OSF Healthcare System

Pioneer Accountable Care Organization (ACO)

Compliance Plan

Approved: July 2012

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DEFINITIONS

The **Act** refers to the Social Security Act**.**

Pioneer Beneficiary means a Medicare Beneficiary who has been aligned to the OSF Pioneer ACO using the methodology described in Appendix C of the Agreement, with such changes, if any, as may be approved from time to time by CMS.

Medicare Beneficiary means an individual who is entitled to benefits under Part A of Title XVIII of the Act or enrolled under Part B of Title XVIII of the Act.

Pioneer Provider means an individual or entity that:

1. Is a hospital, a critical access hospital, a skilled nursing facility, a comprehensive outpatient rehabilitation facility, a home health agency, or a hospice that has in effect an agreement to participate in Medicare, or a clinic, a rehabilitation agency, or a public health agency that has in effect a similar agreement but only to furnish outpatient physical therapy or speech pathology services, or a community mental health center that has in effect a similar agreement but only to furnish partial hospitalization services;
2. Is enrolled in Medicare;
3. Is identified by a National Provider Identifier (NPI) or CMS Certification Number (CCN);
4. Bills for items and services it furnishes to Medicare fee-for-service beneficiaries under a Medicare billing number assigned to a TIN in accordance with applicable Medicare regulations; and
5. Is identified on the current list of NPIs provided pursuant to section IV.F.4 of the Pioneer ACO Model Innovation Agreement.

Pioneer Supplier means an individual or entity that:

1. Is a physician or other practitioner, or an entity other than a provider, that furnishes health care services under Medicare;
2. Is enrolled in Medicare;
3. Is identified by a National Provider Identifier (NPI) or CMS Certification Number (CCN);
4. Bills for items and services it furnishes to Medicare fee-for-service beneficiaries under a Medicare billing number assigned to a TIN in accordance with applicable Medicare regulations; and
5. Is identified on the current list of NPIs provided pursuant to section IV.F.4 of the Pioneer ACO Model Innovation Agreement.

ACO Participant means an individual or group of ACO Provider(s)/Supplier(s) identified by a Medicare-enrolled TIN, which alone or together with one or more other ACO Participants comprise(s) an ACO, and which is included on the list of ACO Participants that is required under 42 CFR 425.204(c)(5).

A **Consumer Advocate** is a person with training or professional experience in advocating for the rights of consumers.

Medically Necessary means reasonable and necessary as determined in accordance with Section 1862(a) of the Act.

Covered Services means the scope of health care benefits described in Sections 1812 and 1832 of the Act for which payment is available under Part A or Part B of Title XVIII of the Act.

Pioneer ACO Activities are activities related to promoting accountability for the quality, cost, and overall care for a Medicare patient population as described in the Pioneer ACO Model Innovation Agreement; managing and coordinating care for Medicare fee-for-service beneficiaries through the Pioneer ACO; encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery for patients, including Medicare Beneficiaries; or carrying out any other obligation or duty of the Pioneer ACO under the Pioneer ACO Model Innovation Agreement. Examples of these activities include, but are not limited to, providing direct patient care to Pioneer Beneficiaries; promoting evidence-based medicine and patient engagement; meeting requirements for reporting on quality and cost measures; coordinating care, such as through the use of telehealth, remote patient monitoring, and other enabling technologies; establishing clinical and administrative systems for the Pioneer ACO; meeting the clinical integration requirements of the Agreement; meeting the quality performance standards of the Pioneer ACO Model Innovation Agreement; evaluating health needs of the Pioneer ACO's aligned population; communicating clinical knowledge and evidence-based medicine to Pioneer Beneficiaries; and developing standards for Pioneer Beneficiary access and communication, including Beneficiary access to medical records.

Marketing Materials and Activities include, but are not limited to, general audience materials such as brochures, advertisements, outreach events, letters to beneficiaries, web pages, mailings, social media, or other activities conducted by or on behalf of the Pioneer ACO or Pioneer Providers/Suppliers, when used to educate, solicit, notify, or contact Medicare Beneficiaries regarding the Pioneer ACO Model. The following beneficiary communications are not Marketing Materials and Activities:

- Certain beneficiary communications that are informational (for example, information regarding care coordination generally would not be considered Marketing Material);
- Materials that cover beneficiary-specific billing and claims issues or other specific individual health-related issues; and
- Educational information on specific medical conditions (for example, flu shot reminders), written referrals for health care items and services, and other materials that are excepted from the definition of "marketing" under the HIPAA Privacy Rule.

Shared Savings means any monetary amount the Payment Arrangement generates relative to the Pioneer ACO's Medicare expenditure benchmark for the applicable Performance Year or portion thereof, if this amount exceeds the applicable minimum savings percentage.

Shared Losses means any monetary amount owed to CMS by the Pioneer ACO according to the Payment Arrangement due to spending in excess of the Pioneer ACO's Medicare expenditure benchmark for the applicable Performance Year or portion thereof, if the amount exceeds the applicable minimum loss percentage.

Payment Arrangement means the compensation arrangement in Appendix D to the Pioneer ACO Model Innovation Agreement under which both CMS and the Pioneer ACO agree to a Medicare expenditure benchmark for the applicable Performance Year, and share in the financial loss or gain in relation to the expenditure benchmark for the duration of the Pioneer ACO Model Innovation Agreement.

The first Performance Year of the Pioneer ACO Model Innovation Agreement begins on January 1, 2012 and ends on December 31, 2012. Subsequent Performance Years are each of twelve (12) months duration, beginning on January 1. Each of these periods is referred to as a **Performance Year**.

Notice refers to the Notice of Waiver of Certain Fraud and Abuse Laws in Connection with the Pioneer ACO Model.

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INTRODUCTION

The OSF Healthcare System Pioneer Accountable Care Organization (the "OSF Pioneer ACO" or the "ACO") and the Center for Medicare and Medicaid Innovation Center of the Centers for Medicare and Medicaid Services (CMS) in the Federal Department of Health and Human Services (HHS) entered into a Pioneer ACO Model Innovation Agreement (the "Agreement") under Section 1115A(b) of the Act. The Agreement stipulates that the OSF Pioneer ACO must maintain a compliance plan and specifies the required elements of the compliance plan.

