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Applicable To:			
SVHC & Affiliated Companies <input checked="" type="checkbox"/> SVMC <input checked="" type="checkbox"/> SCLM <input checked="" type="checkbox"/> SLH <input checked="" type="checkbox"/> FCPC <input checked="" type="checkbox"/>			

POLICY

In furtherance of the Core Values and Mission of SVHC HealthCare (SVHC), SVHC is committed to carrying out its health ministry in a manner consistent with Ascension Health's (AH) Mission, Vision and Values. We are dedicated to following a high ethical standard of individual conduct as well as acting responsibly as corporate citizens.

PURPOSE

In order to ensure that appropriate ethical and legal business standards and practices are maintained and enforced throughout the local health ministry, it is the policy of SVHC to establish an effective Corporate Responsibility Plan (Plan). The Plan shall be applicable to the local health ministry and will focus on business and professional standards of conduct, compliance with federal, state and local laws, promotion of good corporate citizenship, prevention and early detection of misconduct, identification and prioritization of high risk areas and associate education and communication regarding corporate responsibility.

PROCEDURE

Definitions

As used in the CRP, the following terms have the following meanings:

- A. “Ascension Health” (“AH”) means Ascension Health, a Missouri nonprofit corporation.
- B. “Ascension Health CRO” means the Ascension Health Associate who has been designated as Ascension Health’s Corporate Responsibility Officer by the Ascension Health Chief Executive Officer.
- C. “Ascension Health Corporate Responsibility Program” means the program developed and implemented by Ascension Health to ensure corporate responsibility and legal compliance at Ascension Health and, through general guidance and oversight, the System.

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- D. “Associate” means all employees, members of the Medical Staff, leased employees, and volunteers of SVHC HealthCare ("SVHC").
- E. “Audit Committee” means the Audit Committee of the SVHC Board.
- F. “CHAN” means the Catholic Healthcare Audit Network, LLC, the organization that provides internal audit services at Ascension Health and its Health Ministries, including SVHC HealthCare.
- G. “Contractor” means an individual (i) who has an independent contractor agreement with SVHC to provide goods or services to SVHC or its patients, or (ii) who owns, is employed by, or otherwise works for an organization with such a contract, and who has direct contact with any Associate in the performance of the contract.
- H. “Corporate Responsibility Committee” means the committee appointed by the CRO to assist the CRO in the development, implementation, and ongoing operation of the CRP.
- I. “Corporate Responsibility Officer” or “CRO” means that individual assigned responsibility for overseeing the development, implementation and operation of the SVHC CRP.
- J. “Corporate Responsibility Program” or “CRP” means the overall program developed and implemented by SVHC to ensure corporate compliance throughout SVHC.
- K. “Internal Auditor” means the individual appointed by Audit Services to function as an on-site independent auditor at SVHC.
- L. “Legal Counsel” means the attorneys or law firm designated by the CRO to provide legal advice and assistance in the development, implementation, and maintenance of the CRP.
- M. “Participant” means an individual subject to the CRP. Participants shall include all Associates; all directors and officers of SVHC; and all Contractors and Professional Staff Members whom the SVHC Board determines should be subject to the CRP.
- N. “Professional Staff Member” means a physician who is a member of the Medical Staff or an allied health practitioner but who is not an Associate or Contractor.

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- O. “Standards of Conduct” means the principles of associate behavior that promote corporate responsibility. They are described in Ascension Health Policy 14, Corporate Responsibility and Conflicts of Interest.
- P. “SVHC” means SVHC HealthCare of Jacksonville, Florida and all of its divisions and subsidiaries, including but not limited to St. Vincent’s Medical Center, St. Luke’s Hospital, St. Catherine Laboure Manor, SVHC Foundation, and Consolidated Pharmacy Services.
- Q. “SVHC Board” means the Board of Directors of SVHC.
- R. “System” means, collectively, Ascension Health, Health Ministries, and other controlled organizations.

I. Key Characteristics of the Corporate Responsibility Program

- A. Require proactive guidance, self-review, monitoring, auditing, and reporting;
- B. Require good faith effort to comply with laws and regulations;
- C. Require commitment by leadership and senior management;
- D. Heighten awareness and sensitivity to high risk areas through education and communication;
- E. Ensure commitment to implement appropriate corrective action in response to identified compliance issues on a timely basis; and
- F. Be complementary, not duplicative, of existing policies, standards and guidelines.
- G. Comply with the Ascension Health Corporate Responsibility Program (Attachment A).

