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POLICY & PROCEDURE MANUAL</td><td>POLICY NUMBER: 45

SECTION: Universal

SUBJECT: Regulatory Compliance</td></tr>
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Applicable line of business:

Commercial	X	Medicaid	X
Medicare	X	ACA	X

I. POLICY

Geisinger Health Plan, Geisinger Indemnity Insurance Company, and Geisinger Quality Options (hereafter collectively referred to as "the Health Plan"), are committed to maintaining compliance with all applicable statutory, regulatory and other requirements, sub-regulatory guidance, and contractual commitments, including those related to Medicare Part C and D benefits, Medicaid and the Affordable Care Act. To ensure the rules and regulations followed by the Health Plan are the most current and up to date, the Health Plan will continually monitor certain source(s) of the information and, when necessary, update the compliance program to incorporate any modifications to applicable standards.

II. PURPOSE/OBJECTIVE

To identify and define relevant rules and regulations applicable to the Health Plan, as well as describe the methods used for obtaining information of any updates or modifications.

III. RESPONSIBILITY

Compliance Officer and Compliance Staff

IV. DEFINITIONS

A. Health Plan Required Definitions

1. Attachment - a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit - a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised - the date the policy was implemented.
4. Revised - the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed - the date which documents the most recent annual review if the policy has no revisions necessary.

B. Policy Specific Definitions

1. <u>CMS</u> **-** Centers for Medicare and Medicaid Services, an agency under the Department of Health and Human Services, which regulates and contracts with Medicare Advantage Organizations, Medicare Prescription Drug Plan Sponsors, and Qualified Health Plans.

2. <u>Vendor – A third party which is contractually delegated to provide services to the Health Plan or for Health Plan members.</u>

V. PROCEDURE

A. The Health Plan is committed to maintaining compliance with all applicable Federal and state statutory, regulatory and other Medicare and Qualified Health Plan program requirements. These laws and other standards include (but are not limited to):

1. **<u>Federal and state False Claim Acts</u> (31 U.S.C. § 3729-3733 and 42 U.S.C. § 1320a-7b(a))**

For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information: (1) has actual knowledge of the information, (2) acts in deliberate ignorance of the truth or falsity of the information, or (3) acts in reckless disregard of the truth or falsity of the information

Employees and/or vendors of the Health Plan will not:

a. Knowingly present, or cause to be presented, a false or fraudulent claim for payment or approval;

b. Knowingly make, use, or cause to be made or used, a false record or statement material to a false or fraudulent claim;

c. Conspire to commit a violation of subparagraph (a), (b), (d), (e), (f), or (g)

d. Have possession, custody, or control of property or money used, or to be used, by the Government and knowingly deliver, or cause to be delivered, less than all of that money or property

e. Make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, make or deliver the receipt without completely knowing that the information on the receipt is true;

f. Knowingly buy, or receive as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge property.

g. Knowingly make, use, or cause to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceal or knowingly and improperly avoid or decrease an obligation to pay or transmit money or property to the Government.

2. **<u>Anti-Kickback Statute</u> (42 U.S.C. § 1320a-7b(b))**

Employees and/or vendors of the Health Plan will not knowingly and willfully solicit or

receive any remuneration directly or indirectly, overtly or covertly, in cash or in kind:

a. In return for referring an individual to a person furnishing, or arranging for the furnishing, of any item or service for which payment may be made, in whole or in part, under any federal health care program;

b. In return for purchasing, leasing, ordering, or arranging for, or recommending the purchasing, leasing, or ordering of any goods, facility, service or item for which payment may be made in whole or in part, under any federal health care program.

3. **<u>Prohibition on Inducements to Beneficiaries</u> (42 U.S.C. §1320 a-7a(a)(5))**

Employees and/or vendors of the Health Plan will not offer or transfer remuneration to any individual eligible for health care benefits, the person knows or should know is likely to influence the beneficiary to order or receive any item or payment from a particular provider, practitioner, or supplier.

4. **<u>Health Insurance Portability and Accountability Act (HIPAA)</u> (Pub. L. No. 104-191 (from 18 U.S.C. and 42 U.S.C.))**

An amendment to the Internal Revenue Service Code of 1986, requiring the Department of Health and Human Services (DHHS) to publish new rules, in order to ensure:

a. Standardization of electronic patient health, administrative, and financial data;

b. Unique health identifiers for individuals, employers, health plans, and health care providers; and

c. Security standards protecting the confidentiality and integrity of "individually identifiable health information," past, present, and future.