Therefore, the OSF Pioneer ACO has adopted a compliance plan (the "Compliance Plan") that outlines the Compliance Program of the ACO. The Compliance Plan, which is designed to promote compliance with the Agreement and applicable laws and regulations, has been adopted by the Governing Committee of the ACO and applies to ACO Participants and Pioneer Providers/Suppliers and to other individuals and entities performing functions or services related to Pioneer ACO Activities.

The purpose of the Compliance Plan is to provide guidance to Governing Committee members, clinical and operational leaders and managers, ACO Participants and Pioneer Providers/ Suppliers and other individuals and entities performing functions or services related to Pioneer ACO Activities. The Compliance Plan assists the OSF Pioneer ACO in implementing effective internal controls that promote adherence to the Agreement and applicable laws and regulations; safeguards ACO assets from financial penalties; and protects against sanctions on the part of ACO Governing Committee members, clinical and operational leaders and managers, ACO Participants and Pioneer Providers/Suppliers and other individuals and entities performing functions or services related to Pioneer ACO Activities.

It is incumbent upon the clinical and operational leaders and managers of the OSF Pioneer ACO to provide ethical leadership to the organization and to assure that adequate systems and controls are in place to facilitate ethical and legal conduct. The 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 the ACO to maintain high ethical standards, to improve the quality and coordination of care, to promote evidence-based medicine and patient-centered care, to promote engagement on the part of Pioneer Beneficiaries and their caregivers, to reduce waste and to provide a central coordinating mechanism for disseminating information and guidance on applicable laws and regulations.

Compliance efforts are designed to establish a culture within the OSF Pioneer ACO that promotes the prevention, detection and resolution of instances of conduct that do not conform to the Agreement and applicable laws or regulations. The establishment of the Compliance Plan significantly advances the prevention of fraud, waste and abuse in the ACO, 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.

Notwithstanding any arrangements between the OSF Pioneer ACO and ACO Participants or Pioneer Providers/Suppliers or other individuals or entities performing functions or services related to Pioneer ACO Activities, the ACO has ultimate responsibility for adhering to and otherwise complying fully with the terms and conditions of the Agreement and the Compliance Plan. The ACO understands that none of the provisions of the Agreement restricts the authority of the Office of Inspector General (OIG) of the Federal Department of Health and Human Services to audit, evaluate, investigate, or inspect the ACO and ACO Participants and Pioneer Providers/Suppliers and other individuals or entities performing functions or services related to Pioneer ACO Activities.

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BENEFITS OF A COMPLIANCE PROGRAM

In addition to fulfilling the legal duty of ACO Participants and Pioneer Providers/Suppliers to ensure that they are not submitting false or inaccurate claims, the OSF Pioneer ACO enjoys various additional benefits by maintaining an effective Compliance Program. The Compliance Program makes good business sense in that it helps fulfill the fundamental caregiving mission of the ACO to patients and to the community and assists the ACO in identifying weaknesses in internal systems and controls. Other important benefits of the Compliance Program include the ability to:

1. Demonstrate in a concrete way to ACO Participants and Pioneer Providers/Suppliers, to patients and to the communities that OSF serves the ACO's strong commitment to honest and responsible provider and corporate conduct

2. Enhance the ACO's reputation for integrity and quality, increasing the standing of the ACO 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 the ACO 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 the behavior of ACO Participants and Pioneer Providers/ Suppliers and other individuals and entities performing functions or services related to Pioneer ACO Activities pertaining to fraud, waste and abuse

9. Encourage ACO Participants and Pioneer Providers/Suppliers and other individuals and entities performing functions or services related to Pioneer ACO Activities to report potential problems and improve internal communication

10. React quickly to the compliance concerns of ACO Participants and Pioneer Providers/ Suppliers and other individuals and entities performing functions or services related to Pioneer ACO activities and effectively target resources to address their concerns

11. Provide policies and procedures for the prompt and thorough investigation of alleged misconduct by ACO Participants and Pioneer Providers/Suppliers and other individuals and entities performing functions or services related to Pioneer ACO Activities

12. Create a centralized source for distributing information on applicable laws and regulations with respect to fraud, waste and abuse and other issues

The OSF Pioneer ACO recognizes that the Compliance Plan does not, in itself, eliminate fraud, waste and abuse from the ACO. However, a strong internal culture, a commitment to abide by the Compliance Plan and a sincere effort to comply with the Agreement and applicable laws and regulations significantly reduce the risk of unlawful or improper conduct.

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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 Governing Committee has established and maintains the 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 OSF Compliance Committee and the OSF Physician Practice Compliance Committee

3. Developing and implementing effective compliance education programs for ACO Participants and Pioneer Providers/Suppliers, 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 individuals who have violated the Agreement or applicable laws or regulations

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 ACO and an assessment of the effectiveness of the Compliance Program in addressing these risks, and making modifications to the Compliance Program, as needed

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1. Written Standards of Conduct and Policies and Procedures

A. Standards of Conduct

It is the obligation of each ACO Participant and each Pioneer Provider/Supplier and each individual or entity performing functions or services related to Pioneer ACO Activities 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 the Agreement, the Compliance Plan and the OSF Standards of Performance. These foundational documents provide a framework for the ethical performance of the job duties of ACO Participants and Pioneer Providers/ Suppliers and other individuals and entities performing functions or services related to Pioneer ACO Activities. Adherence to these standards of conduct will result in conduct that complies with the Agreement, and applicable laws and regulations.

The OSF Pioneer ACO is committed to operating in accordance with the Agreement and with the Compliance Plan, with an emphasis on preventing fraud, waste and abuse. The ACO expects Governing Committee members, clinical and operational leaders and managers, ACO Participants and Pioneer Providers/Suppliers and individuals and entities performing functions or services related to Pioneer ACO Activities to function in accordance with the Compliance Plan. The ACO is committed to disseminating the Compliance 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 the Compliance Plan.

B. Written Policies and Procedures

The Compliance Program includes compliance policies and procedures for OSF Healthcare System and compliance policies and procedures specific to the OSF Pioneer ACO. Many of the provisions in the Compliance Plan are detailed in the compliance policies and procedures. OSF Healthcare System compliance policies and procedures may be accessed at OSF Pioneer ACO Compliance Policies.

