - Safeguards of PHI
 - Complaints
 - Sanctions
 - Mitigation
 - Intimidation or retaliation
 - Waiver of rights
 - Policies and procedures
 - Documentation in written or electronic form
 - Retention of documentation

Providers who are covered entities must comply with patients' rights to:

- Ask to see and get a copy of their health records
- Have corrections made to their health information
- Receive a notice that tells them how their health information may be used and shared
- Decide if they want to give their permission before their health information can be used or shared for certain purposes, such as for marketing
- Get a report on when and why their health information was shared for certain purposes

Other Federal and State laws offer additional protections for behavioral health and other sensitive information. For example:

- The Illinois Mental Health and Developmental Disabilities Confidentiality Act (740 ILCS 110/) requires written consent, in most instances, for the disclosure of information about mental health and development disability services.
- The Illinois Personal Information Protection Act (815 ILCS 530/) requires notification to individuals in the event of a breach of certain "personal information," such as their name, Social Security number, driver's license number or financial account number.

The OSF Chief Compliance Officer serves as the organization's Chief Privacy Officer.

Security

The Security Rule applies to electronic Protected Health Information (ePHI). The Security Rule requires that all covered entities implement administrative, physical and technical safeguards to protect the confidentiality, integrity and availability of ePHI.

The major risks in terms of the Security Rule include:

- 1. Inadequate security risk assessments
- 2. Incomplete remediation of the risk areas identified in risk assessments
- 3. Failure to implement risk management programs with appropriate approaches to the information system lifecycle

The OSF Chief Information Officer (CIO) serves as the Chief Security Officer.

Transaction and Code Sets (TCS)

Standardized electronic formats using specified code sets are required for all billing transactions. The regulations designate the required data content and format for each type of covered transaction.

The risks involved with failure to use the designated sets include:

- 1. Loss of revenue due to payment delays
- 2. Denial of claims
- 3. The possibility of incurring CMPs

National Provider Identifiers (NPIs)

NPIs are numeric ten-digit identifiers, consisting of nine numbers plus a check-digit in the tenth position. NPIs are accommodated in all standard transactions and contain no embedded information about the health care providers identified. Assigned NPIs do not expire. All providers (as defined in 45 CFR 160.103) are eligible for NPIs. Providers who transmit any health information in electronic form in connection with a transaction for which the HHS Secretary has adopted a standard are covered entities and are required to obtain and use NPIs.

Providers who are not considered covered entities may apply and be assigned NPIs. However, entities that do not provide health care (transportation services, for example) are not eligible to be assigned NPIs because they do not meet the definition of health care provider and are not subject to HIPAA regulations.

In certain situations, it is possible for subparts of organization health care providers, such as hospitals, to be assigned NPIs. These subparts may need to be assigned NPIs in order to conduct standard transactions on their own behalf or to meet Federal regulatory requirements related to their participation in health care programs, including Medicare. Providers must determine if they have subparts that may need NPIs and, if so, obtain NPIs for the subparts or require the subparts to obtain their own NPIs. The subpart concept does not pertain to health care providers who are individuals.

7. Employee and Contractor Screening

No Federal health care program payment may be made for any items or services that are provided by excluded individuals or entities or that are directed or prescribed by excluded physicians. This prohibition applies to all methods of payment, including itemized claims, cost reports, fee schedules or through a prospective payment system (PPS). This ban extends to payment for management or administrative services, including the processing of claims for payment, that are not directly related to patient care, but that are a necessary component of providing items or services to Federal health care program beneficiaries. In addition, many private payers include provisions in their provider contracts that condition payment on compliance with government requirements. In most instances, the practical effect of OIG exclusions is to preclude the employment of excluded individuals in any capacity.

Federal law authorizes the imposition by the Office of Inspector General (OIG) of civil monetary penalties (CMPs) against providers that employ or enter into contracts with excluded individuals or entities to provide items or services to Federal health care program beneficiaries. Civil monetary penalty liability may be imposed when providers that submit claims for items or services furnished, directly or indirectly, by excluded individuals or entities know or should know of the exclusions. Providers have an affirmative duty to check the program exclusion status of individuals and entities before entering into employment arrangements or contractual relationships.

8. Conflicts of Interest

As noted in the Institute of Medicine (IOM) report on Conflict of Interest in Medical Research, Education and Practice, "as they have evolved, relationships between industry and medicine have brought many benefits, primarily in biomedical research. They have also raised concerns that such relationships can—if they are not properly managed—threaten the objectivity of medical research, education, and practice and undermine public trust in critical American institutions."

