**DEPARTMENT:** Ethics & Compliance  
**POLICY DESCRIPTION:** Reporting Compliance Issues and Occurrences to the Corporate Office

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**REPLACES POLICY DATED:** 1/24/09, 9/23/09, 1/15/10, 5/15/10, 2/1/11, 5/1/11, 11/1/11, 9/1/12, 4/1/13, 9/1/13, 9/23/13, 5/1/14, 11/1/16

**EFFECTIVE DATE:** September 1, 2017  
**REFERENCE NUMBER:** EC.025

**APPROVED BY:** Ethics and Compliance Policy Committee

**SCOPE:** All Company-affiliated facilities worldwide, including, but not limited to, hospitals, ambulatory surgery centers, home health centers, home health agencies, physician practices, outpatient imaging centers, service centers, transfer centers, Parallon Workforce Management Solutions, joint ventures and all Corporate Departments, Groups, Divisions and Markets.

**PURPOSE:** To require that certain activities and events be reported to the appropriate Corporate department(s) as set forth in this policy.

**POLICY:** There are a number of events, occurrences or issues, which are described more fully below in the Procedure section that must be reported to the Corporate Office immediately (i.e., no longer than 3 business days after discovery).

**PROCEDURE:** The following events, occurrences or issues must be reported to the facility ECO. The facility ECO or designee should then report the event, occurrence or issue to the Corporate Office department identified at the links listed below:

**Internal Compliance Reporting**

1. Any ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that the **Company-affiliated facility** or **subsidiary** has **committed a crime** or has **engaged in fraudulent activity** – to **Internal Compliance Reporting**.

2. **Physician Relations Issues** – to **Internal Compliance Reporting**.
   a. The Stark law prohibits a physician from referring patients to an entity for certain designated health services if the physician or an immediate family member of the physician has a financial relationship with the entity, unless the financial relationship falls within certain exceptions. A financial relationship may consist of an ownership or investment interest or a compensation arrangement. A compensation arrangement involves, with certain exceptions, anything of value given to a physician, whether directly or indirectly, overtly or covertly, in cash or in kind.
   b. Limited Exceptions:
      i. Changes to the Stark rules, effective 10/01/08, provide for an exception for Temporary Non-Compliance applicable to agreements involving physicians and facilities (**Temporary Non-Compliance Signature Requirement or TNCSR exception** for purposes of this document). The TNCSR exception is applicable to the strict period of disallowance rules when the reason for non-compliance is due to a missing signature on an agreement.
ii. Changes to the Stark rules, effective 12/04/07, provide changes to the exception related to the non-monetary compensation exception (Temporary Non-Compliance Business Courtesies or TNCBC exception for the purposes of this document).

iii. Changes to the Stark rules, effective 07/26/04, provide for an exception for Temporary Non-Compliance applicable to financial arrangements involving physicians and facilities (Temporary Non-Compliance or TNC exception for the purposes of this document).

iv. A legal analysis, to determine whether use of any of these three exceptions is appropriate, must be conducted by Operations Counsel. An entity may use each of the TNCSR, TNCBC, and TNC exceptions only once every three years with respect to the same referring physician. The use of these exceptions must be approved by Operations Counsel and reported to Ethics and Compliance Internal Compliance Reporting for tracking purposes.

c. The Anti-kickback statute makes it unlawful to offer, pay, solicit or receive remuneration to induce or in return for 1) referring an individual for the furnishing or arranging for the furnishing of any item or service payable in whole or in part under a federal health care program, or 2) purchasing, leasing, or ordering (or arranging or recommending purchasing, leasing or ordering) any good, facility, service, or item payable in whole or in part under a federal health care program.