The OSF Pioneer ACO has adopted the compliance policies and procedures of OSF Healthcare System, and OSF Pioneer ACO compliance policies and procedures are incorporated in and appended to the Compliance Plan. In any case in which there is a conflict between the OSF Healthcare System compliance policies and procedures and the ACO compliance policies and procedures, the ACO-specific policies and procedures control so far as the ACO and ACO participants and Pioneer Providers/Suppliers and other individuals and entities performing functions or services related to Pioneer ACO Activities are concerned.

The written compliance policies and procedures communicate the commitment on the part of the OSF Pioneer ACO to comply with the Agreement and applicable laws and regulations, with an emphasis on preventing fraud, waste and abuse.

OSF Healthcare System 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 Compliance Committee of the Board of Directors of OSF Healthcare System, after which the policies and procedures are approved by the Board.

OSF Pioneer ACO policies 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 ACO Governing Committee. Compliance policies and procedures are reviewed at least once every three years and revised, as needed.

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2. Designation of Compliance Officer and Compliance Committees

A. Compliance Officer

The Chief Compliance Officer of OSF Healthcare System serves as the Chief Compliance Officer of the OSF Pioneer ACO. The primary responsibilities of the Chief Compliance Officer include:

1. Directing and monitoring the OSF Pioneer ACO Compliance Program and maintaining the Compliance Plan

2. Providing reasonable assurance to the Governing Committee that all ACO Participants and Pioneer Providers/Suppliers and other individuals and entities performing functions or services related to Pioneer ACO Activities are functioning in compliance with the Agreement and applicable laws and regulations

3. With respect to compliance issues, advising Governing Committee members, clinical and operation leaders and managers and ACO Participants and Pioneer Providers/Suppliers and other individuals and entities performing functions or services related to Pioneer ACO Activities

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 Compliance Program and that promote an understanding of and compliance with the Agreement and applicable laws and regulations

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 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 ACO-wide or at the level of an ACO Participant or Pioneer Provider/Supplier or other individual or entity performing functions or services related to Pioneer ACO Activities

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 is not legal counsel to the OSF Pioneer ACO or a Pioneer Provider/Supplier. The Chief Compliance Officer reports directly to the ACO Governing Committee and has express authority to communicate personally with the Governing Committee. 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 Chief Compliance Officer has established for OSF Healthcare System:

- The OSF Compliance Committee, a management committee composed of the facility and operating division Compliance Officers and Compliance Coordinators and others with compliance expertise. The CEO of each facility and operating division appoints the Compliance Officer for the facility or operating division. The Compliance Officer is accountable, at his or her facility or operating division, for the oversight of the Compliance Program. In turn, the Compliance Officer appoints the Compliance Coordinator, who is responsible, at his or her facility or operating division, for day-to-day compliance activities and initiatives.

- 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 expertise.

OSF Pioneer ACO compliance issues are presented to and discussed with OSF Compliance Committee members and OSF Physician Practice Compliance Committee members. Committee members serve as active, visible and vocal advocates 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 the organization

2. Reviewing the Compliance Plan and revisions to the Compliance Plan

3. Actively participating in quarterly committee meetings

4. Analyzing applicable laws and regulations

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 applicable laws and regulations

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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 Healthcare System 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 applicable laws and regulations.

The OSF Pioneer ACO adopts, and supplements, as needed, the compliance training programs of OSF Healthcare System for use with Governing Committee members, clinical and operational leaders and managers, ACO Participants and Pioneer Providers/Suppliers and other individuals and entities performing functions or services related to Pioneer ACO Activities. These compliance training programs fall into two broad categories: general training aimed at raising awareness of the Compliance Program and training focused on the impact of particular statutory and regulatory 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 applicable laws and regulations affect their work. For example, although all employees should understand the importance of proper billing procedures, it is essential that in-depth 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 Agreement and applicable laws and regulations 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 Governing Committee members, clinical and operational leaders and managers, ACO Participants and Pioneer Providers/Suppliers and other individuals and entities performing functions or services related to Pioneer ACO Activities is logged, and the documentation is maintained and, on request, provided to the Chief Compliance Officer. Failure to comply with compliance training requirements may result in disciplinary action, including, for OSF employees, possible termination of employment, in accordance with the Human Resources policy on Positive Discipline.

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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 Pioneer ACO clinical and operational leaders and managers, ACO Participants and Pioneer Providers/Suppliers and other individuals and entities performing functions or services related to Pioneer ACO Activities, the ACO maintains, to the extent possible, the anonymity of individuals who contact the Chief Compliance Officer. They are assured that no retaliation is permitted.

OSF Pioneer ACO clinical and operational leaders and managers, ACO Participants and Pioneer Providers/Suppliers and other individuals and entities performing functions or services related to Pioneer ACO Activities 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. OSF Employees should report personnel matters to their supervisor or to the Human Resources Department of their facility or operating division.

OSF Pioneer ACO clinical and operational leaders and managers, ACO Participants and Pioneer Providers/Suppliers and other individuals and entities performing functions or services related to Pioneer ACO Activities 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 the Agreement or applicable laws and regulations or to concerns about fraud, waste and abuse.

OSF Pioneer ACO clinical and operational leaders and managers, ACO Participants and Pioneer Providers/Suppliers and other individuals and entities performing functions or services related to Pioneer ACO Activities have an affirmative duty to report illegal or improper conduct and other compliance issues. In the event that they have questions or are uncertain or confused about the requirements of the Agreement or applicable laws and regulations, 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

The OSF Pioneer ACO provides employees and contractors of the ACO, ACO Participants and Pioneer Providers/Suppliers and other individuals and entities performing functions or services related to Pioneer ACO Activities a method to report to the Chief Compliance Officer, on an anonymous basis, suspected problems related to the ACO. The ACO has adopted the OSF Integrity Line of OSF Healthcare System, which contracts with an outside vendor to staff the OSF Integrity Line.

The OSF Integrity Line is a vehicle for OSF 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 www.OSFIntegrityLine.alertline.com. This service is available twenty-four hours a day, seven days a week. OSF Pioneer ACO leaders and managers, ACO Participants and Pioneer Providers/Suppliers and other individuals and entities performing functions or services related to Pioneer ACO Activities who contact the OSF Integrity Line are assigned a report number, a personal identification number (PIN) and a contact date. Individuals may call back or log-on again on the contact date for information about the investigation and resolution of the matter that they reported.

