Banner Health®

POLICY and PROCEDURE

TITLE: Compliance: Reporting and Investigating Potential Compliance Issues			
Number: 6013		**Version: 6013.10**	
Type: Administrative		**Author: Ethics & Compliance Department**	
Effective Date: 7/13/2017	**Original Date: 1/21/2007**	**Approval Date: 4/4/2017**	**Deactivation Date:**
Facility: System			
Population (Define): All Employees			
Replaces:			
Approved by: Administrative Policy Committee, System Operations Team			

TITLE: *Compliance: Reporting and Investigating Potential Compliance Issues*

I. Purpose/Expected Outcome:

A. To ensure that Banner Health (Banner) provides a process for Banner Staff to report Potential Compliance Issues (including, but not limited to, Fraud, Waste, and Abuse) without fear of retaliation.
B. To ensure that Potential Compliance Issues are promptly and thoroughly investigated and any appropriate corrective actions are implemented.

II. Definitions:

A. Abuse: Includes actions that may, directly or indirectly, result in unnecessary costs to Federal Health Care Programs, improper payment, payment for services that fail to meet professionally recognized standards of care, or services that are not medically necessary.
B. Banner Staff: Incudes:
   1. All full-time and part-time employees and volunteers of Banner and of any discrete operating unit owned, operated, or controlled by Banner (except Sonora Quest Laboratories and other entities approved by the Senior Vice President/General Counsel);
   2. All contractors, subcontractors, agents, and other persons/entities who provide patient care items or services or who perform billing or coding functions on behalf of Banner or of any discrete operating unit owned, operated, or controlled by Banner (except Sonora Quest Laboratories and other entities approved by the Senior Vice President/General Counsel); and
   3. All physicians and allied health professionals who are members of Banner's medical staff or allied health professional staff.
C. Compliance Reportable Event: Any event or series of events that involves:
   1. A Substantial Overpayment;
   2. A matter that a reasonable person would consider a probable violation of any criminal, civil, or administrative statute or regulation applicable to any Federal Health Care Program for which penalties or exclusion may be authorized, including, but not limited to, the Stark law, Anti-Kickback Statute, False Claims Act, Emergency Medical Treatment and Labor Act ("EMTALA"), and Health Insurance Portability and Accountability Act ("HIPAA");
   3. The employment of contracting with, or granting privileges to an Ineligible Person or Entity;
   4. A violation of the obligation to provide items or serves of a quality that meets professionally recognized standards of health care where such violation has occurred in one or more instances and presents an imminent danger to the health, safety, or well-being of a Federal Health Care Program beneficiary or unnecessarily places the beneficiary in a high-risk situation.
D. ComplyLine: Banner's confidential compliance hotline available 24 hours a day, 7 days a week that can be accessed by calling 888-747-7989 or online at https://bannerhealthcomplyline.alertline.com.

E. Federal Health Care Program: Any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded in whole or in part by the United States Government, including, but not limited to, Medicare, Medicaid (AHCCCS), managed Medicare/Medicaid, and TRICARE/VA/CHAMPUS.

F. Fraud: An intentional deception or misrepresentation made by a person with the knowledge that the deception or misrepresentation could result in some unauthorized benefit to himself or some other person, such as submitting an erroneous claim with actual knowledge, reckless disregard, or deliberate ignorance of the falsity of the claim.

G. Ineligible Person or Entity: An individual or entity who:
   1. Is currently excluded, debarred, suspended, or otherwise ineligible to participate in Federal Health Care Programs or in federal procurement or non-procurement programs, as evidenced by the individual's or entity's inclusion on the Department of Health and Human Services Office of Inspector General's (OIG) List of Excluded Individuals/Entities (LEIE), the System for Award Management's Excluded Parties List System (EPLS), State Medicaid Exclusion Lists, and any other lists required by the OIG or Centers for Medicare and Medicaid Services; or
   2. Has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a- 7(a)[11] but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

H. Overpayment: Any funds received in excess of the amount due and payable under Federal Health Care Program requirements.

I. Potential Compliance Issue: Any suspected violation of Banner's Code of Conduct or policies and procedures and/or any suspected violation of any laws or regulations relating to a Federal Health Care Program, including, but not limited to, the False Claims Act, the Physician Self-Referral (Stark) Law, and the Anti-Kickback Statute. Potential Compliance Issues include, but are not limited to, Fraud, Waste, and Abuse.

J. Substantial Overpayment: For purposes of this policy, Banner defines a "Substantial Overpayment" as an Overpayment of $100,000 or more on a single claim or on multiple claims of the same nature.