II. Role of Federal and State Laws in Preventing and Detecting Fraud, Waste and Abuse in Federal Healthcare Programs

A. Federal and Florida False Claims Acts

The objectives of the Federal False Claims Acts (“FCA”) and the Florida False Claims Act (“FFCA”) are to protect the funds and property of the federal and state governments from fraudulent claims. A violation of the FCA or FFCA occurs, when an individual or organization knowingly submits a false claim for payment

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or knowingly makes or uses a false record or statement to get a false claim paid. “Knowingly” includes having actual knowledge that a claim is false, or acting in “deliberate ignorance” or “reckless disregard” as to whether a claim is false.

Financial penalties to the organization for submitting a false claim under the FCA or FFCA can total as much as three times the amount of the claim plus fines ranging from \$5,000 to \$11,000 per claim. These penalties and fines are paid to the government. In addition to penalties and fines, an individual or organization that violates the FCA or FFCA is subject to exclusion from participation in federally funded healthcare programs.

The FCA and FFCA contain provisions that allow individuals with original information (i.e., information not already the subject of legal proceedings or activities that have already been publicly disclosed) concerning fraud involving government programs to file a lawsuit on behalf of the government and, if the lawsuit is successful, to receive a portion of recoveries received by the government.

B. Program Fraud Civil Remedies Act

The Program Fraud Civil Remedies Act (“PFCRA”) provides federal agencies, including the agencies responsible for federally funded healthcare programs, with administrative remedies against individuals and organizations that knowingly submit a false claim for payment, or knowingly make or use a false record or statement to get a false claim paid. The PFCRA is limited to situations where a false claim, or a group of related false claims, does not exceed \$150,000. The PFCRA provides civil penalties up to \$6,000 per false claim, plus an assessment equal to twice the amount of the false claim.

C. State Laws

In addition to the above Federal Laws, the Florida Medicaid Provider Fraud Law makes it a third degree felony for anyone to knowingly and willfully cause to be made, or aid and abet in the making of, any false statement or false representation of a material fact, by commission or omission, in any claim submitted to the Agency for Health Care Administration or its fiscal agent for payment.

Various laws, including the FCA and FFCA, protect associates from being fired, demoted, threatened or harassed by their employer for providing information in good faith relative to a false claims investigation or lawsuit.

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III. Elements of the Corporate Responsibility Plan

3.1 Oversight of Governance and Management

3.1-1 The Board of Trustees and/or its Audit Committee will:

- Approve the Corporate Responsibility Program.
- Review periodic reports regarding the status of the CRP.

3.1-2 The SVHC CEO will assign the responsibility of overseeing the implementation and operation of the CRP to an associate who will be designated as the Corporate Responsibility Officer (CRO).

3.1-3 The CRO will have direct access to the CEO, Board of Trustees, Audit Committee, senior management and Legal Counsel. The CRO will report directly to the SVHC Chief Executive Officer in this role.

3.1-4 The CRO will:

- Implement and manage the CRP.
- Make regular reports to the Board of Trustees, Audit Committee and other management concerning the status of the CRP and any significant compliance issues affecting the SVHC.
- Maintain appropriate documentation related to the CRP.
- Participate in System-wide activities and programs as requested by the Ascension Health CRO.

3.1-5 The CRO will establish a CRP Committee to assist with the maintenance of the CRP. The CRP Committee will be responsible for advising the CRO with respect to the following:

- Ongoing operation of the CRP
- Policies and procedures
- Training and education
- The annual CRP risk assessment
- CRP investigations and corrective actions
- Compliance with new laws and regulations
- Auditing and monitoring systems and procedures

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- 3.1-6 The CRO will have certain reporting requirements to the Ascension Health CRO which include:
- Annual report on the achievement of requirements in the CRP effectiveness assessment
 - Periodic reports on the status of significant compliance issues

3.2 Policies and Procedures

- 3.2-1 The CRP will incorporate the Ascension Health CRP Standards of Conduct for associates and other Participants.
- 3.2-2 The CRO will establish written policies and procedures to address the elements of the CRP and other general compliance issues. Policies and procedures that pertain to general compliance issues will be made available to associates.