3. Potential violation of the patient inducement guidelines – to Internal Compliance Reporting. Providers are prohibited from offering patients any remuneration to order or receive items or services from a particular provider that are likely to influence the patient’s choice of provider that do not meet the exceptions of the OIG Special Advisory Bulletin dated August 2002, entitled, “Offering Gifts and Other Inducements to Beneficiaries”. Remuneration is defined as anything of value, including waivers of co-payments and deductible amounts, in full or in part, and transfers of items or services for free or for less than fair market value. See Compliance Alert #15 for details regarding patient inducement guidelines.

a. Exceptions (The facility’s Operations Counsel should be consulted prior to using any HIPAA patient inducement exception to the law to justify providing any free service(s), test(s), etc.)

i. **Inexpensive Gifts** – OIG Special Advisory Bulletin states that the law allows providers to offer beneficiaries inexpensive gifts, other than cash or cash equivalents. The OIG defines inexpensive gifts as those with “a retail value of no
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more than $10 individually, and no more than $50 in the aggregate annually per patient."

ii. **Other Statutory Exceptions** *(Please refer to the Special Advisory Bulletin for more detail on these exceptions.)*

(a) Non-routine, unadvertised waivers of co-payments or deductible amounts based on individualized determinations of financial need or exhaustion of reasonable collection efforts

(b) Properly disclosed differentials in a health insurance plan’s co-payments or deductibles

(c) Incentives to promote the delivery of certain preventive care services

(d) Any practice permitted under the federal anti-kickback statute

(e) Waivers of co-payment amounts in excess of the minimum co-payment amounts under the Medicare hospital outpatient fee schedule.

b. **Examples of Prohibited Activities** - Providing Free Sports Clinics under certain circumstances, Expensive Gifts, Free Tests or Services under certain circumstances, Waiving the difference between out-of-network charges and in-network charges for Medicare and Medicaid PPOs and HMOs, Providing Hotel Accommodations or Hospital Rooms, and/or Providing Complimentary Transportation Programs. See Compliance Alert #15 for details regarding patient inducement.

4. Potential violations of **federal or state regulations** related to the providing of medical care in the emergency department – to Internal Compliance Reporting.

5. **Federal or state surveys** related to the providing of medical care in the emergency department or surveys related to comparable state statutes regarding providing emergency care – to Internal Compliance Reporting. *(See number 16 below for separate reporting requirements to CSG.)*

6. **Potential Regulatory Issues** - Licensure, Registration, Certification or Privileges: Federal, State, Local or Payor mandated licensure, registration, certification, and privileging requirements of individuals or health care related equipment; or individuals providing services outside their scope of practice or without being appropriately licensed, registered, certified or privileged. *(Certification requirements that are required by the facility as part of the staff member’s job description and are not required by Federal, State, Local or Payor regulations are not Reportable Issues)* - to Internal Compliance Reporting.

7. **Potential Controlled Substance Incidents:** DEA or state controlled substance violations related to the theft or loss of controlled substances; unauthorized use of a facility's or practitioner's DEA number or state required controlled substance registration number; investigations and arrests conducted by the DEA, state agency or local law enforcement regarding theft or loss of controlled substances or unauthorized use of a facility's or practitioner's prescription pad - to Internal Compliance Reporting.
8. Potential Deliberately Incorrect Abstraction or Altering of Medical Records to Ensure High Core Measures Scores – to Internal Compliance Reporting.

9. Issues regarding Ineligible Persons (OIG/GSA/State exclusion lists) - any individual or entity that: (i) is currently excluded, suspended, debarred or is otherwise ineligible to participate in Federal health care programs; (ii) has been convicted of a criminal offense related to the provision of health care items or services but has not yet been excluded, debarred or otherwise declared ineligible; or (iii) is currently excluded on a state exclusion list – to Internal Compliance Reporting.


11. Any issue not listed in this section as a Reportable Issue to Internal Compliance Reporting, or in the sections below related to Regs or Clinical Services Group, but believed by the facility to be a compliance issue - to Internal Compliance Reporting.

