

<b>DEPARTMENT:</b> Ethics & Compliance	<b>POLICY DESCRIPTION:</b> Reporting Compliance Issues and Occurrences to the Corporate Office
<b>PAGE:</b> 1 of 9	<b>REPLACES POLICY DATED:</b> 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, 9/1/17
<b>EFFECTIVE DATE:</b> October 1, 2020	<b>REFERENCE NUMBER:</b> EC.025
<b>APPROVED BY:</b> Ethics and Compliance Policy Committee	

<p><b>SCOPE:</b> All Company-affiliated facilities worldwide, including, but not limited to, hospitals, ambulatory surgery centers, hospice centers, home health agencies, physician practices, outpatient imaging centers, service centers, transfer or patient access centers, HealthTrust Workforce Solutions, joint ventures, business units and all Corporate Departments, Groups, Divisions and Markets (individually and collectively “Company Affiliates”).</p>
<p><b>PURPOSE:</b> To require that certain activities and events be reported to the appropriate Corporate department(s) as set forth in this policy.</p>
<p><b>POLICY:</b> There are a number of events, occurrences or issues (“Issues”), which are described more fully below in the Procedure section that must be reported to the Corporate Department, identified below, <b>no later than later than three (3) business days after discovery.</b></p>
<p><b>PROCEDURE:</b> The following Issues must be reported to the Ethics and Compliance Officer of the Company Affiliate (“Responsible ECO”). The Responsible ECO or designee should then report the Issue to the appropriate Corporate Department by using the links embedded below, or as otherwise directed by such Corporate Department.</p> <p><b>A. Corporate Ethics and Compliance - Internal Compliance Reporting</b></p> <ol style="list-style-type: none"> <li>1. <b>Federal or State Government Investigations, Inquiries, Surveys or Legal Proceedings.</b> A Company Affiliate must report to <a href="#">Internal Compliance Reporting</a> any <b>ongoing investigation or legal proceeding</b> conducted or brought by a Federal or state governmental entity or its agents involving an allegation that the <b>Company Affiliate</b> has <b>committed a crime</b> or has <b>engaged in fraudulent or improper activity.</b></li> <li>2. <b>Potential Violations of the Physician Self-Referral Law, 42 U.S.C. § 1395nn (commonly known as Stark Law).</b> <ol style="list-style-type: none"> <li>a. The Stark Law prohibits a Physician (including a Physician Entity) 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.</li> <li>b. A Company Affiliate must report to <a href="#">Internal Compliance Reporting</a> any financial relationships or arrangements (involving compensation, investment or ownership interests) with a Physician or Physician Entity which fails to satisfy a specific exception under the Stark Law or may pose a potential risk of violation of the Stark Law.</li> </ol> </li> </ol>

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- c. For illustrative purposes only, examples of Issues involving a Physician or Physician Entity which must be reported to [Internal Compliance Reporting](#) include, but are not limited to: (1) commencement of services or payments for items or services without a fully executed written agreement; (2) payments inconsistent with the terms of a written agreement; (3) payments for items or services by a Company Affiliate at greater than fair market value; (4) use of a Company Affiliate’s space, equipment or resources without a written agreement or at a rate below fair market value; (5) purchase of items or services from a Company Affiliate at less than fair market value; and (6) provision of an inappropriate Business Courtesy or a Business Courtesy with a value in excess of the annual limit set forth in the Stark Law. (This list of examples is not intended to be a comprehensive list).
- d. Temporary Noncompliance exceptions under Stark. The Stark Law provides three (3) exceptions for non-compliance: (1) Temporary Noncompliance (“**TNC**”); (2) Temporary Noncompliance with the Signature Requirement (“**TNCSR**”); and (3) Temporary Noncompliance with the Nonmonetary Compensation (“Business Courtesies”) Exception (“**TNCBC**”). **A Company Affiliate must obtain approval from Operations Counsel prior to the use of or reliance upon these exceptions.**
- i. The exceptions for **TNC** and **TNCBC** may be used by an entity **only once every 3 years** with respect to the Company Affiliate and the same referring Physician. Company Affiliate’s use of or reliance upon **TNC** and **TNCBC** must be reported to Internal Compliance Reporting **for tracking purposes**.
- ii. The exception for **TNCSR** has no limit as to the number of times a Company Affiliate and the same referring Physician or Physician Entity may rely upon **TNCSR**. However, if an arrangement for the provision of items or services is not supported by a written agreement, fully executed and in the contract management system as described in LL.001, or an agreement is signed by a Physician (including a Physician Entity) or Company Affiliate after the effective date or commencement of services, then the Company Affiliate must consult with their Operations Counsel to determine whether or not such arrangement must be reported to Internal Compliance Reporting.
3. **Potential violations of any other Federal healthcare laws, including but not limited to the Anti-kickback Statute, 42. U.S. § 1320a-7b (b).**
- a. The Anti-kickback Statute makes it unlawful to offer, pay, solicit or receive remuneration to induce or in exchange 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 healthcare program; or (2) purchasing, leasing, or ordering (or arranging or