OSF Pioneer ACO leaders and managers, ACO Participants and Pioneer Providers/ Suppliers and other individuals and entities performing functions or services related to Pioneer ACO Activities 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 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 individuals who contact the OSF Integrity Line is not tolerated. Any reported retaliation by OSF employees is handled through the OSF Positive Discipline process.

Details about the OSF Integrity Line are provided to new OSF 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. Current OSF employees are reminded through various means of the importance of 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 Compliance Committee of the Board of Directors of OSF Healthcare System. A report that shows the number and types of ACO-specific issues reported to the OSF Integrity Line is presented, as the number and types of contacts warrant, to the Governing Committee of the OSF Pioneer ACO.

Assertions of fraud, waste and abuse by individuals 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.

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5. Disciplinary Guidelines

A. Discipline Policy and Actions

OSF Pioneer ACO Governing Committee members, clinical and operational leaders and managers and ACO Participants and Pioneer Providers/Suppliers and other individuals and entities performing functions or services related to Pioneer ACO Activities are expected to comply with the requirements in the OSF Human Resources Handbook, the OSF Standards of Performance and the Rules of Conduct in the OSF Human Resources policy on Positive Discipline. OSF 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 on the part of OSF employees 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.

Neither the OSF Pioneer ACO nor the OSF Healthcare System knowingly employs or engages 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 OSF Pioneer ACO has adopted the OSF Healthcare System processes for screening all current employees, business vendors and independent contractors against the Federal and State government exclusion databases.

The Human Resources department in OSF facilities and operating divisions conducts 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 OSF Corporate Finance and Accounting Division screens all new business vendors prior to completing a contract for services.

OSF Healthcare System contracts with a third-party provider of comprehensive exclusion list checking services (referred to in the 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/

3. **SDN/OFAC** – The Federal Office of Foreign Assets Control maintains the Specially Designated Nationals List.
   http://www.treasury.gov/ofac/downloads/t11sdn.pdf

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.
   http://www.hfs.illinois.gov/all/062609n.html
   https://www.idfpr.com/dpr/licenselookup/default.asp

5. **Michigan MDCH** – The Michigan Department of Community Health maintains a list of sanctioned providers.
   http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-16459--,00.html

If a current OSF 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 OSF 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 OSF 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.

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6. Auditing and Monitoring

The OSF Pioneer ACO recognizes that, in order for the Compliance Program to be successful and effective, auditing and monitoring are necessary to test and verify compliance with the Agreement and applicable laws and regulations. Together with conducting risk assessments (discussed below), compliance auditing and monitoring are mechanisms for identifying and addressing compliance problems related to the ACO's operations and performance.

An audit is typically a more formal review of compliance with a particular set of internal (OSF Pioneer ACO compliance policies, for example) or external (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 OSF Corporate Compliance Division maintains, on behalf of OSF Healthcare System, a Compliance Audit Program, which has been adopted by the OSF Pioneer ACO. The Compliance Audit Program is coordinated by Compliance, Reimbursement and Clinical Auditors from the OSF Corporate Compliance Division, which contracts, as needed, with external auditors who have expertise in applicable laws and regulations. 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 OSF Pioneer ACO leaders and managers, ACO Participants and Pioneer Providers/Suppliers and other individuals and entities performing functions or services related to Pioneer ACO Activities is in compliance with the Agreement and with applicable laws and regulations

5. Appropriate interaction occurs between regulatory authorities and the various OSF facilities and operating divisions

Specifically, the OSF 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 risk-based 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. The Agreement

2. Applicable laws and regulations, especially new legal or regulatory requirements

3. The annual work plan of the Office of Inspector General (OIG) of the Federal Department of Health and Human Services (HHS)

4. The enforcement priorities of regulatory authorities

5. The reimbursement policies of government contractors

6. The results of compliance risk assessments

7. The risks identified by the Compliance Committee of the Board of Directors of OSF Healthcare System, the Governing Committee of the OSF Pioneer ACO, the OSF Compliance Committee, the OSF Physician Practice Compliance Committee and OSF and ACO leadership

8. 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 Healthcare System and the OSF Pioneer ACO

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 applicable laws and regulations, including determinations of the effectiveness of the Compliance Program

5. Reviews of compliance with OSF and ACO 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 Compliance Committee of the Board of Directors of OSF Healthcare System. ACO-specific elements of the annual Compliance Audit Plan and the results of ACO-specific audit and monitoring activity are reported to the Governing Committee of the OSF Pioneer ACO. The annual Compliance Audit Plan and the results of audit and monitoring activity are also reported to the OSF Compliance Committee and the OSF Physician Practice Compliance Committee.

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7. Responding to Detected Offenses and Developing Corrective Action Initiatives

A. Violations and Investigations

Violations of the Agreement or the Compliance Plan, failures to comply with applicable laws or regulations and other types of misconduct threaten the status of the OSF Pioneer ACO as an honest, trustworthy and reliable provider eligible to participate in the Pioneer ACO program. 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 ACO.

OSF Pioneer ACO leaders and managers, ACO Participants and Pioneer Providers/Suppliers and other individuals and entities performing functions or services related to Pioneer ACO Activities 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 the Compliance Plan has occurred, and if so, to take the steps necessary to correct the problem.

The OSF 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 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 apply to 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, including any OSF Pioneer ACO leader or manager, ACO Participant or Pioneer Provider/Supplier or any individual or entity performing functions or services related to Pioneer ACO Activities, 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, the 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 government agency and the most suitable means of self-reporting available. Prompt reporting would demonstrate the good faith and willingness of the organization 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.

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8. Compliance Risk Assessments

Compliance risk analysis is performed, on behalf of OSF Healthcare System, by the OSF Corporate Compliance Division, by OSF facilities and operating divisions and by external parties engaged by OSF. The OSF Pioneer ACO has adopted the risk assessment protocol of OSF Healthcare System. It is incumbent on ACO Governing Committee members, clinical and operational leaders and managers, ACO Participants and Pioneer Providers/Suppliers and other individuals and entities performing functions or services related to Pioneer ACO Activities to be vigilant and proactive in identifying and bringing compliance risks to the attention of the OSF Corporate Compliance Division. Together with auditing and monitoring (discussed above), risk assessments are mechanisms for identifying and addressing compliance problems related to the ACO's operations and performance.