3.3 Training and Education Program

- 3.3-1 The CRP will include training and education programs for Participants. Such education and training will be part of initial orientation programs and occur annually for each Participant. Certain Participants may have additional education and training requirements depending on their title, position, or responsibilities. A mechanism for tracking the completion of required training will be maintained.
- 3.3-2 Training and education programs will include:
- Purpose and operation of the CRP
 - Identity and role of the CRO
 - Identity and role of the Privacy Officer
 - Standards of Conduct
 - Reporting practices and systems and non-retaliation approach
 - Consequences of failure to comply with rules and regulations
 - Administrative policies and procedures related to the CRP
 - Role of Associates in corporate responsibility
 - Other subjects determined by the CRO
- 3.3-3 SVHC will offer corporate responsibility training and education programs to Professional Staff Members.
- 3.3-4 All Associates will sign a statement acknowledging their awareness of the CRP, their responsibility to report illegal or questionable activity, and their agreement to abide by the Standards of Conduct.

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3.4 Risk Assessment

- 3.4-1 The CRO will perform a SVHC risk assessment based on the current healthcare business and regulatory environment. This assessment will be prepared at least annually. Generally, all issues identified for inclusion in the Ascension Health CRP risk assessment (i.e., CRP focus areas) must be addressed in the SVHC risk assessment, unless it can be demonstrated that the issue is not applicable or significant. Each SVHC will also consider in its risk assessment any other compliance issues that may uniquely apply to that SVHC.
- 3.4-2 The CRO will review the operations of SVHC in these risk areas to determine where exposure may exist and how each risk area will be addressed (e.g., policies and procedures; training and education; and auditing).

3.5 Reporting

- 3.5-1 CRP issues can be identified by various reporting sources including direct reporting by Associates; auditing and monitoring activities; and external governmental agency inquiries and investigations.
- 3.5-2 The SVHC reporting system includes a confidential process by which any Associate should feel comfortable in seeking guidance and disclosing information about potential violations without feeling any threat of retribution.
- 3.5-3 The Associate CRP reporting system will include the following:
- Direct access to the associate's supervisor, management staff and Human Resource staff
 - Direct access to the CRO
 - An anonymous reporting system
- 3.5-4 SVHC will make available to its associates the Ascension Health CRP Values Line. The Ascension Health CRP Values Line provides a means by which any Associate can report a potential corporate responsibility issue in an anonymous and confidential manner. The Values Line is provided by an outside vendor and has confidential phone and email reporting available 24 hours a day and 7 days a week.

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3.6 CRP Investigations

3.6-1 The CRO or his/her designee will thoroughly investigate (or coordinate/supervise the investigation of) each report on a timely basis.

- A thorough investigation includes, but is not limited to, gathering and reviewing relevant documents and identifying and interviewing those associates, former associates and others who may be able to provide pertinent information.
- Each investigation will be carefully documented in a systematic manner.
- The CRO or his/her designee will respond to the reporting party, as appropriate, regarding the status of the investigation and any corrective action taken.
- It may be necessary for individuals other than the CRO to become involved. This determination will be made on a case-by-case basis. The CRO may choose to involve other individuals or committees as necessary.
- When a potential violation is identified, the CRO and Legal Counsel, as necessary will attempt to determine whether a violation has occurred and will assist in determining the need for and the terms of any repayment or voluntary disclosure.
- Depending on the nature of the potential violation, SVHC may seek legal guidance regarding the steps necessary to investigate and remedy, if necessary, the potential violation. In such cases, the CRO will coordinate with Legal Counsel regarding the appropriate approach and steps to take in conducting the investigation. The attorney-client privilege is used when Legal Counsel is conducting an investigation for the purpose of providing legal advice regarding the subject matter of the investigation. It may be appropriate to have Legal Counsel engage any outside experts involved in the investigation so that reports issued to Legal Counsel can be protected by the attorney-client privilege. Refer to Ascension Health System Procedure OL-8 *Attorney-Client Privilege/Work Product Doctrine* for additional information.

3.6-2 The CRO or his/her designee is responsible for ensuring that Values Line calls are appropriately investigated and that a response is provided to the caller on a timely basis.

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3.6-3 The CRO will provide periodic reports to the Ascension Health CRO on significant compliance issues as defined by the Ascension Health CRO.

3.7 Response and Corrective Action

3.7-1 Reasonable steps will be taken to appropriately respond to any CRP issue detected or reported.