K. Waste: The overutilization of services or other practices that, directly or indirectly, result in unnecessary costs to Federal Health Care Programs. Waste is generally considered the misuse of resources.

III. Policy:

A. **Reporting Potential Compliance Issues**
   1. It is the responsibility of Banner Staff to immediately report Potential Compliance issues upon discovery.
      a. Banner Staff should contact their compliance officer or the Ethics & Compliance Department if they have any questions whether an issue is a Potential Compliance Issue.
      b. Banner Staff should also report violations of the Health Insurance Portability and Accountability Act (HIPAA) by complying with the respective HIPAA policies.
   2. Banner has implemented several avenues for reporting Potential Compliance Issues:
      a. Banner Staff may report Potential Compliance Issues directly to their supervisor, department manager or director, compliance officer, or the Ethics & Compliance Department. If a report is made to a supervisor or a department manager or director, that individual will immediately forward the report to the compliance officer or the Ethics & Compliance Department.
      b. Banner Staff may also report Potential Compliance Issues through the ComplyLine. Although following the chain of command is encouraged, Banner Staff may use the ComplyLine whenever they have exhausted normal channels, want to report anonymously, or are

[1] The statute provides for mandatory exclusion from participation in any Federal Health Care Program for individuals and entities convicted of (1) program-related crimes, (2) patient abuse, (3) felonies relating to health care fraud, and (4) felonies relating to controlled substances.

uncomfortable for any reason reporting directly to their supervisor, department manager or director, compliance officer, or the Ethics & Compliance Department. If a Potential Compliance Issue is reported through the ComplyLine, the Compliance: ComplyLine policy (#12648) will be followed.

3. Banner Staff are free to report Potential Compliance Issues in good faith without fear of retribution or retaliation. *See* Compliance: Prohibition Against Retaliation for Reporting Suspected Non-Compliance (#2749).

B. **Assigning Issues to Investigator(s)**

1. The compliance officer or the Ethics & Compliance Department will determine if the matter is a Potential Compliance Issue and, if so, will assign investigative responsibility to the applicable department or individual.
   a. If the matter is not a Potential Compliance Issue, the compliance officer or the Ethics & Compliance Department will refer the matter to the appropriate department for handling, including, but not limited to the following:
      i. **HIPAA**: Patient privacy issues will be referred to the HIPAA Privacy Office.
      ii. **Human Resources**: Human resources issues (such as hostile work environment, employee relations, and staffing/scheduling issues) will be referred to the Human Resources Department.
      iii. **Risk Management**: Risk management issues (such as certain patient safety issues and issues that may result in litigation) will be referred to the Business Health Department (risk management/loss control).
   b. If the Potential Compliance Issue involves more than one business area, clinic, or facility, the investigative responsibility may be assigned to more than one department or individual. If this occurs, the departments or individuals will coordinate their investigations to minimize redundancies in interviews and document requests to the extent possible.

C. **Investigating Potential Compliance Issues**

1. The assigned investigator(s) will investigate the Potential Compliance Issue and will involve other individuals or departments as needed.
   a. The investigation may include obtaining documents, conducting interviews, and/or performing other activities as appropriate.
   b. If appropriate, the investigator(s) will involve the Legal Department and/or outside legal counsel.
   c. If an investigation reveals that the Potential Compliance Issue may be a potential Compliance Reportable Event, the investigator(s) will immediately contact the Ethics & Compliance Department.
      i. Potential Compliance Reportable Events include, but are not limited to, the issues identified by way of example in Appendix A.
      ii. HIPAA, EMTALA, and quality of care violations will be addressed in accordance with applicable policies. These violations may also constitute potential Compliance Reportable Events if they involve an intentional and/or reckless act, a pattern or practice of behavior, and/or a financial benefit incurred by the wrongdoer(s).
   d. Investigations will be completed as soon as reasonably possible, but the amount of time spent on each investigation may vary depending on the nature and complexity of the issue(s). However, investigations will generally be completed within six (6) months or receipt of credible information of a potential Overpayment, except in extraordinary circumstances.
2. Once an investigation is completed, the investigator(s) will implement any necessary corrective action and will, if appropriate, provide a response to the Banner Staff who initially reported the Potential Compliance Issue.

3. The investigator(s) will document and maintain an electronic or paper investigative file, which includes, at a minimum, a description of the Potential Compliance Issue, the investigation, and any actions taken as a result of the findings (such as corrective action). As a general rule, these investigative files are confidential and will not be shared with third parties or other departments absent approval from the Ethics & Compliance Department or the Legal Department. These files will be provided to the Ethics & Compliance Department upon request.

