Hennepin Healthcare System

Title: Key Providers, Identified Team Members, and Board Members Annual Conflict of

Interest Disclosure **Policy** # 020251

Policy Sponsor: Vice President (VP) Risk and Chief Compliance Officer

Review Body(s): Medical Executive Committee (MEC), Hennepin Healthcare System (HHS)

Board Audit and Compliance Committee

Approval Body: HHS Board of Directors

Original Approval Date: 12/15/2009

Reviewed/Revised:

PURPOSE

To enable key providers, identified team members and board members of Hennepin Healthcare System (HHS) to understand, identify, disclose, avoid (where possible), or manage actual, potential, or perceived conflicts of interest, commitment, and/or the institution's mission. This will ensure key providers, identified team members and board members are able to exercise objectivity in judgment, actions, decision making, and performance of their HHS responsibilities in the best interest of HHS.

Unresolved conflicts can lead to violations of law including the False Claims Act, Stark Law, and Anti-Kickback Statute. Unknown and/or unresolved conflicts can also lead to loss of trust and goodwill with patients, team members, and community, and reputational damage.

POLICY

The primary responsibility of HHS team members is fulfillment of the duties and responsibilities assigned to them. Key providers and identified team members will, upon hire and annually thereafter, disclose financial and outside interests that may give a rise to potential conflicts of interest, commitment, and mission to HHS. This includes outside activities, financial relationships, and compensation that could compromise or have the potential to compromise their objectivity or commitment when fulfilling responsibilities or providing services to, or on behalf of, HHS.

Whenever a key provider, identified team member or board member becomes aware of a new outside financial interest and activity that may indicate a potential or perceived conflict of interest, commitment, or mission, it must be promptly disclosed to their manager or Department Chief and the VP Risk and Chief Compliance Officer.

This policy must be followed in addition to applicable HHS and departmental policies, and Medical Staff Bylaws.

SCOPE

This policy applies to key providers, identified team members and board members of HHS. All other team members are covered under the Conflict of Interest policy #003937. In accordance

with Minnesota Statutes 383B.905, Subd. 3a., this policy does not apply to County Commissioners who also serve on the board of Hennepin Healthcare System, Inc.

DEFINITIONS

Board Member: Board members and Board committee members of HHS and HHS Foundation Boards.

Centers for Medicare & Medicaid Services (CMS) Open Door Payments: A national database program that promotes a more transparent and accountable health care system. Open Payments houses a publicly accessible database of payments that reporting entities, including drug and medical device companies, make to covered recipients like physicians. Financial relationships reported in the Open Payments database include, but are not limited to, travel and lodging; fees, including consulting and speaking; honoraria, teaching, and licenses; charitable contributions; entertainment (e.g., food, beverages, and gifts); royalties; and research activities

COI- SMART: Conflict of interest software vendor used by HHS to collect and manage conflict of interest disclosures.

Conflict of Commitment: A conflict that exists when an outside activity or relationship may deter an individual from devoting an appropriate amount of time, energy, dedication, or other personal resources to the individual's HHS responsibilities.

Conflict of Interest: Any situation in which financial or other personal interests may compromise, have the potential to compromise, or have the appearance of compromising:

- A. A team member's business or professional judgment;
- B. The delivery of patient care;
- C. A team member's ability to perform their job duties; or
- D. The institution's mission or values.

An actual or potential conflict of interest may occur when a team member is in a position to influence a decision that may directly or indirectly result in personal gain for the team member or a family member. Examples of conflicts:

- A. Business Relationships: Team member has an actual or potential conflict of interest if team member or a family member is affiliated with a business or organization that may interfere with their role at HHS. Examples of business relationships that must be disclosed are when:
 - 1. The business is a contractor or vendor of HHS;
 - 2. The business competes with HHS; or
 - 3. The relationship could harm HHS's reputation.
- B. Ownership: Team member has an actual or potential conflict of interest if team member or a family member own any stake in a privately owned vendor or competitor or own more than a small portfolio interest in a publicly owned vendor or competitor.
- C. Boards: Team member may sit on a board provided the commitment does not interfere with their role at HHS, the relationship will not harm HHS's reputation, and team member has received appropriate approval from their supervisor or manager. (See the Conflict of Interest policy #003937 for more information as to what constitutes a conflict.)

Conflict of Interest Review Committee (COIRC): A committee convened to review disclosures and recommend management plans in order to mitigate, reduce, or eliminate actual or perceived conflicts of interest, conflicts of commitment, or conflicts of mission.

Conflict of Mission: A situation in which the outside activities an team members engages in either is or appears to be contrary to the mission or values of HHS. A conflict of mission may be difficult to disclose as a conflict of mission will likely be identified by the Internal Review Team or the COIRC.

Family Member: Includes spouse, domestic partner or spousal equivalent, child, stepchild, parent, or sibling of the team member or their spouse or domestic partner, or any other person who is a member of the team member's household for tax or insurance purposes, or a relative currently living with a team member or whose assets the team member controls.

Financial Interest: An actual or anticipated/planned interest or relationship that are any of the following:

- A. Equity interest; or
- B. Compensation interest; or
- C. Gifts.