Appendix D of the IOM report lists various studies that have attempted to understand the relationship between physicians and industry. To take one example, a 1998 analysis of marketing literature and interactions between physicians and industry representatives found that "the provision of gifts by sales personnel encourages an automatic response of indebtedness on the part of the receiver who will then look for ways to make repayment." The IOM report concludes, "Although it may seem to be intuitively and easily recognized that people are biased in assessing themselves, the fact that these biases are often unconscious and unintentional is not intuitive and is largely underappreciated. The findings of research on the influence of industry on medical practice correspond closely to the findings of psychological research."

For their part, Board members, officers, OSF-employed physicians, managers and employees have a duty to act honestly and with integrity and to make decisions on behalf of, and in the best interest of, OSF and its patients. They also have a duty to avoid the appearance of improper conduct or activity that may jeopardize patient safety or the public's trust in OSF. Improper conduct or activity that may threaten the business operations or reputation of OSF must also be avoided. The organization expects that individuals in positions of making or influencing decisions about vendor agreements or arrangements or other business transactions on behalf of OSF and its patients act in good faith in fulfilling their responsibilities.

Physicians involved in industry interactions should always bear in mind the Philosophy and Values, Mission and Vision of The Sisters of the Third Order of St. Francis. OSF seeks to ensure that relationships with industry remain principled; protective of the integrity of medical education, research and clinical decision-making; capable of withstanding government scrutiny; and able to uphold public expectations, including the reputations of the physicians themselves.

Conflicts of interest generated by pharmaceutical, biotechnology, medical device or other health care-related industry activities must be resolved consistent with obligations to patient care and safety, and consistent with the business and other interests of OSF. Industry support of physicians, students and trainees or other medical professionals should be free of actual or apparent conflicts of interest.

OSF expects clinical researchers to act ethically and in full compliance with Federal regulations, including the requirements of HHS, the National Institutes of Health (NIH), the Public Health Service (PHS) and the Food and Drug Administration (FDA). OSF seeks to reduce or eliminate any actual or apparent conflicts of interest related to research, to encourage transparency and to protect the rights and welfare of its patients.

The IOM understands the importance of disclosure of industry relationships as the first step in the process of identifying and responding to conflicts of interest. The IOM report states that, "Institutions that carry out medical research, medical education, patient care, and practice guideline development depend on individuals' disclosure of their financial relationships with industry. Without such disclosure, institutions will lack the information they need to identify and assess conflicts of interest and determine what additional steps—such as eliminating or managing the conflicting interest—may be necessary. The report goes on to state, "The disclosures need to be sufficiently specific and comprehensive to allow an initial assessment of the risk of undue influence."

In order to manage conflicts of interest, OSF requires Board members, officers, OSF-employed physicians and other designated individuals who are engaged in making or influencing decisions on behalf of OSF or its patients to disclose significant financial and personal interests related to their respective responsibilities. Designated individuals must disclose any interests that may result in a conflict. Disclosure is required at least once in each calendar year, with any subsequent disclosures submitted by the end of the same calendar year.

Employees who fail to disclose timely are subject to the Human Resources policy on Positive Discipline, and to the possible loss of specific privileges, such as participation in medical research or educational programs.

9. Pioneer Accountable Care Organization (ACO)

CMS, through its Center for Medicare and Medicaid Innovation, is authorized to contract directly with groups of providers and suppliers to test innovative payment and service delivery models in an effort to reduce Federal health care program expenditures, while preserving or enhancing the quality of care for Medicare, Medicaid and Children's Health Insurance Program (CHIP) beneficiaries. One such group of providers and suppliers is the Pioneer Accountable Care Organizations (ACOs). OSF has been designated a Pioneer ACO and has signed an agreement with CMS that specifies various requirements, including compliance requirements, on the part of OSF.

Pursuant to the contract, OSF has established a Governing Committee for the Pioneer ACO. In addition to other reporting relationships, the Chief Compliance Officer reports directly to the Pioneer ACO Governing Committee. The Chief Compliance Officer has the authority to engage outside legal counsel, as warranted, and to review all documents, records and other information that are relevant to the compliance activities of the Pioneer ACO.

The Pioneer ACO has developed a Compliance Plan, which has been approved by the Governing Committee. OSF compliance policies and procedures, training materials and requirements, Integrity Line and other reporting processes, auditing and monitoring programs, as well as processes for responding to detected issues and for imposing disciplinary sanctions apply to the Pioneer ACO Governing Committee members, officers, employees, providers, suppliers, contractors and others who have any role in administering the Pioneer ACO or in serving beneficiaries assigned to the Pioneer ACO. In addition, compliance policies and procedures specific to the Pioneer ACO have been developed and approved by the Governing Committee.