D. **Investigating Compliance Reportable Events**
1. The Ethics & Compliance Department will lead or coordinate the investigation of any potential Compliance Reportable Events.
2. A potential Compliance Reportable Event will be investigated in a similar manner as a Potential Compliance Issue.
3. If an investigation reveals that a Compliance Reportable Event has occurred, the Ethics & Compliance Department, in consultation with the Legal Department, will be responsible for any notification provided to the appropriate government authority.
4. The investigative file will include copies of any documentation provided to or received from the government authority.

IV. Procedure/Interventions:

A. **Reporting Potential Compliance Issues** (**BANNER STAFF**)
1. Immediately report a Potential Compliance Issue to a supervisor, department manager, department director, compliance officer, or the Ethics & Compliance Department or by contacting the ComplyLine at 888-747-7989 or https://bannerhealthcomplyline.alertline.com.
2. Provide as much information as possible about the Potential Compliance Issue.

B. **Forwarding Potential Compliance Issues** (**SUPERVISOR OR DEPARTMENT MANAGER OR DIRECTOR**)
1. Forward the Potential Compliance Issue reported by Banner Staff to the compliance officer or the Ethics & Compliance Department.

C. **Assigning Issues to an Investigator** (**COMPLIANCE OFFICER OR ETHICS & COMPLIANCE DEPARTMENT**)
1. Follow the Compliance: ComplyLine policy (#12648) if the Potential Compliance Issue is reported using the ComplyLine.
2. If reported directly to a supervisor, department manager or director, compliance officer, or the Ethics & Compliance Department, determine if the matter reported is a Potential Compliance Issue:
   a. If a Potential Compliance Issue, assign investigative responsibility of the Potential Compliance Issue. A Potential Compliance Issue that appears to be a Compliance Reportable Event will be assigned to the Ethics & Compliance Department.
   b. If not a Potential Compliance Issue, assign to the appropriate individual or department based on the type of issue.
3. Note: A Potential Compliance Issue involving or relating to a Banner Board Member or the Banner President, regardless of how the matter is brought forth, will be handled as follows:
   a. The Chair of the Audit Committee of the Banner Board will be notified immediately by the Vice President of Ethics & Compliance of any allegations concerning a Banner Board Member or the Banner President. The Audit Committee may oversee the investigation into the allegations, using any internal and/or external resources deemed appropriate.

D. **Investigating Potential Compliance Issues** (**INVESTIGATOR(S)**)

1. Make a preliminary, good faith inquiry into the allegations of a Potential Compliance Issue to determine whether further investigation is warranted.
2. Investigate the Potential Compliance Issue, if one is deemed necessary, which may include:
   a. Obtaining relevant documents from the identified department, clinic, or business area;
   b. Interviewing individuals who may have relevant information; and/or
   c. Conducting other activities as appropriate (including, when appropriate, involving the Legal Department or outside legal counsel).
3. Contact the Ethics & Compliance Department immediately if the investigation reveals that the matter may be a potential Compliance Reportable Event. *See* Section E.
4. Determine whether any corrective actions need to be taken as a result of the investigation and, if so, ensure that the corrective action(s) are implemented.
5. Report and return any Overpayments to the applicable Federal Health Care Program no later than sixty (60) days after they are identified in accordance with the Compliance: 60-Day Report/Repay Overpayments policy (#15847).
6. Provide a response, if appropriate, to the Banner Staff who initially reported the Potential Compliance Issue.
7. Maintain an electronic or paper file that includes all documentation related to the Potential Compliance Issue, including, but not limited to, the case report, investigative notes, and any actions taken as a result of the investigation.
8. Retain investigative files in accordance with the Records Retention and Destruction Policy (#5767).
9. Provide the investigative file to the Ethics & Compliance Department upon request.