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 or the ACO

2. The complexity of the risk

3. The impact on the culture, reputation, finances and clinical and business operations of OSF or the ACO

4. The organization's previous experience

5. Industry trends

6. Government enforcement priorities

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

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

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OSF Healthcare System
Pioneer ACO
Compliance Plan

GENERAL COMPLIANCE RISKS

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

The OSF Pioneer ACO believes that the development and submission of complete and accurate claims, other requests for payment and financial reports 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 Pioneer Beneficiaries. Claims must comply with applicable laws and regulations. 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 ACO Participants or Pioneer Providers/Suppliers. 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 result in a determination 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 claims 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 Medicare Beneficiaries' financial liability when Medicare claims are disallowed is outlined in Sections 1879(a)-(g) of the Social Security 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 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, including Pioneer 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, including ACO Participants and Pioneer Providers/Suppliers, 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).

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

The OSF Pioneer ACO agrees and requires ACO Participants and Pioneer Providers/Suppliers and other individuals and entities performing functions or services related to Pioneer ACO Activities to agree to comply with applicable laws, including, but not limited to:

- Federal criminal law
- The Federal False Claims Act – 30 USC 3729 *et seq*.
- The Federal anti-kickback Statute – 42 USC 1320a-7b(b)
- The Federal civil monetary penalties law – 42 USC 1320a-7a
- The physician self-referral ("Stark") law – 42 USC 1395nn

Information on the Federal False Claims Act and the Federal civil monetary penalties law is found throughout the Compliance Plan. An overview of the Federal anti-kickback statute and the Stark law is below.

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

Neither OSF Healthcare System nor the OSF Pioneer ACO enters into financial arrangements—either ownership/investment or compensation arrangements—with physicians that are designed to provide inappropriate remuneration to OSF or the ACO in return for the physicians' providing services to Medicare beneficiaries at OSF facilities or operating divisions or Pioneer Providers.

Neither OSF Healthcare System nor the OSF Pioneer ACO submits or causes to be submitted to Medicare (or other Federal health care programs) claims for patients who were referred to OSF hospitals or Pioneer Providers pursuant to financial arrangements—either ownership/investment or compensation arrangements—designed to induce the referrals in violation of the anti-kickback statute, the Stark law or other applicable 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 or 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.

Notwithstanding the information above, the Secretary of Health and Human Services has waived certain fraud and abuse laws, including the Federal anti-kickback statute and the Stark law, as the Secretary has deemed necessary to carry out the Pioneer ACO model. The Notice of Waiver of Certain Fraud and Abuse Laws in Connection with the Pioneer ACO Model outlines the conditions for the OSF Pioneer ACO to meet in order to qualify for a waiver and specifies the period of time during which the waiver is in effect. Detailed information about the various waivers is found in the OSF Pioneer ACO Compliance policies on the Pioneer ACO Participation Waiver, the Shared Savings Distribution Waiver, the Compliance with the Physician Self-Referral Law Waiver, and the Waiver for Patient Incentives.

For an arrangement to be protected, it needs to fit in only one waiver established by the Notice. A waiver under the Notice is not needed for an arrangement to the extent that it:

- Does not implicate a specific fraud and abuse law, or
- Implicates the law, but either fits within an existing safe harbor or exception, as applicable, or does not otherwise violate the law.

There is no need for the OSF Pioneer ACO to apply for an individualized waiver.

Arrangements that do not fit in a waiver established by the Notice have no special protection and must be evaluated for compliance on a case-by-case basis. Failure to fit in a waiver established by the Notice does not constitute, in and of itself, a violation of the laws.

Nothing in the Notice affects the obligations of the OSF Pioneer ACO or ACO Participants or Pioneer Providers/Suppliers to comply with the provisions of the Internal Revenue Code and other Federal and State laws and regulations. Nothing in the Notice changes any reimbursement or coverage rule with respect to the Medicare program.

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

EMTALA is the Federal law that prohibits the dumping of patients. A hospital has the obligation under EMTALA to evaluate and treat 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 individual is suffering from an emergency medical condition, the hospital may not delay the MSE nor 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 Social Security Act: http://www.ssa.gov/OP_Home/ssact/title18/1867.htm. CMS provides guidance at: http://www.cms.hhs.gov/EMTALA/. Additional guidance is offered by the OIG in its supplemental compliance program guidance for hospitals.

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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. 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 Medicare 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 Medicare (and other 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: http://www.cms.gov/CFCsAndCoPs/.

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5. Relationships with Federal Health Care Program Beneficiaries

It is inappropriate to offer or transfer remuneration to a Medicare 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 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.

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

Notwithstanding the information above, the Secretary of Health and Human Services has waived certain fraud and abuse laws, including the beneficiary inducement civil monetary penalties law, as the Secretary has deemed necessary to carry out the Pioneer ACO model. The Notice of Waiver of Certain Fraud and Abuse Laws in Connection with the Pioneer ACO Model outlines the conditions for the OSF Pioneer ACO to meet in order to qualify for a waiver and specifies the period of time during which the waiver is in effect. Detailed information about the various waivers is found in the OSF Pioneer ACO Compliance policy on the Waiver for Patient Incentives.

For an arrangement to be protected, it needs to fit in only one waiver established by the Notice. A waiver under the Notice is not needed for an arrangement to the extent that it:

- Does not implicate a specific fraud and abuse law, or
- Implicates the law, but either fits within an exception or does not otherwise violate the law.

There is no need for the OSF Pioneer ACO to apply for an individualized waiver.

Arrangements that do not fit in a waiver established by the Notice have no special protection and must be evaluated for compliance on a case-by-case basis. Failure to fit in a waiver established by the Notice does not constitute, in and of itself, a violation of the laws.

Nothing in the Notice affects the obligations of the OSF Pioneer ACO or ACO Participants or Pioneer Providers/Suppliers to comply with the provisions of the Internal Revenue Code or other Federal and State laws and regulations. Nothing in the Notice changes any reimbursement or coverage rule with respect to the Medicare program.