5. **<u>Privacy of Consumer Health Information</u> (31 Pa Code § 146b.11.)**

Employees and/or vendors will not disclose nonpublic personal health information about a consumer unless an authorization is obtained from the consumer whose nonpublic personal health information is sought to be disclosed, with the exception of that nonpublic personal health information which is necessary for the purpose of treatment, payment, or health care operations.

6. **<u>Criminal Wire and Mail Fraud</u> (18 U.S.C. § 1341, § 1343)**

Employees and/or vendors will not devise and/or implement a scheme to defraud a governmental agency or health care benefit program, which uses the U.S. Postal Service, private postal carriers or telephone lines to perpetrate the fraud.

7. **<u>Theft or Embezzlement in Connection with Health Care</u> (18 U.S.C. § 669)**

Employees and/or vendors will not knowingly or willfully embezzle, steal or otherwise without authority convert to the use of any person other than the rightful owner, or intentionally misapply money, funds, securities, premiums, credits, property, or other assets of a health care benefit program.

8. **<u>Obstruction of Criminal Investigations of Health Care Offenses</u> (18 U.S.C. § 1518)**

Employees and/or vendors will not willfully prevent, obstruct, mislead, delay, or attempt to prevent, obstruct, mislead or delay the communication of information or records relating to a violation of a federal health care offense to a criminal investigator.

9. **<u>Health Care Fraud</u> (18 U.S.C. §1347)**

Employees and/or vendors will not knowingly or willfully execute or attempt to execute, a scheme or artifice to: defraud any health care benefit program; or obtain, by means of false or fraudulent pretense, representation, or promise any of the money or property owned by or under the custody or control of any health care benefit program, in connection with the delivery of, or payment for, health care benefits, items, or services.

10. **<u>Health Insurance for the Aged and Disabled</u>**

Employees and/or vendors will abide by the requirements of Title XVIII Section C - Medicare Advantage Program of the Social Security Act, specifically regarding the following sections:

- Section 1853 Payments to Medicare Advantage organizations
- Section 1854 Premiums and Premium Amounts
- Section 1855 Organizational and financial requirements for Medicare Advantage organizations; provider-sponsored organizations
- Section 1857 Contracts with Medicare Advantage organizations
- Section 1860D-1. Eligibility, enrollment, and information
- Section 1860D-2. Prescription drug benefits
- Section 1860D-3. Access to a choice of qualified prescription drug coverage
- Section 1860D-4. Beneficiary protections for qualified prescription drug coverage

11. **<u>Non-Discrimination</u>**

Employees and/or vendors will be respectful of members' individual and cultural differences. We will treat all members, patients and others with respect, dignity and fairness. Benefits will be administered without regard to race, color, gender, gender identity, sexual orientation, national origin, age, or disability.

12. **<u>Affordable Care Act</u>**

Employees and/or vendors will abide by the requirements regarding each of the following sections of the Act.

- Health Insurance Market Reforms
- Long term care
- Medicaid and CHIP
- Individual Mandate
- Employer requirements
- Qualified Health Plans

13. Physician Self Referral Act

All Providers must abide by the requirements regarding Section 1877 of the Social Security Act (the Act) (42 U.S.C. 1395nn), also known as the physician self-referral law and commonly referred to as the "Stark Law": Providers must self report and GHP employees must likewise report any known or suspected incidences contrary to the law.

- Prohibits a physician from making referrals for certain designated health services Designated Health Services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership, investment, or compensation), unless an exception applies.
- Prohibits the entity from presenting or causing to be presented claims to Medicare (or billing another individual, entity, or third party payer) for those referred services.
- Establishes a number of specific exceptions and grants the Secretary the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse.

The following items or services are Designated Health Services:

- Clinical laboratory services.
- Physical therapy services.
- Occupational therapy services.
- Outpatient speech-language pathology services.
- Radiology and certain other imaging services.
- Radiation therapy services and supplies.
- Durable medical equipment and supplies.
- Parenteral and enteral nutrients, equipment, and supplies.
- Prosthetics, orthotics, and prosthetic devices and supplies.
- Home health services.
- Outpatient prescription drugs.
- Inpatient and outpatient hospital services.