3.7-2 Appropriate corrective actions will be taken that address the specific CRP issue and that helps similar issues from occurring in the future. Corrective actions include:

- Taking reasonable steps to modify practices and procedures
- Refunding inappropriately paid claims and reporting corrective actions to the government contractor, on a voluntary disclosure basis, when appropriate
- Developing and/or amending existing policies and educating and training associates, as applicable
- Providing feedback to any party reporting violations, in good faith, whenever possible
- Thoroughly documenting the corrective actions taken for each issue
- Following up on corrective actions, and re-auditing if applicable, in a timely fashion to ensure they have been implemented

3.8 Auditing and Monitoring System

3.8-1 The CRO will ensure that periodic audits are conducted for those CRP risk areas determined by the Ascension Health CRO.

3.8-2 The CRO may conduct periodic audits for SVHC specific CRP areas identified in the SVHC risk assessment.

3.8-3 The CRO will ensure that audits are conducted in conjunction with internal or external investigations of specific CRP issues.

3.8-4 Depending on the nature of the audits, it may be appropriate to engage CHAN, outside consultants and/or perform self-audits of high-risk

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compliance areas. In some cases, Legal Counsel may engage CHAN or outside consultants under the attorney-client privilege to conduct audits of high-risk compliance areas to assist Legal Counsel in providing legal advice related to the subject matter of the audit.

3.8-5 The CRO will ensure that monitoring systems are implemented to address high-risk CRP issues. Monitoring systems may include the automated review and analysis of data for potential errors or anomalies; observation of systems and processes; and reviews of small samples of claims.

3.8-6 The CRO will ensure that issues identified through the auditing and monitoring process are followed up on a timely basis and that corrective actions are properly implemented.

3.9 Review of Corporate Responsibility Program

3.9-1 On a periodic basis, the CRO and CRP Committee will review the CRP Program to ensure that it is updated to address organizational changes and other changing requirements of the SVHC.

The CRO will ensure that the CRP Program incorporates any revisions from the Ascension Health CRO that may be based on changes in the business and regulatory environment.

ASCENSION HEALTH CORPORATE RESPONSIBILITY PROGRAM ATTACHMENT A

Ascension Health, its Health Ministries, associates, and contractors are committed to carrying out their healthcare ministry in a manner consistent with the Ascension Health Mission, Vision, and Values. We are dedicated to following a high ethical standard of individual conduct as well as acting responsibly as corporate citizens. In support of these commitments, the Board of Trustees of Ascension Health has formally established a System Policy on the Corporate Responsibility Program. The Corporate Responsibility Program will focus on business and professional standards of conduct, compliance with federal, state and local laws, promotion of good corporate citizenship, prevention and early detection of misconduct, identification/prioritization of high risk areas and communication/education regarding corporate responsibility.

I. Definitions:

As used in this document, the following terms are defined below:

- A. “Affiliate Organization” shall mean any legal entity that is part of the System but is not controlled by Ascension Health, a Health Ministry, a Subsidiary Organization or by a National Subsidiary.
- B. “Ascension Health” shall mean Ascension Health, a Missouri nonprofit corporation.
- C. “Ascension Health Corporate Responsibility Program” (“Ascension Health CRP”) means the program developed and implemented by Ascension Health to ensure corporate responsibility and legal compliance at Ascension Health and, through general guidance and oversight, the System.
- D. “Associate” means an employee of Ascension Health, its Health Ministries, Subsidiary Organizations, National Subsidiaries and Affiliate Organizations.
- E. “Audit Committee” means the Audit Committee of Ascension Health.