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<p>recommending purchasing, leasing or ordering) any good, facility, service, or item payable in whole or in part under a Federal healthcare program.</p> <p>b. A Company Affiliate must report to <a href="#">Internal Compliance Reporting</a> and <b>Operations Counsel</b> financial relationships or arrangements with a Physician, Physician Entity or any other potential Referral Source that may pose a potential risk of violation of the fraud and abuse laws, including but not limited to the Anti-kickback Statute.</p> <p>4. <b>Potential violations of the Emergency Medical Treatment and Labor Act, 42 U.S.C. § 1395dd (“EMTALA”) or comparable State laws or regulations.</b> A Company Affiliate must report to <a href="#">Internal Compliance Reporting</a> any EMTALA related Issue related to its Emergency Department, provider-based or off-campus Emergency Departments or the provision of emergency medical services in other locations, departments or units on its main campus, or comparable state law or regulation related to the provision of emergency medical services.</p> <p>5. <b>Federal or State Governmental Surveys related to the EMTALA or emergency medical services.</b> A Company Affiliate must report to <a href="#">Internal Compliance Reporting</a> any ongoing surveys conducted by a Federal or State governmental agency related to EMTALA or the provision of emergency medical services. (See Section E below for separate reporting requirements to Clinical Operations Group).</p> <p>6. <b>Potential Controlled Substance Incidents.</b> A Company Affiliate must report to <a href="#">Internal Compliance Reporting</a> the following potential incidents related to controlled substances:</p> <p>a. Violations of the registration requirement of the Federal Drug Enforcement Agency (DEA) or state comparable state law registration requirement for the administration of controlled substance;</p> <p>b. Violations related to the theft or loss of controlled substances;</p> <p>c. Unauthorized use of a Company Affiliate’s or practitioner’s DEA number or state required controlled substance registration number; or</p> <p>d. Investigations of a Company Affiliate and investigations or arrests of an employee, contractor or medical staff member by the DEA, state agency or local law enforcement regarding theft or loss of controlled substances or unauthorized use of a Company Affiliate’s or practitioner’s prescription pad.</p> <p>7. <b>Issues regarding Ineligible Persons (OIG/GSA/State exclusion lists).</b> A Company Affiliate must report to <a href="#">Internal Compliance Reporting</a> 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</p>
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<p>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.</p> <p>8. <b>Potential violations of the Global Anti-Corruption Policy, <a href="#">LL.AC.001</a>.</b> A Company Affiliate must report to <a href="#">Internal Compliance Reporting</a> any potential violation of the Foreign Corrupt Practices Act or any other applicable anti-corruption laws.</p> <p>9. <b>Potential violations of Federal, state, local or third party payor mandated licensure, registration, certification, and privileging requirements.</b> A Company Affiliate must report to <a href="#">Internal Compliance Reporting</a> any potential of violations of any Federal, state, local or third party payor mandated licensure, registration, certification, and privileging requirements individuals or healthcare related equipment; or individuals providing services outside their scope of practice or without being appropriately licensed, registered, certified or privileged. Notwithstanding the above, the certification requirements that are required by the Company Affiliate as part of the employee’s job description, but are not required by Federal, state, local laws or regulations or third party payor requirements are not reportable to Internal Compliance Reporting.