POTENTIAL COMPLIANCE RISKS BY TYPE OF FACILITY, OPERATING DIVISION OR SERVICE

Hospitals

The footnote numbers correspond to the compliance risks explained in the OIG compliance program guidance for hospitals.

1998 Compliance Program Guidance (63 FR 8987–8998 (February 23, 1998))

- 1. Billing for items or services not actually rendered¹³
- 2. Providing medically unnecessary services¹⁴
- 3. Upcoding¹⁵
- 4. "DRG creep"¹⁶
- 5. Outpatient services rendered in connection with inpatient stays¹⁷
- 6. Teaching physician and resident requirements for teaching hospitals
- 7. Duplicate billing 18
- 8. False cost reports¹
- 9. Unbundling²⁰
- 10. Billing for discharge in lieu of transfer²¹
- 11. Patients' freedom of choice 22
- 12. Credit balances
- 13. Hospital incentives that violate the anti-kickback statute or similar Federal or State statute or regulation²³
- 14. Joint ventures²⁴
- 15. Financial arrangements between hospitals and hospital-based physicians²⁵
- 16. Stark physician self-referral law
- 17. Knowing failure to provide covered services or necessary care to members of a health maintenance organization
- 18. Patient dumping 26

2005 Supplemental Compliance Program Guidance (70 FR 4858-4876 (January 31, 2005))

- 19. Billing on an outpatient basis for inpatient-only procedures¹⁴
- 20. Submitting claims for medically unnecessary services by failing to follow the MAC's local policies^{15/16}
- 21. Submitting duplicate claims or otherwise not following the National Correct Coding Initiative (NCCI) guidelines¹⁷
- 22. Submitting incorrect claims for ancillary services because of outdated charge description masters (CDMs)¹⁸
- 23. Circumventing the multiple procedure discounting rules¹⁹
- 24. Improper billing for observation services²⁰
- 25. Failure to follow the "same-day rule"²¹
- 26. Abuse of partial hospitalization payments²²

- Same-day discharges and readmissions²³ 27.
- Violation of Medicare's post-acute transfer policy^{24/25} 28.
- Improper churning of patients by long-term care hospitals co-located in acute care 29. hospitals²⁶
- Improper reporting of the costs of "pass-through" items²⁷ Abuse of DRG outlier payments²⁸ 30.
- 31.
- Improper claims for incorrectly designated "provider-based" entities²⁹ Improper claims for clinical trials³⁰ 32.
- 33.
- Improper claims for organ acquisition costs^{31/32/33} 34.
- Improper claims for cardiac rehabilitation services³⁴ 35.
- Failure to follow Medicare rules³⁵ 36.
- 37. Use of information technology³⁶

Nursing Facilities

The footnote numbers correspond to the compliance risks explained in the OIG compliance program guidance for nursing facilities (65 FR 14289-14306 (March 16, 2000)).

Quality of Care

- 1. Absence of a comprehensive, accurate assessment of all residents' functional capacity and a comprehensive care plan that includes measurable objectives and timetables to meet the residents' medical, nursing, and mental and psychosocial needs²⁶
- 2. Inappropriate or insufficient treatment and services to address residents' clinical conditions, including pressure ulcers, dehydration, malnutrition, incontinence of the bladder and mental or psychosocial problems²⁷
- 3. Failure to accommodate residents' needs and $preferences^{28}$
- 4. Failure to properly prescribe, administer, or monitor prescription drug usage²⁹
- 5. Inadequate staffing levels or insufficiently trained or supervised staff to provide medical, nursing, and related services³⁰
- 6. Failure to provide appropriate therapy services³¹
- 7. Failure to provide appropriate services to assist residents with activities of daily living, including feeding, dressing, and bathing
- 8. Failure to provide an ongoing activities program to meet the individual needs of all residents
- 9. Failure to report incidents of mistreatment, neglect, or abuse to the administrator of the facility and other officials as required by law³²

Residents' Rights

- 1. Discriminatory admission or improper denial of access to care³⁵
- 2. Verbal, mental, or physical abuse, corporal punishment, or involuntary seclusion³⁶
- 3. Inappropriate use of physical or chemical restraints³⁷
- 4. Failure to ensure that residents have personal privacy and have access to their personal records upon request and that the privacy of their records is protected³⁸
- 5. Denial of residents' right to participate in care and treatment decisions³⁹
- 6. Failure to safeguard residents' financial affairs⁴⁰