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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.

The OSF Pioneer ACO acknowledges that it is a covered entity or a business associate of Pioneer Providers/Suppliers who are covered entities. The ACO has developed procedures to protect the confidentiality of all information that identifies individual Pioneer Beneficiaries. These procedures specify that the information is confidential and that it may not be disclosed directly or indirectly except for purposes under HIPAA and in accordance with applicable laws and regulations. The ACO has put in place all appropriate administrative, technical and physical safeguards to protect the privacy and security of protected health information in accordance with 45 CFR § 164.530(c).

All data sharing within the ACO and communications from the ACO or Pioneer Providers/ Suppliers to Pioneer Beneficiaries complies with the HIPAA Privacy and Security Rules and all HIPAA privacy and security guidance applicable to the use and disclosure of protected health information (PHI) by covered entities. The ACO uses this data to develop and implement activities related to coordinating care and improving the quality and efficiency of care for all Pioneer Beneficiaries.

Privacy

The Privacy Rule addresses the use and disclosure of PHI by providers and other covered entities, including ACO Participants and Pioneer Providers/Suppliers. The Privacy Rule also provides certain rights to patients, including Pioneer Beneficiaries, 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, including ACO Participants and Pioneer Providers/ Suppliers, 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 Chief Compliance Officer serves as the Chief Privacy Officer.

Security

The Security Rule applies to electronic Protected Health Information (ePHI). The Security Rule requires that all covered entities, including ACO Participants and Pioneer Providers/Suppliers, 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 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 civil monetary penalties

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 Secretary of Health and Human Services 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 Medicare (and other Federal health care programs). 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, including Pioneer Suppliers, who are individuals.

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7. Employee and Contractor Screening

No Medicare or other 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 Medicare Beneficiaries or other Federal health care program beneficiaries. 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 Medicare Beneficiaries or other 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.

In the event that an OSF Pioneer ACO Participant or Pioneer Provider/Supplier is excluded from participation in any Federal health care program, the ACO is required to inform CMS no later than thirty (30) days after the exclusion and to update the list of participating Tax Identification Numbers (TINs)/National Provider Identifiers (NPIs) to remove the ACO Participant or Pioneer Provider/Supplier.

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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, OSF Pioneer ACO Governing Committee members, clinical and operational leaders and managers, ACO Participants and Pioneer Providers/Suppliers and other individuals and entities performing functions or services related to Pioneer ACO Activities have a duty to act honestly and with integrity and to make decisions on behalf of, and in the best interest of, the ACO and Pioneer Beneficiaries. 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 the ACO. Improper conduct or activity that may threaten the business operations or reputation of the ACO must also be avoided. The ACO expects that individuals in positions of making or influencing decisions about vendor agreements or arrangements or other business transactions on behalf of the ACO and Pioneer Beneficiaries 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 Healthcare System and the OSF Pioneer ACO seek 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 Healthcare System and the OSF Pioneer ACO. Industry support of physicians, students and trainees or other medical professionals should be free of actual or apparent conflicts of interest.

OSF Healthcare System and the OSF Pioneer ACO expect 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 Healthcare System and the OSF Pioneer ACO seek 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 patients, including Pioneer Beneficiaries.

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, the OSF Pioneer ACO has established a policy that:

1. Requires each member of the Governing Committee to disclose relevant financial interests;
2. Provides a procedure to determine whether a conflict of interest exists and sets forth a process to address any conflicts that arise; and
3. Addresses remedial action for members of the governing body that fail to comply with the policy.

Each member of the Governing Committee is required to complete an online disclosure form annually. The OSF Pioneer ACO has adopted the disclosure application put in place by OSF Healthcare System.

Instructions are provided in the e-mail notice that is sent to each member of the Governing Committee, and additional information is provided in the disclosure application. Upon completion of the online disclosure form, a member of the Governing Committee attests that he or she has read, understands and agrees to comply with the conflict of interest policies of OSF Healthcare System. The Governing Committee member also certifies that he or she has made all disclosures to the best of his or her knowledge.

Once the member of the Governing Committee has submitted the online disclosure form, it is reviewed and evaluated by the OSF Corporate Compliance Division. If an actual or apparent conflict of interest is identified, then the Governing Committee member is informed of the status of the review process, including the need for additional information or for a management plan. (A notification is sent after review of the disclosure if no actual or apparent conflict of interest exists.)

Failure to comply with the disclosure process may incur administrative action, up to and including loss of membership on the Governing Committee. A member of the Governing Committee who is an employee of OSF Healthcare System and who fails to comply with the disclosure process is subject to the Positive Discipline Process of OSF Healthcare System.

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9. Right to Audit ACO Records

The OSF Pioneer ACO agrees, and requires Pioneer Providers/Suppliers and other individuals and entities performing functions or services related to Pioneer ACO Activities to agree, that CMS, the Federal Department of Health and Human Services (HHS) and the Comptroller General or their designee(s) have the right to audit, inspect, investigate and evaluate any books, contracts, records, documents and other evidence of the ACO, Pioneer Providers/Suppliers and other individuals or entities performing functions or services related to Pioneer ACO Activities that pertain to all of the following:

- The ACO's compliance with the Agreement,
- The quality of services performed and determination of the amount due to or from CMS under the Agreement, and
- The ability of the ACO to bear the risk of potential losses and to repay any losses to CMS.

If, as a result of any inspection, evaluation, investigation or audit, it is determined that the amount of Shared Savings due to the ACO or the amount of shared losses owed by the ACO has been calculated in error, then CMS reserves the right to recalculate the amount of Shared Savings or Shared Losses.

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10. Maintenance of ACO Records

The OSF Pioneer ACO agrees, and requires Pioneers Providers/Suppliers and other individuals and entities performing functions or services related to Pioneer ACO Activities to agree, to maintain and provide CMS, the Federal Department of Health and Human Services (HHS) and the Comptroller General or their designee(s) access to all books, contracts, records, documents and other evidence (including data related to Medicare utilization and costs, quality performance measures, Shared Savings distributions and other financial arrangements related to ACO activities) sufficient to enable the audit, evaluation, inspection or investigation of the ACO's compliance with program requirements, quality of services performed, right to any Shared Savings payment, or obligation to repay losses, ability to bear the risk of potential losses and ability to repay any losses to CMS.