</p> <p>10. <b>Other Compliance Issues.</b> Any issue not identified in this policy as a Reportable Issue to Internal Compliance Reporting, Regulatory Compliance Support, Information Protection and Security or Clinical Operations Group, but believed by the Company Affiliate to be a compliance issue may be reported to <a href="#">Internal Compliance Reporting</a>.</p> <p><b>B. Corporate Legal Department - Operations Counsel</b></p> <p>1. <b>Potential violation of the prohibitions on Beneficiary Inducement under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) must be reported to Operations Counsel.</b></p> <p>a. Under HIPAA, providers are prohibited from offering or giving patients any remuneration that is likely to influence the patient’s choice of particular provider, practitioner or supplier of Medicare or Medicaid payable items or services, unless such remuneration satisfies a specific exception under the Beneficiary Inducement prohibitions as set forth in HIPAA. 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 <b>Compliance Alert #15</b> for further guidance).</p> <p>b. A Company Affiliate must consult with Operations Counsel <u>prior to</u> using or relying upon any specific statutory exception to the prohibitions on Beneficiary Inducement under HIPAA.</p>
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<p>c. The statutory exceptions to HIPAA Beneficiary Inducement prohibitions may permit the following:</p> <ul style="list-style-type: none"> <li>i. Inexpensive Gifts offered or given to beneficiaries, other than cash or cash equivalents, with a retail value of no more than \$15 individually and no more than \$75 in the aggregate annually per beneficiary. In no event shall a Corporate Affiliate offer or pay cash or a cash equivalent to a patient or family member of a patient.</li> <li>ii. Non-routine, unadvertised waivers of co-payments or deductible amounts based on individualized determinations of financial need or exhaustion of reasonable collection efforts.</li> <li>iii. Properly disclosed differentials in a health insurance plan's co-payments or deductibles.</li> <li>iv. Incentives to promote the delivery of certain preventive care services.</li> <li>v. Any practice permitted under the Federal Anti-Kickback Statute.</li> <li>vi. Waivers of co-payment amounts in excess of the minimum co-payment amounts under the Medicare hospital outpatient fee schedule.</li> </ul> <p>2. <a href="#">Compliance Alert #15</a> provides additional guidance and examples of prohibited activities under the HIPAA Beneficiary Inducement Laws. Some examples of activity that may be considered inappropriate beneficiary inducements include, but are not limited to: (1) providing free sports clinics under certain circumstances; (2) expensive gifts; (3) free tests or services under certain circumstances; (4) waiving the difference between out-of-network charges and in-network charges for Medicare and Medicaid PPOs and HMOs; (5) providing hotel accommodations or hospital rooms to patients or their family members free of charge; (6) providing certain complimentary transportation services or programs; and (7) any practice prohibited under the Federal Anti-kickback Statute.</p> <p><b>C. Regulatory Compliance Support (Regs)</b></p> <p>1. <b>Company Affiliate must report the following Issues to <a href="#">Regs Helpline</a>:</b></p> <ul style="list-style-type: none"> <li>a. 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 <a href="#">Governmental Entity Review Matrix</a>, an attachment to Responding to Governmental Requests for Claims Reviews or Surveys Policy, <a href="#">REGS.GEN.013</a>) must be reported to Regs Helpline.</li> </ul>
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- b. 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 must be reported 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.*