E. **Investigating Potential Compliance Reportable Events** (**ETHICS & COMPLIANCE DEPARTMENT**)

1. Make (or request a designee to make) a preliminary, good faith inquiry into the allegations of a potential Compliance Reportable Event to determine whether further investigation is indicated.
2. Lead or assist in the investigation, if one is deemed necessary, to determine whether an actual Compliance Reportable Event has occurred. The investigation may include:
   a. Obtaining relevant documents from the identified department, clinic, or business area;
   b. Interviewing individuals who may have relevant information; and/or
   c. Conducting other activities as appropriate (including, when appropriate, involving the Legal Department or outside legal counsel).
3. Determine whether any corrective action needs to be taken as a result of the investigation and, if so, ensure that it is implemented.
4. Provide a response, if appropriate, to the Banner Staff who initially reported the potential Compliance Reportable Event.
5. If it is determined an actual Compliance Reportable Event has occurred, assist the affected department(s) with gathering the following information (if applicable) as soon as reasonably possible:
   a. A complete description of the relevant facts, persons involved, third party sources of payment, and Federal Health Care Program(s) implicated;
   b. A complete description of actions taken to correct the Compliance Reportable Event;
   c. A complete description of any other actions planned to address the Compliance Reportable Event and the steps to prevent it from recurring;
   d. If applicable, the amount of any Overpayment and a description of the steps taken to identify and quantify the Overpayment; and
   e. For these Compliance Reportable Events:
      i. Violations of law: A statement of the criminal, civil, or administrative laws that were potentially violated by the Compliance Reportable Event.

ii. Ineligible Person: The dates of the Ineligible Person's employment or contractual relationship, and a description of how the Compliance Reportable Event was discovered.
iii. Quality violations: A summary of any related reports made to federal or state regulatory or enforcement agencies and professional licensing bodies.

6. Decide if, when, and how to notify the appropriate government authorities.
   a. If it has not done so already, decide whether to involve the Legal Department and/or outside legal counsel.
   b. Report and return any Overpayments to the applicable Federal Health Care Program no later than sixty (60) days after they are identified in accordance with the Compliance: 60-Day Report/Repay Overpayments policy (#15847).
   c. Decide, in consultation with the Legal Department, whether to use the OIG Self-Disclosure Protocol (SDP), the CMS Voluntary Self-Referral Disclosure Protocol (SRDP), or any other reporting method. When engaged in either the SDP or SRDP process, the Ethics & Compliance Department will use the reporting process described in the applicable protocol.
7. Decide if, when, and how to notify appropriate third party payers.
   a. If it has not done so already, decide whether to involve the Legal Department and/or outside legal counsel.
   b. Ensure that any notification is provided in accordance with contract requirements.
8. Maintain an electronic or paper file that includes all documentation related to the potential or actual Compliance Reportable Event, including, but not limited to, the case report, investigative notes, and any actions taken as a result of the investigation (including any documentation provided to or received from a government authority).
9. Retain investigative files in accordance with the Records Retention and Destruction Policy (#5767).

V. Procedural Documentation:

A. Any disciplinary action given under this Policy must be documented in accordance with Banner Corrective Action Policy (#7647).

VI. Additional Information:

A. N/A

VII. References:

A. N/A

VIII. Other Related Policies/Procedures:

A. Code of Conduct (Ethics and Compliance Website)
B. Compliance: Prohibition Against Retaliation for Reporting Suspected Non-Compliance (#2749)
C. Compliance: ComplyLine (#12648)
D. Compliance: 60-Day Report/Repay Overpayments (#15847)
E. Records Retention and Destruction Policy (#5767)
F. Corrective Action Policy (#7647)

IX. Keywords and Keyword Phrases:

A. Reporting
B. Investigating
C. Potential Compliance Issue
D. Retaliation
E. Fraud

F. Waste
G. Abuse
H. Compliance Reportable Events

X. Appendix:

A. Appendix A: Examples of Potential Reportable Events

APPENDIX A
Examples of Potential Compliance Reportable Events*

Billing and Coding
- Coding and/or billing error(s) resulting in a Substantial Overpayment (≥ $100,000)

Documentation
- False or fraudulent documentation

Cost Reporting
- Submission of false or fraudulent cost reports

HIPAA
- Security or privacy breach affecting 500 or more individuals

Quality
- Pattern or practice of providing medically unnecessary care or performing medically unnecessary procedures
- Pattern or practice of patient abuse, patient neglect, or unknown sources of injury
- Any legal or regulatory violations that may threaten the facility's certification, licensure, or accreditation

Excluded Individuals or Entities
- Services provided by employees or providers who are excluded from Federal Health Care Programs

Violations of Law
- Potential violations of the Stark law and/or anti-kickback statutes
- Potential violations of EMTALA that could result in civil monetary penalties

* This Appendix only provides a few examples of potential Compliance Reportable Events and does not represent a comprehensive list of all potential Compliance Reportable Events that could occur. If you have any questions regarding whether an issue is a potential Compliance Reportable Event, please contact your Compliance Officer or the Ethics & Compliance Department.