Provided, however, team members generally will not be expected to identify the following as financial interests unless specifically requested by HHS:

- A. Income from seminars, lectures, or teaching engagements sponsored by or service on advisory committees or review panels for a federal, state, or local government agency, and institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or
- B. Income from and equity interests in diversified investment vehicles (such as mutual funds, pensions, certificates of deposit, and/or other retirement accounts), and as long as the team member does not directly control the investment decisions made by or directly influence the performance of the interests held in these vehicles, that exceeds \$10,000 in fair market value or represents more than a five percent ownership interest in any single entity.

Gift: Any gratuity, favor, discount, entertainment, hospitality, loan, forbearance, good, service, training, transportation, lodging, meal, or other item (in cash or in kind) that provides a personal benefit to the recipient. It does not include an award given for merit, excellence in a certain field of expertise, or a particular accomplishment. It also does not include a gift made to HHS Foundation for HHS purposes.

Internal Review Team (IRT): Team formed to review all disclosures identified during the annual disclosure process. The team is comprised of members of the Compliance Department who conduct first level reviews

Key Providers and Identified Team Members:

- A. Key Providers: All employed medical staff who provide patient care.
- B. Identified Team Members: Certain team members designated by HHS who are in

leadership positions, who have positions in which they have the potential to influence purchases of goods or services, or whose positions otherwise have the potential to influence HHS business decisions.

Outside Activity: Involvement with any person, trust, organization, enterprise, or other entity that is not an entity associated with or under the control of HHS and that may interfere with the fulfillment of HHS responsibilities.

Outside Employment: Includes provision of services to outside entities that currently do business with, compete with, or seek to do business with HHS. Services provided or an assigned role may or may not be compensated. Examples include a position on a board of directors or consulting services which have the potential to conflict with employment responsibilities.

PROCEDURE

I. Key Providers, Identified Team Members and Board Members Responsibilities

- A. Complete an initial Health Care Provider Disclosure of Financial Interest Form:
 - 1. Upon hire, job change, or promotion when an individual becomes a key provider, identified team members or board member they must promptly complete a Health Care Provider Disclosure of Financial Interest Form, identifying actual or perceived conflicts or attesting that none exist.
 - 2. In cases where a particular role or circumstance presents unique risks for a conflict of interest or commitment, the Compliance Department may require completion of a disclosure form as part of the offer/consideration process of selecting a person for the HHS role, and to allow the individual to determine whether to accept the conflict management plan required to hold the role.
- B. Complete an annual Health Care Provider Disclosure of Financial Interest Form:
 - 1. All key providers, identified team members and board members shall annually complete a disclosure form in COI-SMART within four weeks of the date of the receipt.
 - 2. Sunshine Act/CMS Open Door Payment: HHS requires that key providers disclosure activities be consistent with the information reported in the CMS database.
 - a. Key providers who received payments or gifts from companies in the previous year should affirm or dispute any errors in reporting on the CMS Open Payment database (https://openpaymentsdata.cms.gov/).
 - b. Submitted disclosures will be reviewed and compared to the CMS Open Payments data by the COIRC.
- C. <u>Ongoing Obligation to Update the Health Care Provider Disclosure of Financial Interest Form:</u>
 - 1. If at any time after submitting a disclosure form, a key provider, identified team members or board member becomes aware of or acquires an outside interest or activity subject to disclosure, the individual must disclose the outside interest and/or activity by submitting an updated disclosure form within 30 days.
 - 2. Contact the Compliance Department at COISupport@hcmed.org and ask for the COI Smart annual form to be reopened to be updated.

II. Review of Disclosure of Health Care Provider Disclosure of Financial Interest Form

- A. HHS designates individuals who are responsible for the initial review of disclosed interests, evaluation for conflicts of interest or conflicts of commitment, and management of any identified conflicts, which may vary based on a person's role at HHS. The designated reviewer will review responses and updates to the disclosure forms and determine whether each outside interest presents a possible conflict of interest that may require a conflict management plan. To carry out this evaluation, the designated reviewer may make further inquiry and investigation of disclosed relationships and interests as it deems appropriate.
- B. The VP Risk and Chief Compliance Officer and IRT reserve the right to escalate to and work with the respondents' leaders and the Office of the Medical Staff on appropriate measures in order to address completion and/or reported disclosures.

III. Conflict Management Measures and Plans

A. Conflicts of Interest.

- 1. If an outside interest is determined to present a conflict of interest, the IRT, in consultation with the COIRC, will establish a plan for management of that conflict of interest. If the IRT concludes that the conflict of interest is sufficiently managed by compliance with the requirements of this policy and any related policies, procedures, rules, guidelines, or forms, an individual conflict management plan may not be needed. Measures that may be implemented alone or in combination to acceptably manage an individual's conflict of interest include, but are not limited to:
 - a. Disclosure or information about the interest to specified groups, individuals, or in specified circumstances;
 - b. Recusal from discussions or/and decisions related to products, services, transactions, or other matters related to the interest or relationship that presents the conflict of interest;
 - c. Review or monitoring of practice patterns;
 - d. Firewalls to limit the individual's access to information about a decision-making process or about HHS relationship with the person or entity;
 - e. Designation of an individual to receive and respond to concerns;
 - f. Divestiture; and/or
 - g. Any other measure or conflict management plan deemed necessary or appropriate by the COIRC, General Counsel, or Vice President Compliance, with the individual's supervisor/manager.
- 2. In some rare circumstances, a conflict of interest may be so significant that the individual cannot simultaneously have the outside interest and perform their responsibilities for HHS. Any such case will be reported to the COIRC and, if applicable, the individual's manager/supervisor and Human Resources, to evaluate and determine how to proceed. The individual may have to relinquish the interest or the HHS duties with which it conflicts.