Billing and Cost Reporting

- 1. Billing for items or services not rendered or provided as claimed⁴³
- 2. Submitting claims for equipment, medical supplies and services that are medically unnecessary⁴⁴
- 3. Submitting claims to Medicare Part A for residents who are not eligible for Part A coverage⁴⁵
- 4. Duplicate $billing^{46}$
- 5. Failing to identify and refund credit balances⁴⁷
- 6. Submitting claims for items or services not ordered⁴⁸
- 7. Knowingly billing for inadequate or substandard care⁴⁹
- 8. Providing misleading information about residents' medical conditions on the Minimum Data Set (MDS) or otherwise providing inaccurate information used to determine the Resource Utilization Group (RUG) assigned to the residents
- 9. Upcoding the level of service provided⁵⁰

- 10. Billing for individual items or services when they either are included in the facility's per diem rate or are of the type of item or service that must be billed as a unit and may not be unbundled⁵¹
- 11. Billing residents for items or services that are included in the per diem rate or otherwise covered by a third-party payer
- 12. Altering documentation or forging physician signatures on documents used to verify that services were ordered or provided⁵²
- 13. Failing to maintain sufficient documentation to support the diagnosis, justify treatment, document the course of treatment and results, and promote continuity of care
- 14. False cost reports⁵³

Hospices

The footnote numbers correspond to the compliance risks explained in the OIG compliance program guidance for hospices (64 FR 54031-54049 (October 5, 1999)).

- 1. Uninformed consent to elect the Medicare hospice benefit²²
- 2. Admitting to hospice care patients who are not terminally ill^{23}
- 3. Arrangements with other health care providers that a hospice knows is submitting claims for services already covered by the Medicare hospice benefit²⁴
- 4. Under-utilization²⁵
- 5. Falsified medical records or plans of $care^{26}$
- 6. Untimely or forged physician certifications on plans of care
- 7. Inadequate or incomplete services rendered by the interdisciplinary group²⁷
- 8. Insufficient oversight of patients, in particular, patients receiving more than six consecutive months of hospice care²⁸
- 9. Hospice incentives to actual or potential referral sources (such as physicians, nursing homes, hospitals and patients) that may violate the anti-kickback statute or other similar Federal or State statute or regulation,²⁹ including improper arrangements with nursing homes³⁰
- 10. Overlap in the services that nursing homes provide, which results in insufficient hospice care provided to nursing home residents³¹
- 11. Improper relinquishment of core services and professional management responsibilities to nursing homes or to volunteers and privately-paid professionals³²
- 12. Providing hospice services in nursing homes before written agreements have been finalized, if required³³
- 13. Billing for higher levels of care than were necessary 34
- 14. Knowingly billing for inadequate or substandard care
- 15. Applying pressure on patients to revoke the Medicare hospice benefit when the patients are still eligible for and desire care, but care has become too expensive to deliver³⁵
- 16. Billing for hospice care provided by unqualified or unlicensed clinical personnel³⁶
- 17. False dating of amendments to medical records³⁷
- 18. High-pressure marketing of hospice care to ineligible beneficiaries³⁸
- 19. Improper patient solicitation activities, such as "patient charting"³⁹
- 20. Inadequate management and oversight of subcontracted services, which results in improper billing⁴⁰
- 21. Sales commissions based on length of hospice stay⁴¹
- 22. Deficient coordination of volunteers⁴²
- 23. Improper indication of the locations where hospice services were delivered⁴³
- 24. Failure to comply with applicable requirements for verbal orders for hospice services⁴⁴
- 25. Non-response to late hospice referrals by physicians⁴⁵
- 26. Knowing misuse of provider certification numbers, which results in improper billing 46
- 27. Failure to adhere to hospice licensing requirements and the Medicare conditions of participation⁴⁷
- 28. Knowing failure to return overpayments made by Federal health care programs⁴⁸

Home Health Agencies

The footnote numbers correspond to the compliance risks explained in the OIG compliance program guidance for home health agencies (63 FR 42410-42426 (August 7, 1998)).