#### D. Information Protection Department

1. **Patient Privacy Issues.** A Company Affiliate must report the following patient privacy related Issues to Information Protection and Security “(IPS)” by using the [Privacy Reportable Issue Form](#).
  - a. **An Issue involving a breach of unsecured protected health information (“PHI”)** must be reported using the [Privacy Reportable Issue Form](#). For purposes of this policy, “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; and
      - (b) Such information is not further used or disclosed in a manner not permitted.
    - 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.

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<p>iv. Information considered sensitive and may warrant additional safeguards 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.</p> <p>v. See the Protected Health Information Breach Risk Assessment and Notification Policy, <a href="#">IP.PRI.011</a>, for details regarding notification to the patient, the Department of Health and Human Services, and if applicable, the media.</p> <p>b. <b>Issues involving an intentional inappropriate and/or unauthorized access, use, and/or disclosure of PHI must be reported using the Privacy Reportable Issue Form.</b> For illustrative purposes, Issues which must be reported to IPS including, but not limited to, inappropriately accessing a patient's PHI, gossiping about a patient's PHI, stealing PHI, exposing family and friends to PHI, posting PHI in social media or allowing students to observe patients without an affiliation agreement or authorization.</p> <p>c. <b>Issues involving notification from the Office of Civil Rights of a privacy-related inquiry/investigation, even if the issue is not substantiated, must be reported using the <a href="#">Privacy Reportable Issue Form</a>.</b></p> <p>2. A Company Affiliate is not required to report privacy related Issues to IPS 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.</p> <p><b>E. Clinical Operations Group ("COG")</b></p> <p>1. A Company Affiliate must report the following Issues to the Clinical Operations Group:</p> <p>a. Any <b>unscheduled survey</b> by any third party agency for any reason must be reported to COG pursuant to <a href="#">COG.RAS.001</a>. <i>(See Section A.5 above for separate reporting requirements to Internal Compliance Reporting.)</i></p> <p>b. Any <b>request for copies of patient records</b> for use in an investigation of an alleged compliance violation must be reported to COG pursuant to <a href="#">COG.RAS.001</a>.</p> <p>c. Any <b>written communication from the Company Affiliate' Quality Improvement Organization (QIO)</b> pertaining to a formal project that will involve aggregate reporting of data or information to the QIO must be reported to COG pursuant to <a href="#">COG.RAS.001</a>.</p>
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d. Any deliberate incorrect abstraction or altering of records to potentially impact Core Measure scores must be reported to [COG](#).

2. A Company Affiliate must report compliance related Issues in clinical research (e.g., FDA-related issues, ethical violations) to [Clinical Operations Group](#).

**DEFINITIONS:**

**Immediate Family Member:** An immediate family member of a Physician is defined as a spouse; natural or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and the spouse of a grandparent or grandchild.

**Physician:** Physician means any person who is a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or chiropractor, licensed by a jurisdiction within the United States. The term “Physician” does not include any persons who do not provide clinical care or order tests (e.g., physicians who provide non-clinical consulting or other leadership services to an HCA Healthcare affiliated entity and do not provide clinical services, such as non-referring Chief Medical Officers).

**Physician Entity:** Physician entity includes any partnership, professional service corporation, limited liability company, or association authorized to engage in the practice of medicine or any other entity, which has financial relationships or arrangements (including compensation, investment or ownership interests) with Physicians.

**Referral Sources:** Referral sources include, but are not limited to, Physicians and their Immediate Family Members, long-term acute care centers, hospice centers, skilled nursing facilities, nursing homes, rehabilitation centers, clinics, therapists, emergency medical services (EMS) agencies and other individuals and entities who may be in a position to influence referrals. Company colleagues should consult the definition of Foreign Official, provided in the Global Anti-Corruption Policy, [LL.AC.001](#), and be aware that physicians and other employees of hospitals or other facilities owned or controlled by national, state or local governments of any Foreign Country may be considered Foreign Officials under the Global Anti-Corruption Policy and Foreign Corrupt Practices Act.

**REFERENCES:**

1. [Internal Compliance Reporting](#) Atlas Connect site
2. Internal Compliance Reporting [Flowchart](#) of the Reportable Issue Process
3. Regulatory Compliance Notification Policy, [COG.RAS.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](#)



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| <ul style="list-style-type: none"> <li>6. Correction of Errors Related to Federal and State Healthcare Program FFS Reimbursement Policy, <a href="#">REGS.GEN.015</a></li> <li>7. Global Anti-Corruption Policy, <a href="#">LL.AC.001</a></li> <li>8. EC.025 <a href="#">Toolkit</a></li> <li>9. <a href="#">Compliance Alert #15</a></li> </ul> |
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