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- F. “Board of Trustees” means the Board of Trustees of Ascension Health.
- G. “Contractor” means an individual (i) who has an independent contractor agreement with a System entity to provide goods or services to the System entity, or (ii) who owns, is employed by, or otherwise works for an organization with such a contract, and who has direct contract with any System entity Associate in the performance of the contract, and in both cases are determined by Ascension Health management to be subject to the CRP.
- H. “Corporate Responsibility Officer” (“CRO”) means that individual assigned responsibility for the System Corporate Responsibility Program.
- I. “Health Ministry” shall mean the organization in a regional or local area through which Ascension Health carries out its mission and in which Ascension Health serves as the sole or controlling member.
- J. “Legal Counsel” means the attorney or law firm designated by the CRO to provide legal advice and assistance in the development, implementation and maintenance of the CRP.
- K. “National Subsidiary” shall mean an organization, other than a Health Ministry or a Subsidiary Organization, which is controlled by Ascension Health.
- L. “Participant” means an individual subject to the CRP. Participants will include all Associates; all directors and officers of Ascension Health; and all Contractors.
- M. “Professional Staff Member” shall mean a physician who is a member of a Health Ministry medical staff or an allied practitioner, but who is not an Associate or Contractor.
- N. “Standards of Conduct” shall mean the principles of Associate behavior that promote corporate responsibility. They are described in Ascension Health Policy 14, *Corporate Responsibility and Conflicts of Interest*.
- O. “Subsidiary Organization” shall mean any legal entity directly or indirectly controlled by a Health Ministry or National Subsidiary.
- P. “System” shall mean, collectively, Ascension Health, Health Ministries, Subsidiary Organizations, National Subsidiaries, and Affiliate Organizations.

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- Q. “System Office” shall mean the Missouri nonprofit corporation known as Ascension Health that provides corporate services, shared services and other services to the Health Ministries.

II. Key Characteristics of the Corporate Responsibility Program

The Corporate Responsibility Program will:

- A. Require proactive guidance, self-review, monitoring, auditing, and reporting;
- B. Require good faith effort to comply with law and regulations;
- C. Require commitment of high level personnel;
- D. Heighten awareness and sensitivity to high risk areas through education and communication;
- E. Ensure commitment to timely implement appropriate corrective action in response to identified compliance issues;
- F. Be complementary, not duplicative, of existing policies, standards, and guidelines; and
- G. Provide Health Ministries with implementation guidance while allowing flexibility to meet local needs.

III. Elements of the Corporate Responsibility Program

A. Oversight by Governance and Management

- A.1** The Ascension Health Board of Trustees and/or its Audit Committee will:
- Approve the System Policy on Corporate Responsibility;
 - Provide general oversight of the Ascension Health CRP; and
 - Review periodic reports, at least annually, regarding the status of the Ascension Health CRP and more frequently as necessary regarding the status of any significant compliance issues.

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- A.2** The Ascension Health Chief Executive Officer (“CEO”) will approve System Procedures on Corporate Responsibility and will assign management responsibility for the implementation and operation of the CRP to a high-level Ascension Health Associate, who will be designated as Ascension Health’s Corporate Responsibility Officer (“Ascension Health CRO”).
- A.3** The Ascension Health CRO will have direct access to the Ascension Health CEO, Board of Trustees, Audit Committee, senior management and Legal Counsel. The Ascension Health CRO will report directly to the Ascension Health CEO in this role.
- A.4** The Ascension Health CRO will:
- Establish and maintain the Ascension Health CRP;
 - Manage the CRP for the Ascension Health System Office and its National Subsidiaries and establish the administrative policies and procedures for the Ascension Health System Office CRP;
 - Establish certain standards, elements and focus areas to be made part of all Health Ministries’ corporate responsibility programs and provided as part of the Ascension Health CRP Manual;
 - Monitor the effectiveness of the corporate responsibility programs of all Health Ministries;
 - Meet with Health Ministry governance and management periodically to assess the Health Ministry CRP;
 - Provide guidance and support to the System on corporate responsibility matters;
 - Receive reports from the Health Ministries regarding the status of any identified significant compliance issues; and
 - Make regular reports to the Ascension Health Board of Trustees, Audit Committee and other members of Ascension Health management concerning the status of the CRP and any significant compliance issues.

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- A.5** The Ascension Health CRO will establish an Advisory Council comprised of certain Health Ministry CROs, members of the Ascension Health System Office leadership team and others as appropriate. The Ascension Health CRO will serve as the Chair of this Council.
- A.6** Each Health Ministry Board will provide general oversight of the CRP for its respective Health Ministry.
- A.7** Each Health Ministry will adopt a CRP that is consistent with corporate compliance guidance issued by the Office of Inspector General of the Department of Health and Human Services (OIG). The Health Ministry CRP will be consistent with the Ascension Health CRP and includes policies, procedures, protocols, and other guidance as issued by the Ascension Health CRO.
- A.8** Each Health Ministry will appoint a Health Ministry Corporate Responsibility Officer who is responsible for the implementation and management of the CRP. The Health Ministry CRO will report directly to the Health Ministry Chief Executive Officer in this role.
- A.9** The Health Ministry CRO will periodically report to the governing board of the Health Ministry or its committees on matters of corporate responsibility and regulatory compliance and will provide a written report at least annually.