- 1. Billing for items or services not actually rendered²⁰
- 2. Billing for medically unnecessary services²¹
- 3. Duplicate billing²²
- 4. False cost reports²³
- 5. Failure to refund credit balances²⁴
- 6. Home health agency incentives to actual or potential referral sources (such as physicians, hospitals and patients) that may violate the anti-kickback statute for other similar Federal or State statute or regulation²⁵
- 7. Joint ventures between parties, one of which may refer Medicare or Medicaid business to the other²⁶
- 8. Stark physician self-referral law²⁷
- 9. Billing for services to Medicare patients who are not confined to their residence (or are "homebound")²⁸
- 10. Billing for visits to patients who do not have a qualifying service²⁹
- 11. Knowing misuse of provider certification numbers that result in improper billing.
- 12. Over-utilization³⁰ and under-utilization³¹
- 13. Knowingly billing for inadequate or substandard care
- 14. Insufficient documentation to evidence that services were performed and to support reimbursement
- 15. Billing for unallowable costs of home health coordination³²
- 16. Billing for services provided by unqualified or unlicensed clinical personnel
- 17. False dating of amendments to nursing notes
- 18. Falsified plans of care³³
- 19. Untimely or forged physician certifications on plans of care
- 20. Forged beneficiary signatures on visit slips or logs that verify that services were performed
- 21. Improper patient solicitation activities and high-pressure marketing of uncovered or unnecessary services³⁴
- 22. Inadequate management and oversight of subcontracted services, which results in improper billing
- 23. Discriminatory admission and discharge of patients
- 24. Billing for unallowable costs associated with the acquisition and sale of home health agencies
- 25. Compensation programs that offer incentives for the number of visits performed and the revenue generated³⁵
- 26. Improper influence over referrals by hospitals that own home health agencies
- 27. Patient abandonment in violation of applicable statutes, regulations and Federal health care program requirements³⁶
- 28. Knowing misuse of provider certification numbers, which results in improper billing
- 29. Duplication of services provided by assisted living facilities, hospitals, clinics, physicians and other home health agencies

- 30. Knowing or reckless disregard of willing and able caregivers when providing home health services³⁷
- 31. Failure to adhere to home health licensing requirements and the Medicare conditions of participation³⁸
- 32. Knowing failure to return overpayments by Federal health care programs³⁹

Individual and Small Group Physician Practices

The footnote numbers correspond to the compliance risks explained in the OIG compliance program guidance for individual and small group physician practices (65 FR 59434-59452 (October 5, 2000)).

Coding and Billing

- 1. Billing for items or services not rendered or not provided as claimed¹²
- 2. Submitting claims for equipment, medical supplies, or services that are not medically reasonable and necessary¹³
- 3. Double-billing resulting in duplicate payment¹⁴
- 4. Billing for non-covered services as if covered¹⁵
- 5. Knowing misuse of provider identification numbers, which results in improper billing¹⁶
- 6. Unbundling¹⁷
- 7. Failure to use coding modifiers properly¹⁸
- Clustering¹⁹
 Up-coding²⁰

Reasonable and Necessary Services

Medicare only pays for services that meet the Medicare definition of "reasonable & necessary" for the diagnosis and treatment of patients.²³

Documentation

Medical Record Documentation

Medical records may be used to validate—

- 1. The sites of service
- 2. The appropriateness of the services provided
- 3. The accuracy of the billing
- 4. The identity of the caregivers

Examples of suggested internal guidelines²⁴—

- 1. The medical record is complete and legible.
- 2. The documentation of patient encounters includes the reason for encounters; any relevant history; physical examination findings; prior diagnostic test results; assessments, clinical impressions, or diagnoses; plans of care; and date and legible identity of the observers.
- 3. If not documented, the rationale for ordering diagnostic and other ancillary services can be easily inferred by independent reviewers or third parties with appropriate medical training.
- 4. Appropriate health risk factors are identified. Patients' progress, their response to, and any changes in, treatment, and any revisions in diagnosis are documented.

Claim Forms

Suggested practices—

- 1. Link the diagnosis code with the reason for the visit or service
- 2. Use modifiers appropriately
- 3. Provide Medicare with all the information about beneficiaries' other insurance coverage under the Medicare Secondary Payer (MSP) policy

Improper Inducements, ^{29/30} Kickbacks^{25/27} and Self-Referrals^{26/28}

- 1. Financial arrangements with outside entities to whom the practice may refer Federal health care program business³¹
- 2. Joint ventures with entities supplying goods or services to physician practices or their patients³²
- 3. Consulting contracts or medical directorships
- 4. Office and equipment leases with entities to which the physicians refer
- 5. Soliciting, accepting or offering any gifts or gratuities of more than nominal value to or from those who may benefit from physician practice referrals of Federal health care program business³³

Ambulance Suppliers

In the OIG compliance program guidance for ambulance suppliers (68 FR 14245-14255 (March 24, 2003)), extensive explanation of each compliance risk area is provided within the body of the document, rather than with footnotes. Therefore, the Federal Register page numbers and section numbers are provided.