The OSF Pioneer ACO maintains such books, contracts, records, documents and other evidence, except as provided in Appendix E of the Agreement, for a period of ten (10) years from the date on which the Agreement terminates or the date of completion of any audit, evaluation, inspection or investigation, whichever is later, unless:

1. CMS determines that there is a special need to retain a particular record or group of records for a longer period, and CMS notifies the ACO at least thirty (30) days before the normal disposition date; or

2. There has been a termination, dispute or allegation of fraud or similar fault against the Pioneer ACO, Pioneer Providers/Suppliers or other individuals or entities performing functions or services related to Pioneer ACO Activities, in which case the ACO retains records for an additional six (6) years from the date of any resulting final resolution of the termination, dispute or allegation of fraud or similar fault.

The OSF Pioneer ACO retains copies of all written and electronic Marketing Materials and Activities and appropriate records for all other Marketing Materials and Activities provided to Pioneer Beneficiaries for a period of ten (10) years from the date on which the Agreement terminates.

The OSF Pioneer ACO also retains copies of all written and electronic communications from Pioneer Beneficiaries to the ACO, including, but not limited to, Pioneer ACO Model Notifications, Opt-Out Notifications for Data Sharing and Substance Abuse Opt-In Notifications, and retains appropriate records of all other communications from Pioneer Beneficiaries to the ACO for a period of ten (10) years from the final date of the period of the Agreement. (The OSF Pioneer ACO Policy on Notifications to Pioneer Beneficiaries explains Pioneer ACO Model Notifications, Opt-Out Notifications for Data Sharing and Substance Abuse Opt-In Notifications.)

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OSF Healthcare System
Pioneer ACO
Compliance Plan

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 rendered[13]
2. Providing medically unnecessary services[14]
3. Upcoding[15]
4. "DRG creep"[16]
5. Outpatient services rendered in connection with inpatient stays[17]
6. Teaching physician and resident requirements for teaching hospitals
7. Duplicate billing[18]
8. False cost reports[19]
9. Unbundling[20]
10. Billing for discharge in lieu of transfer[21]
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 regulation[23]
14. Joint ventures[24]
15. Financial arrangements between hospitals and hospital-based physicians[25]
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 procedures[14]
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) guidelines[17]
22. Submitting incorrect claims for ancillary services because of outdated charge description masters (CDMs)[18]
23. Circumventing the multiple procedure discounting rules[19]
24. Improper billing for observation services[20]
25. Failure to follow the "same-day rule"[21]

26. Abuse of partial hospitalization payments[22]
27. Same-day discharges and readmissions[23]
28. Violation of Medicare's post-acute transfer policy[24/25]
29. Improper churning of patients by long-term care hospitals co-located in acute care hospitals[26]
30. Improper reporting of the costs of "pass-through" items[27]
31. Abuse of DRG outlier payments[28]
32. Improper claims for incorrectly designated "provider-based" entities[29]
33. Improper claims for clinical trials[30]
34. Improper claims for organ acquisition costs[31/32/33]
35. Improper claims for cardiac rehabilitation services[34]
36. Failure to follow Medicare rules[35]
37. Use of information technology[36]

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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 needs[26]
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 problems[27]
3. Failure to accommodate residents' needs and preferences[28]
4. Failure to properly prescribe, administer, or monitor prescription drug usage[29]
5. Inadequate staffing levels or insufficiently trained or supervised staff to provide medical, nursing, and related services[30]
6. Failure to provide appropriate therapy services[31]
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 law[32]

Residents' Rights

1. Discriminatory admission or improper denial of access to care[35]
2. Verbal, mental, or physical abuse, corporal punishment, or involuntary seclusion[36]
3. Inappropriate use of physical or chemical restraints[37]
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 protected[38]
5. Denial of residents' right to participate in care and treatment decisions[39]
6. Failure to safeguard residents' financial affairs[40]

Billing and Cost Reporting

1. Billing for items or services not rendered or provided as claimed[43]
2. Submitting claims for equipment, medical supplies and services that are medically unnecessary[44]
3. Submitting claims to Medicare Part A for residents who are not eligible for Part A coverage[45]
4. Duplicate billing[46]
5. Failing to identify and refund credit balances[47]
6. Submitting claims for items or services not ordered[48]
7. Knowingly billing for inadequate or substandard care[49]
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 provided[50]

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 unbundled[51]
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 provided[52]
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 reports[53]

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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 benefit[22]
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 benefit[24]
4. Under-utilization[25]
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 group[27]
8. Insufficient oversight of patients, in particular, patients receiving more than six consecutive months of hospice care[28]
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 homes[30]
10. Overlap in the services that nursing homes provide, which results in insufficient hospice care provided to nursing home residents[31]
11. Improper relinquishment of core services and professional management responsibilities to nursing homes or to volunteers and privately-paid professionals[32]
12. Providing hospice services in nursing homes before written agreements have been finalized, if required[33]
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 deliver[35]
16. Billing for hospice care provided by unqualified or unlicensed clinical personnel[36]
17. False dating of amendments to medical records[37]
18. High-pressure marketing of hospice care to ineligible beneficiaries[38]
19. Improper patient solicitation activities, such as “patient charting”[39]
20. Inadequate management and oversight of subcontracted services, which results in improper billing[40]
21. Sales commissions based on length of hospice stay[41]
22. Deficient coordination of volunteers[42]
23. Improper indication of the locations where hospice services were delivered[43]
24. Failure to comply with applicable requirements for verbal orders for hospice services[44]
25. Non-response to late hospice referrals by physicians[45]
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 participation[47]
28. Knowing failure to return overpayments made by Federal health care programs[48]

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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 rendered[20]
2. Billing for medically unnecessary services[21]
3. Duplicate billing[22]
4. False cost reports[23]
5. Failure to refund credit balances[24]
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 regulation[25]
7. Joint ventures between parties, one of which may refer Medicare or Medicaid business to the other[26]
8. Stark physician self-referral law[27]
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 service[29]
11. Knowing misuse of provider certification numbers that result in improper billing.
12. Over-utilization[30] and under-utilization[31]
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 coordination[32]
16. Billing for services provided by unqualified or unlicensed clinical personnel
17. False dating of amendments to nursing notes
18. Falsified plans of care[33]
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 services[34]
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 generated[35]
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 requirements[36]
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 services[37]
31. Failure to adhere to home health licensing requirements and the Medicare conditions of participation[38]
32. Knowing failure to return overpayments by Federal health care programs[39]

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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 claimed[12]
2. Submitting claims for equipment, medical supplies, or services that are not medically reasonable and necessary[13]
3. Double-billing resulting in duplicate payment[14]
4. Billing for non-covered services as if covered[15]
5. Knowing misuse of provider identification numbers, which results in improper billing[16]
6. Unbundling[17]
7. Failure to use coding modifiers properly[18]
8. Clustering[19]
9. Up-coding [20]

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 guidelines[24]—

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 business[31]
2. Joint ventures with entities supplying goods or services to physician practices or their patients[32]
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 business[33]

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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)

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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)

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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)

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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)).