B. Conflicts of Commitment.

HHS also may consider conflicts of commitment related to the outside interests disclosed by a covered individual. The individual's manager/supervisor may elect to consult with

HHS Human Resources in determining how to address an outside interest determined to present a conflict of commitment.

IV. Compliance Department Responsibilities

- A. Update at least annually the list of positions designated by HHS as key providers and identified team members.
- B. Coordinate and manage processes to collect disclosures, review and analyze disclosures, document decisions, handle appeals, communicate to the affected team member, and summarize reportable data.

V. VP Risk and Chief Compliance Officer, IRT, and COIRC Responsibilities

- A. The VP Management and Chief Compliance Officer will convene the COIRC to:
 - 1. Review the Conflict of Interest Review Committee (COIRC) Worksheet that summarizes disclosure data of key providers and identified team members.
 - 2. Review and make recommendations for more than minimal risk disclosures that are referred for committee review by the IRT.
- B. Factors including, but not limited to, the following criteria will be considered during review by the IRT and COIRC:
 - 1. Whether the team member or family member is a party to or may directly or indirectly benefit from a proposed agreement or transaction with HHS.
 - 2. Whether the team member's desire for, or expectation of, direct or indirect external economic advantage could influence a decision by, for, or on behalf of HHS.
 - 3. Whether the team member or family member is engaging in an activity, business, or transaction in which HHS is likely to engage.
 - 4. Whether the team members outside activities may conflict with the rights of, or the obligations to, HHS or its patients.
 - 5. Whether the team member's outside activities may either directly or significantly interfere with their fulfillment of assigned HHS responsibilities, including care of patients.
 - 6. Whether there is an appearance of a conflict of interest, commitment, and/or mission.
- C. If the COIRC determines that a conflict of interest, commitment, and/or mission exists, or that there is a reasonable appearance of one, the committee will determine whether the conflict can be managed, reduced, or eliminated by recusal or other action.
- D. If the COIRC determines the conflict can be managed, reduced, or eliminated:
 - 1. A developed written plan with steps for management, reduction or elimination of the conflict will be prepared by the Compliance Department.
 - 2. The affected key provider, identified team member or board member will be notified in writing of the determination.
 - 3. The key provider, identified team member or board member will sign the management plan to indicate their intent to comply with the provisions of the plan.
 - 4. If the key provider, identified team member or board member wishes to appeal the determination of the COIRC, they should contact the VP Risk and Chief Compliance Officer and appropriate escalations will commence:
 - a. Key provider appeals will first be heard by the Medical Executive Committee (MEC).
 - 1) If MEC approves the appeal, the Executive Leadership Team (ELT) will determine if the risk is acceptable or if the management plan must be accepted.

- 2) If MEC rejects the appeal and asserts the management plan is appropriate, the appeal process ends.
- b. Identified team member appeals will be heard by ELT. ELT will determine if the risk is acceptable or if the management plan must be accepted.
- E. The VP Risk and Chief Compliance Officer will summarize and report the outcome of the disclosure processes and the COIRC's analyses to the ELT and the HHS Board or Board committees as appropriate annually or more often as necessary.

VI. Discipline

Failure to comply with this policy or any conflict management plans created under it may result in disciplinary action up to and including termination of employment.

SUPPORTING DOCUMENTS

Health Care Provider Disclosure of Financial Interest Conflict of Interest Review Committee (COIRC) Worksheet

SUPPORTIVE INFORMATION

Regulatory Statute/Standard Reference: Joint Commission Standards LD.02.02.01 (Hospital) and LD.04.02.01 (Behavioral Health/Home Care); The Stark Law [42 US § 1395nn]; The Anti-Kickback Statute [42 USC § 1320a-7b(b)]. Minnesota Statutes 383B.905 Subd. 3a.

Related Policies: Conflict of Interest #003937; Outside Employment #001948; Humanitarian Work #080302; Attendance Expectations #001935; Gifts and Interactions with Outside Parties #010766; Prohibition on Providing Free/Discounted Services to Unregistered Patients #021951.

References: Open Payments program, also known as the "Sunshine Act" [Section 6002 of the Patient Protection and Affordable Care Act, Public Law No. 111-148, as amended by the Health Care and Education Reconciliation Act of 2010, Public Law No. 111-152.]

Communication/Employee Education: New Employee Orientation; Annual Required Training

Patient Education: N/A