- 1. Improper transport of individuals with other acceptable means of transportation (14250, III.A.2)
- 2. Medically unnecessary trips (14250, III.A)
- 3. Trips claimed, but not rendered (14254, Appendix A.1)
- 4. Misrepresentation of transport destinations in order to make it appear as if transport was covered (14251, III.B.2)
- 5. False documentation (14250-14251, III.B)
- 6. Billing for each patient transported in a group as if he or she was transported separately (14254, Appendix A.2)
- 7. Upcoding from basic life support to advanced life support services (14250, III.A.1)
- 8. Payment of kickbacks (14251-14253,V)

Clinical Laboratories

In the OIG compliance program guidance for clinical laboratories (63 FR 45076-45087 (August 24, 1998)), extensive explanation of each compliance risk area is provided within the body of the document, rather than with footnotes. Therefore, the Federal Register page numbers are provided.

- 1. Medical necessity (45079-45080)
 - Requisition design
 - Notices to physicians
 - Physician acknowledgments
 - Use of Advance Beneficiary Notices (ABNs)
 - Test utilization monitoring
- 2. Billing (45080-48081)
 - Selection of CPT or HCPCS codes
 - Selection of ICD-9-CM codes
 - Tests covered by claims for reimbursement
 - Billing of calculations
 - Reflex testing
- 3. Reliance on standing orders (45081)
- 4. Compliance with applicable HHS fraud alerts (45081)
- 5. Marketing (45081)
- 6. Prices charged to physicians (45081)
- 7. Retention of records (45081)

Pharmaceutical Manufacturers

In the OIG compliance program guidance for pharmaceutical manufacturers (68 FR 23731-23743 (May 5, 2003)), extensive explanation of each compliance risk area is provided within the body of the document, rather than with footnotes. Therefore, the Federal Register page numbers are provided.

- 1. Integrity of data used to establish or determine government reimbursement (23733-23734)
- 2. Kickbacks and other illegal remuneration (23734-23737)
 - Relationships with purchasers and their agents
 - Discounts
 - Product support services
 - Educational grants
 - Research funding
 - Formularies and formulary support activities
 - Relationships with formulary committee members
 - Payments to pharmacy benefit managers (PBM)
 - Formulary placement payments
 - Average wholesale price (AWP)
 - Relationships with physicians and other persons and entities in a position to make or influence referrals (23737-23738)
 - Nature of the relationship between the parties
 - Manner in which the remuneration is determined
 - Value of the remuneration
 - Potential Federal program impact of the remuneration
 - Potential conflicts of interest
 - "Switching" arrangements
 - Payments for detailing
 - Business courtesies and other gratuities
 - Educational and research funding
 - Relationships with sales agents (23738-39)
 - Amount of compensation
 - Identity of the sales agent engaged in the marketing or promotional activity
 - Sales agent's relationship with his or her audience
 - Nature of the marketing or promotional activity
 - Item or service being promoted or marketed
 - Composition of the target audience
- 3. Drug samples (23739)

Third-Party Billing Companies

The footnote numbers correspond to the compliance risks explained in the OIG compliance program guidance for third-party billing companies (63 FR 70138-70152)).

- Billing for items or services not actually documented²⁷ 1.
- Unbundling²⁸ 2.
- 3.
- Upcoding²⁹ "DRG creep"³⁰ 4.
- Inappropriate balance billing³¹ 5.
- Inadequate resolution of overpayments³² 6.
- Lack of integrity in computer systems³³ 7.
- Computer software programs that encourage billing personnel to enter data in fields 8. indicating that services were rendered although not actually performed or documented
- Failure to maintain the confidentiality of information or records³⁴ 9.
- Knowing misuse of provider identification numbers, which results in improper billing³⁵ 10.
- Outpatient services rendered in connection with inpatient stays³⁶ 11.
- Duplicate billing in an attempt to gain duplicate payment³⁷ 12.
- Billing for discharge in lieu of transfer³⁸ 13.
- Failure to use modifiers properly³⁹ 14.
- Billing company incentives that violate the anti-kickback statute or other similar Federal or 15. State statutes or regulations⁴⁰
- 16. Joint ventures⁴¹
- Routine waiver of co-payments and billing third-party insurance only⁴² 17.
- 18. Discounts and professional courtes y^{43}
- 19. Internal coding practices⁴⁸
- 20. "Assumption" coding⁴⁹
- Alteration of documentation 21.
- Coding without proper documentation of all physician and other professional services⁵⁰ 22.
- Billing for services provided by unqualified or unlicensed clinical personnel 23.
- Lack of availability of all necessary documentation at the time of coding 24.
- Employment of sanctioned individuals⁵¹ 25.

Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry

The footnote numbers correspond to the compliance risks explained in the OIG compliance program guidance for the durable medical equipment, prosthetics, orthotics and supply industry (64 FR 36368-36389)).

- 1. Billing for items or services not provided³⁰
- 2. Billing for services that the DMEPOS supplier believes may be denied³¹
- 3. Billing patients for denied charges without a signed written notice 32
- 4. Duplicate billing 33
- 5. Billing for items or services not ordered 34
- 6. Using a billing agent whose compensation arrangement violates the reassignment rule³⁵
- 7. $Upcoding^{36}$
- 8. Unbundling items or supplies³⁷
- 9. Billing for new equipment while providing used equipment³⁸
- 10. Continuing to bill for rental items after they are no longer medically necessary³⁹
- 11. Resubmission of denied claims with different information in an attempt to be improperly reimbursed⁴⁰
- 12. Refusing to submit a claim to Medicare for which payment is made on a reasonable charge or fee schedule basis⁴¹
- 13. Inadequate management and oversight of contracted services, which results in improper billing⁴²
- 14. Charge limitations⁴³
- 15. Providing or billing for substantially excessive amounts of DMEPOS items or supplies⁴⁴
- 16. Providing or billing for items or services that do not meet the quality standards of the DMEPOS items or services claimed⁴⁵
- 17. Capped rentals⁴⁶
- 18. Failure to monitor medical necessity on an ongoing basis⁴⁷
- 19. Delivering or billing for certain items or supplies prior to receiving physician orders or appropriate Certificates of Medical Necessity (CMN)⁴⁸
- 20. Falsifying information on claim forms, CMN or accompanying documentation⁴⁹
- 21. Completing portions of CMN reserved for completion only by treating physicians or other authorized persons.⁵⁰
- 22. Altering medical records⁵¹
- 23. Manipulating patients' diagnoses in an attempt to receive improper payment⁵²
- 24. Failure to maintain medical necessity documentation⁵³
- 25. Inappropriate use of place of service codes⁵⁴
- 26. Cover letters that encourage physicians to order medically unnecessary items or services⁵⁵
- 27. Improper use of the ZX modifier⁵⁶
- 28. Routine waiver of deductibles and coinsurance⁵⁷
- 29. Providing incentives to actual or potential referral sources (such as physicians, hospitals, patients, skilled nursing facilities and home health agencies) that may violate the anti-kickback statute or other similar Federal or State statute or regulation⁵⁸
- 30. Compensation programs that offer incentives for items or services ordered and revenue generated⁵⁹
- 31. Joint ventures between parties, one of whom may refer Medicare or Medicaid business to the other⁶⁰

- 32. Billing for items or services that are furnished pursuant to a prohibited referral under the Stark physician self-referral law⁶¹
- 33. Improper telemarketing practices⁶²
- 34. Improper patient solicitation activities and high-pressure marketing of non-covered or unnecessary services⁶³
- 35. Co-location of DMEPOS items and supplies with referral sources⁶⁴
- 36. Non-compliance with the Federal, State and private payer supplier standards⁶⁵
- 37. Providing false information on the Medicare DMEPOS supplier enrollment form⁶⁶
- 38. Not notifying the National Supplier Clearinghouse in a timely manner of changes to information previously provided on the Medicare DMEPOS supplier enrollment form⁶⁷
- 39. Misrepresenting a person's status as an agent or representative of Medicare⁶⁸
- 40. Knowing misuse of a supplier number, which results in improper billing⁶⁹
- 41. Failure to meet individual payer requirements⁷⁰
- 42. Performing tests on beneficiaries to establish medical necessity⁷¹
- 43. Failing to refund overpayments to a health care $\operatorname{program}^{72}$
- 44. Failing to refund overpayments to patients⁷³
- 45. Improper billing resulting from lack of communication between the DMEPOS supplier, physicians and patients⁷⁴
- 46. Improper billing resulting from lack of communication between different departments within the DMEPOS supplier⁷⁵
- 47. Employing persons excluded from participation in Federal health care programs⁷⁶

Medicare+Choice Organizations Offering Coordinated Care Plans

In the OIG compliance program guidance for Medicare+Choice organizations offering coordinated care plans, extensive explanation of each compliance risk area is provided within the body of the document, rather than with footnotes. Therefore, the Federal Register page numbers are provided.