1. Billing for items or services not actually documented[27]
2. Unbundling[28]
3. Upcoding[29]
4. "DRG creep"[30]
5. Inappropriate balance billing[31]
6. Inadequate resolution of overpayments[32]
7. Lack of integrity in computer systems[33]
8. Computer software programs that encourage billing personnel to enter data in fields indicating that services were rendered although not actually performed or documented
9. Failure to maintain the confidentiality of information or records[34]
10. Knowing misuse of provider identification numbers, which results in improper billing[35]
11. Outpatient services rendered in connection with inpatient stays[36]
12. Duplicate billing in an attempt to gain duplicate payment[37]
13. Billing for discharge in lieu of transfer[38]
14. Failure to use modifiers properly[39]
15. Billing company incentives that violate the anti-kickback statute or other similar Federal or State statutes or regulations[40]
16. Joint ventures[41]
17. Routine waiver of co-payments and billing third-party insurance only[42]
18. Discounts and professional courtesy[43]
19. Internal coding practices[48]
20. "Assumption" coding[49]
21. Alteration of documentation
22. Coding without proper documentation of all physician and other professional services[50]
23. Billing for services provided by unqualified or unlicensed clinical personnel
24. Lack of availability of all necessary documentation at the time of coding
25. Employment of sanctioned individuals[51]

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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 provided[30]
2. Billing for services that the DMEPOS supplier believes may be denied[31]
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 rule[35]
7. Upcoding[36]
8. Unbundling items or supplies[37]
9. Billing for new equipment while providing used equipment[38]
10. Continuing to bill for rental items after they are no longer medically necessary[39]
11. Resubmission of denied claims with different information in an attempt to be improperly reimbursed[40]
12. Refusing to submit a claim to Medicare for which payment is made on a reasonable charge or fee schedule basis[41]
13. Inadequate management and oversight of contracted services, which results in improper billing[42]
14. Charge limitations[43]
15. Providing or billing for substantially excessive amounts of DMEPOS items or supplies[44]
16. Providing or billing for items or services that do not meet the quality standards of the DMEPOS items or services claimed[45]
17. Capped rentals[46]
18. Failure to monitor medical necessity on an ongoing basis[47]
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 documentation[49]
21. Completing portions of CMN reserved for completion only by treating physicians or other authorized persons.[50]
22. Altering medical records[51]
23. Manipulating patients' diagnoses in an attempt to receive improper payment[52]
24. Failure to maintain medical necessity documentation[53]
25. Inappropriate use of place of service codes[54]
26. Cover letters that encourage physicians to order medically unnecessary items or services[55]
27. Improper use of the ZX modifier[56]
28. Routine waiver of deductibles and coinsurance[57]
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 regulation[58]
30. Compensation programs that offer incentives for items or services ordered and revenue generated[59]
31. Joint ventures between parties, one of whom may refer Medicare or Medicaid business to the other[60]

32. Billing for items or services that are furnished pursuant to a prohibited referral under the Stark physician self-referral law[61]
33. Improper telemarketing practices[62]
34. Improper patient solicitation activities and high-pressure marketing of non-covered or unnecessary services[63]
35. Co-location of DMEPOS items and supplies with referral sources[64]
36. Non-compliance with the Federal, State and private payer supplier standards[65]
37. Providing false information on the Medicare DMEPOS supplier enrollment form[66]
38. Not notifying the National Supplier Clearinghouse in a timely manner of changes to information previously provided on the Medicare DMEPOS supplier enrollment form[67]
39. Misrepresenting a person's status as an agent or representative of Medicare[68]
40. Knowing misuse of a supplier number, which results in improper billing[69]
41. Failure to meet individual payer requirements[70]
42. Performing tests on beneficiaries to establish medical necessity[71]
43. Failing to refund overpayments to a health care program[72]
44. Failing to refund overpayments to patients[73]
45. Improper billing resulting from lack of communication between the DMEPOS supplier, physicians and patients[74]
46. Improper billing resulting from lack of communication between different departments within the DMEPOS supplier[75]
47. Employing persons excluded from participation in Federal health care programs[76]

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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)

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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.

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).

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.

CMS has issued a Final Rule implementing the provisions of the Patient Protection and Affordable Care Act (PPACA) that relate to Medicare payments to providers of services and suppliers participating in ACOs under the Medicare Shared Savings Program. The Agreement incorporates various provisions of this Final Rule, which is available at http://ecfr.gpoaccess.gov/cgi/t/text/textidx?c=ecfr&sid=da9451e0726c3f2a5c347b1a2ba9f5bb&rgn=div5&view=text&node=42:3.0.1.1.12&idno=42

Familiarity with these materials and the means of accessing these items is critical for all OSF Healthcare System employees and all OSF Pioneer ACO Participants and Pioneer Providers/ Suppliers and other individuals and entities performing functions or services related to Pioneer ACO Activities who participate in or contribute to producing or processing claims for Medicare. This information must be provided to all individuals, including individuals 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.

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CONCLUSION

The OSF Pioneer ACO is guided in day-to-day clinical and business operations by an awareness of the need to comply with the Agreement and with applicable laws and regulations. The ACO is committed to abiding by the Compliance Plan and 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.

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GOVERNING COMMITTEE APPROVAL

_____ _____
Robert C. Sehring, Chairperson Date

Note: Original signature appears in the original document filed at the Corporate Office.

Approved:

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