B. Corporate Responsibility Program Measures and Assessment

- B.1** The Ascension Health CRO will monitor the effectiveness of CRPs for Health Ministries through the establishment of appropriate measures and/or standards that are to be included as part of all Health Ministries' CRPs.
- B.2** All Health Ministries will participate in an annual effectiveness assessment and provide an annual report to the Ascension Health CRO that demonstrates performance with respect to the CRP measures and standards.

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C.1 All Health Ministries' CRPs will include training and education programs for Participants. Such education and training should be part of initial orientation programs and should occur annually for each Participant. Certain Participants may have additional education and training requirements depending on their title, position, or responsibilities.

C.2 Training and education programs should include:

- Purpose and operation of the corporate responsibility program
- Standards of Conduct
- Reporting practices and systems and our non-retaliation approach to the same
- Administrative policies and procedures related to corporate responsibility
- Role of Associates in corporate responsibility
- Other subjects determined by the CRO

C.3 All Health Ministries will offer CRP training and education programs to Professional Staff Members.

C.4 All Associates will sign a statement acknowledging their awareness of the CRP, their responsibility to report illegal or questionable activity, and their agreement to abide by the Standards of Conduct.

D. Risk Assessment

D.1 The Ascension Health CRO will review the current healthcare business and regulatory environment and determine the CRP risk areas that are to be assessed.

D.2 The Ascension Health CRO will conduct an annual CRP risk assessment on the Ascension Health System Office and its National Subsidiaries as appropriate.

D.3 The Health Ministry CRO will conduct an annual CRP risk assessment in accordance with direction from the Ascension Health CRO and that addresses any other compliance issues that may apply to the Health Ministry.

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E. Corporate Responsibility Reporting

E.1 The Ascension Health CRO will establish and maintain a confidential hotline (“Hotline”) for the System. The Hotline will provide a means by which any Associate can report a potential corporate responsibility or compliance issue in an anonymous and confidential manner. The Hotline will have confidential phone and email reporting available 24 hours a day and 7 days a week.

E.2 Health Ministry CROs will be accessible in person, by phone, or by electronic communication to Associates for all corporate responsibility matters. Associates should feel comfortable in seeking guidance and disclosing information about potential violations without feeling any threat of retribution.

E.3 Health Ministry CROs will report significant or potentially significant CRP issues to the Ascension Health CRO on a timely basis and provide updates regarding the same on a quarterly basis and in accordance with guidance provided by the Ascension Health CRO.

F. Investigation

F.1 The Health Ministry CROs will conduct a prompt investigation of potential CRP issues in accordance with requirements of the Ascension CRO.

F.2 Health Ministry CROs will provide to the Ascension Health CRO a report on the investigation of significant CRP matters through the reporting system or otherwise at the request of the Ascension Health CRO.

F.3 The Ascension Health CRO may initiate an investigation or engage System Counsel on significant CRP matters as determined by the Ascension Health CRO and Ascension Health General Counsel.

G. Response and Corrective Action

G.1 All Health Ministries will take reasonable steps to appropriately respond to any CRP issue detected or reported.

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G.2 All Health Ministries will take the appropriate corrective action that addresses the specific CRP issue and that helps prevent similar issues from occurring in the future. Corrective actions include:

- Refunding inappropriately paid claims and reporting corrective actions to the government contractor, on a voluntary disclosure basis, when appropriate.
- Taking reasonable steps to modify practices and procedures
- Developing and/or amending existing policies and educating and training associates, as applicable
- Providing feedback to any party reporting violations, in good faith, whenever possible
- Thoroughly documenting the corrective actions taken for each issue
- Following up on corrective actions, and re-auditing if applicable, in a timely fashion to ensure they have been properly implemented.

H. Auditing and Monitoring System

H.1 All Health Ministries will conduct periodic audits for those risk areas determined by the Ascension Health CRO.

H.2 To strengthen their respective CRPs, Health Ministry CROs will initiate audits and implement monitoring systems for risk areas specific to the Health Ministry.

H.3 The Ascension Health CRO may initiate an audit for specific risk areas at certain Health Ministries when appropriate.

REFERENCES

45 CFR § 160 and 164
SVHC: 21.42; 21.43