- 1. Marketing materials and personnel (61897-61898)
- 2. Selective marketing and enrollment (61898-61899)
- 3. Disenrollment (61899)
- 4. Underutilization and quality of care (61899-61900)
- 5. Data collection and submission process (61900-61901)
- 6. Anti-kickback statute and other inducements (61901-61902)
- 7. Emergency services (61902)

COMPLIANCE RESOURCES

Medicare-related and other laws are codified in the United States Code (USC). The Centers for Medicare and Medicaid Services (CMS) and other government agencies provide detail and explanation of these laws in the Code of Federal Regulations (CFR). CMS further clarifies many of these regulations by issuing detailed instructions in a number of manuals. This information changes frequently and use of the electronic versions is encouraged. The CMS Internet Only Manual is found at http://www.cms.gov/Manuals/IOM/list.asp.

States also produce provider manuals in connection with Medicaid. The Illinois Medicaid Provider Handbooks are found at <u>http://www.hfs.illinois.gov/handbooks/</u>, and the Michigan Medicaid Provider Manual is found at <u>http://www.mdch.state.mi.us/dch-</u> medicaid/manuals/MedicaidProviderManual.pdf.

Medicare contractors, including Fiscal Intermediaries (FIs), carriers, Medicare Administrative Contractors (MACs), Durable Medical Equipment (DME) MACs and Home Health and Hospice MACs are required to provide instructions. These instructions take the form of newsletters, bulletins and local coverage determinations (LCDs). Private payer contracts including specific provisions related to reimbursement, and private payers issue provider manuals and other instructions.

Familiarity with these materials and the means of accessing these items is critical for all OSF employees who participate in or contribute to producing or processing claims for Federal or State health care programs. This information must be provided to all employees and health care professionals, including employees in departments and areas such as the Emergency Department (ED), Registration, Scheduling, Medical Records, Quality Management, Patient Safety, Patient Accounts and Fiscal Services. It is the responsibility of the facility or operating division CEO or designee to ensure that this information is appropriately shared, and, more importantly, that there is an understanding of the content and application of this information.

The OIG has issued compliance program guidance (CPG) on a provider-specific basis. The guidance addresses both health care industry-wide compliance concerns and compliance issues particular to the provider type being addressed. The following is a list of the CPG documents available and the date of issue:

01/27/05	Supplemental Compliance Program Guidance for Hospitals	
04/28/03	Final Compliance Program Guidance for Pharmaceutical Manufacturers	
03/24/03	Final Compliance Program Guidance for Ambulance Suppliers	
09/25/00	Final Compliance Program Guidance for Individual and Small Group Physician	
	Practices	
03/16/00	Final Compliance Program Guidance for Nursing Facilities	
11/16/99	Final Compliance Program Guidance for Medicare+Choice Organizations	
09/30/99	Compliance Program Guidance for Hospices	
06/22/99	Compliance Program Guidance for the Durable Medical Equipment Prosthetics,	
	Orthotics, and Supply Industry	
11/30/98	Compliance Program Guidance for Third-Party Medical Billing Companies	
08/07/98	Compliance Program Guidance for Home Health Agencies; IG Remarks	
08/24/98	Compliance Program Guidance for Clinical Laboratories	
02/23/98	Compliance Program Guidance for Hospitals	

Every year, the OIG issues a Work Plan that outlines the new and ongoing reviews undertaken by the OIG. In the Work Plan, the agency responds to existing and emerging industry compliance risks and to concerns raised by Congress, HHS management and the Office of Management and Budget. The current OIG Work Plan is available at http://oig.hhs.gov/reports-and-publications/workplan/index.asp#current.

CONCLUSION

OSF is guided in day-to-day clinical and business operations by an awareness of the need to comply with Federal and State laws and regulations and the program requirements of Federal, State and private payers. OSF is committed to abiding by this Compliance Plan and the organization's compliance policies and procedures. OSF is mindful of the vital importance of remaining faithful to the Philosophy and Values, and Mission and Vision of The Sisters of the Third Order of St. Francis.

BOARD APPROVAL

OSF Healthcare System

Sister Diane Marie, O.S.F., President	Date	
OSF Saint Francis, Inc.		
Kevin D. Schoeplein, President	Date	
HeartCare Midwest		
Sister Diane Marie, O.S.F., President	Date	

Note: Original signatures appear in the original document filed at the Corporate Office.