Regulatory Compliance Support (Regs)

12. Unscheduled arrival of governmental agents or auditors, or notice of audit for claims review conducted or brought by a governmental entity or its agents (as outlined in the Governmental Entity Review Matrix, an attachment to Responding to Governmental Requests for Claims Reviews or Surveys Policy, REGS.GEN.013) – to Regs Helpline.

13. Federal healthcare program coding or billing errors that may indicate a pattern of potential overpayments or with an overpayment amount of $100,000 or more – to Regs Helpline. Generally, isolated clerical errors, unintended patient specific coding/charging/billing errors, or any other non-repetitive errors (i.e., errors that only affect a single claim or handful of claims) resulting in an overpayment should be dealt with in the ordinary course of business and should be refunded within 30 days, when practicable, but in no event later than 60 days. (Reference Correction of Errors Related to Federal and State Healthcare Program FFS Reimbursement, REGS.GEN.015.) However, if there is a question about whether an error needs to be reported, the Regs Helpline should be contacted for assistance.

Information Protection Department

14. Privacy issues – via Privacy Reportable Issue Form

   a. Involving a breach of unsecured protected health information (PHI) – Breach is defined as any unauthorized acquisition, access, use, or disclosure of unsecured
PHI which compromises the security or privacy of such information. Breach does not include:

i. Any unintentional acquisition, access, or use of PHI by a workforce member or individual acting under the authority of a covered entity or business associate if:
   (a) Such acquisition, access, or use was made in good faith and within the course and scope of authority

   (b) Such information is not further used or disclosed in a manner not permitted; or

ii. Any inadvertent disclosure by a person who is authorized to access PHI at the same covered entity or business associate, or organized health care arrangement in which the covered entity participates; and any such information received as a result of such disclosure is not further used or disclosed in a manner not permitted; or

iii. A disclosure of PHI where a covered entity or business associate has a good faith belief that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such information.

Information considered sensitive includes information related to cancer, male or female reproduction-related issues, mental health, genetic testing, substance abuse, communicable diseases/HIV/STDs, confidential patients, employee-employer relationships, social security numbers, driver’s license numbers, bank account numbers.

See the Protected Health Information Breach Risk Assessment and Notification Policy, IP.PRI.011, for details regarding notification to the patient, the Department of Health and Human Services, and if applicable, the media.

b. **Involving an intentional inappropriate and/or unauthorized access, use, and/or disclosure of PHI** – To include, but not limited to, inappropriately accessing a patient’s PHI, gossiping about a patient’s PHI, stealing PHI, exposing family and friends to PHI, or allowing students to observe patients without an affiliation agreement or authorization.

c. **Involving notification from the Office of Civil Rights of a privacy-related inquiry/investigation**, even if the issue is not substantiated.
Facilities are not required to report privacy issues that do not meet the definition of a breach as defined above, are not intentional in nature, or do not generate from an Office of Civil Rights inquiry or investigation.

**Clinical Services Group**

15. Any unscheduled survey by any third party agency for any reason – pursuant to CSG.QS.001. *(See number 5 above for separate reporting requirements to Internal Compliance Reporting.)*

16. Any request for copies of patient records for use in an investigation of an alleged compliance violation – pursuant to CSG.QS.001.

17. Any written communication from the facility's Quality Improvement Organization (QIO) pertaining to a formal project that will involve aggregate reporting of data or information to the QIO – pursuant to CSG.QS.001.

18. Compliance-related issues in clinical research *(e.g., FDA-related issues, ethical violations)* – to Clinical Services Group.

**REFERENCES:**

1. Internal Compliance Reporting Atlas site
2. Internal Compliance Reporting Flowchart of the Reportable Issue Process
3. Regulatory Compliance Notification Policy, CSG.QS.001
4. Protected Health Information Breach Risk Assessment and Notification Policy, IP.PRI.011
5. Responding to Governmental Requests for Claims Reviews or Surveys Policy, REGS.GEN.013
6. Correction of Errors Related to Federal and State Healthcare Program FFS Reimbursement Policy, REGS.GEN.015
7. EC.025 Toolkit