14. Prohibition against employing or contracting with persons or entities that have been excluded from doing business with the Federal Government.

The Health Plan will abide by the requirements regarding the regulations and specific sections of **50.6.8 – OIG/GSA Exclusion (Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12) (Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12) The Act §1862(e)(1)(B), 42 C.F.R. §§ 422.503(b)(4)(vi)(F), 422.752(a)(8), 423.504(b)(4)(vi)(F), 423.752(a)(6), 1001.1901**

Specific Requirements:

- Medicare payment may not be made for items or services furnished or prescribed by an

excluded provider or entity. Sponsors shall not use federal funds to pay for services, equipment or drugs prescribed or provided by a provider, supplier, employee or First tier, downstream, or related entity (FDR) excluded by the DHHS OIG or GSA.

- Sponsors must review the DHHS OIG List of Excluded Individuals and Entities (LEIE list) and the GSA Excluded Parties Lists System (EPLS) prior to the hiring or contracting of any new employee, temporary employee, volunteer, consultant, governing body member, or FDR, and monthly thereafter, to ensure that none of these persons or entities are excluded or become excluded from participation in federal programs.
- OIG's LEIE includes all health care providers and suppliers that are excluded from participation in federal health care programs, including those health care providers and suppliers that might also be on the EPLS. In addition to health care providers (that are also included on the OIG LEIE) the EPLS includes non-health care contractors.
- After entities are initially screened against the entire LEIE and EPLS at the time of hire or contracting, sponsors need only review the LEIE supplement file provided each month, which lists the entities added to the list that month, and review the EPLS updates provided during the specified monthly time frame.

15. **Fraud Enforcement and Recovery Act of 2009**

Employees and/or vendors will abide by the requirements regarding the following act.

Under the FCA, if a person presents a false or fraudulent claim for payment, makes a false statement regarding a claim, conspires to commit a violation of the FCA or has knowing and improper possession of government property, that person is subject to civil penalties of between US$5,000 and US$10,000, plus three times the amount of damages the government sustains as a result of the violation.

- The Fraud Enforcement and Recovery Act of 2009 (FERA) became law on May 20, 2009.
- FERA expanded the scope of the federal False Claims Act (FCA). Specifically, the law extended FCA liability to vendors of government contractors (including health care providers) even if the vendor does not directly "present" a claim for payment to the federal government.
- The health care reform law (Affordable Care Act, ACA) also strengthened existing fraud and abuse laws. ACA imposes new requirements on physicians relying on the "in-office ancillary services." ACA reduces the level of intent required for the government to prove violations of the Anti-Kickback Statute, and specifically requires, under the FCA, that health care providers return Medicare overpayments within 60 days of discovering that an overpayment has been made.

16. **Code of Federal Regulations (specifically, 42 C.F.R. § 400, 403, 411, 417, 422, 423, 1001, and 1003)**

17. **Contractual commitments**

B. In order to continually monitor all Federal and state regulations, the Health Plan subscribes to, and reviews, various trade publications and services.

C. In addition, the following websites are monitored or utilized as resources to ensure compliance:

- HHS (U.S. Department of Health and Human Services)
- CMS (Centers for Medicare and Medicaid Services)

- CCIIO (Center for Consumer Information & Insurance Oversight)
- AHIP (America's Health Insurance Plans)
- HCCA (Health Care Compliance Association)
- Federal Register
- Pennsylvania Bulletin
- Health Plan Management System (HPMS)

D. Any modification to applicable standards are incorporated into the Health Plan's compliance plan by the Compliance Officer. Changes to laws, regulations and sub regulatory guidance are reflected in policy updates and communicated to Health Plan employees via e-mail within a reasonable time frame.

Approved:
Signed: ____
Keith McRee

Title: Chief Compliance Officer

Date: 3/30/2017

This policy will be revised as necessary and reviewed no less than annually.

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Devised: 05/31/07
Reviewed: 06/03/08, 04/06/11, 03/13/12, 05/01/14
Revised: 05/19/10, 05/15/12, 05/16/13, 4/17/15, 7/28/15, 3/30/16, 3/30/17