I. PURPOSE: Laws regulating contractual and financial relationships between physicians and other providers of health care services, including hospitals and long-term care facilities, are complicated and difficult to interpret and apply.\(^1\) Moreover, violations, whether or not intentional, may result in criminal penalties of an extremely serious nature. This policy is intended to provide important guidance with regard to the structuring and approval of HHSC’s contractual and financial relationships with physicians in order to ensure, to the extent possible, that these relationships are in full compliance with all applicable federal and State laws and regulations.

II. DEFINITION:

As used herein:

A. The term "contract" means any agreement or arrangement, written or verbal, entered between or among parties, one of which is HHSC, which creates financial or any other obligation or obligations. A contract includes financial arrangements and agreements.

B. The term "physician" means a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor, as defined in section 1861(r) of the Social Security Act.

C. The term "physician contract" means any contract (regardless of amount or cost and including no-cost contracts) with physician(s), physician group(s), and/or other entities owned, in whole or in part, by one or more physicians and/or physician groups

III. POLICY:

A. In General:

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\(^1\) The rules discussed here apply both with respect to physicians and other healthcare providers who refer patients or order services from HHSC facilities, including chiropractors and psychologists. For ease of reference, and because most financial arrangements are with physicians, this policy refers only to physicians.
1. HHSC employees shall not enter into any physician contract without prior legal review and approval of the proposed agreement by HHSC General Counsel or designee, as provided below.

2. HHSC has determined that it may, from time to time, enter into financial contracts with physicians of the following types: (i) employment agreements, (ii) personal services contracts, (iii) equipment/space rental or lease agreements, (iv) joint venture agreements, and (v) physician recruitment contracts. In full recognition of the complex and sensitive nature of the relevant statutes and regulations, all HHSC personnel shall at all times, beginning with the initial discussions regarding facility-physician agreements, be subject to the policies and procedures set forth in this policy.

3. HHSC shall provide mandatory education and training to all employees who may, in the course of their jobs, participate in the development and/or implementation of physician contracts. In addition to the initial education and training of all such employees, HHSC shall provide, and designated employees shall participate in, further education and training: (i) at regular intervals, according to a schedule which HHSC shall establish, to maintain an appropriate level of knowledge and awareness; (ii) as needed, in response to enactment of new or revised statutes and/or regulations governing such contractual relationships; (iii) and, as needed, upon the hiring of new employees whose positions may include the development and/or implementation of physician contracts.

4. HHSC employees shall not under any circumstances offer to enter into any physician contract unless specifically authorized under this policy.

B. Approval of Proposed Contracts:

1. Preparation of Contract. Every proposed contract shall be in writing, clearly marked “DRAFT”, and shall include a cover sheet containing the names of the parties, the proposed title of the contract, a one-sentence summary of the nature and purpose of the contract and the name of the contact person(s) at the facility bearing responsibility for negotiation and drafting of the contract. A detailed description of the scope of work and compensation arrangement under consideration shall be included.

2. Submission to Legal Department. Every proposed contract shall be submitted to HHSC General Counsel or designee via the corporate contract technicians. A copy of the proposed contract shall concurrently be submitted, for informational purposes, to the appropriate Regional CEO.

3. Notification. After careful review, HHSC General Counsel or designee shall provide written notification and comments, as required, via the corporate contract technicians, to the contact person(s) and the Regional CEO.

   a. Approval in present form; or

   b. Qualified approval, with or without request to resubmit following revisions; or

   c. Rejection.
C. **Documentation**: Copies of the final, executed contract shall be retained in accordance with HHSC procurement policies and procedures.

D. **Fair Market Value Compensation**:

1. **In General.** In all permissible financial relationships with physicians, the payment of compensation to the physician or the payment of rental/lease payments by the physician must be at *fair market value* for the services received.

2. **Fair Market Value Determination.** The facility CEO/Administrator and/or CFO/Chief Accountant shall make a determination that the compensation proposed to be paid to the Physician, or the rental/lease payments to be made by the physician(s), is at fair market value, taking into account all relevant factors used in making this determination. At a minimum, these factors shall include comparable compensation or rent paid in similar circumstances in the community. Financial data paid under circumstances which do not involve referrals is particularly helpful in determining fair market value. If no comparable local data is available, the facility should indicate why this is the case. The value of referrals are never used to determine fair market value. The guidelines described here apply to all determinations of fair market value.

3. **Fair Market Value Documentation.** Any and all information obtained as described in D (2) above for purposes of the Fair Market Value Determination, shall be:
   - Completely and accurately documented, including such materials as relevant letters, reports, schedules, charts, memoranda of meetings and telephone conferences;
   - Attached to the draft proposed contract for submittal to the contract technicians and the Regional CEO, as described above; and
   - Retained on file, with the executed contract, where contract files are retained in each facility.

IV. **REQUIRED TERMS OF COMMON AGREEMENTS**: HHSC commonly uses the types of agreements listed below. Whenever possible, the agreements should satisfy all requirements listed for each. In any instance, including where a facility believes the agreements satisfy the requirements, the facility should submit the agreement to the HHSC General Counsel or designee for review and approval prior to execution.

A. **Employment Agreements**: HHSC shall from time to time enter into employment agreements with physicians to obtain administrative and/or clinical services. Typically, such agreements shall be for services of a medical director. All employment agreements shall meet the following requirements:

1. **Identifiable Services.** The agreement shall in reasonable detail, describe services to be provided by the physician.

2. **Fair Market Compensation.** The agreement shall provide compensation consistent with the fair market value for the identified services and shall not be determined in a
manner which takes into account the volume or value of any referrals made by the physician to the specific program, the facility or any other division of HHSC.

3. **Commercial Reasonableness.** The agreement would be commercially reasonable even if no referrals were made to the employer.

4. **Incentive Exception.** Notwithstanding the basic ban on volume or value-based compensation, a physician entering into a bona fide employment arrangement with a provider may receive a productivity bonus based on services personally performed by the employee physician. The bonus may not include any ancillary services ordered by the physician. Further, the bonus may be based on gross revenues attributable to the physician but not on net revenues.

**B. Personal Services Agreements:**

1. **Purpose of Personal Services Agreements.** Personal services agreements are intended to obtain the administrative and/or medical services of licensed physicians, as individuals or as a group. An individual physician may be hired to serve as medical director of a facility or a department within a facility, or in other specific capacities. A group of physicians may be engaged to provide all medical services for a department, typically in radiology, emergency room, or anesthesia.

2. All personal services agreements shall meet the following requirements:
   a. The agreement shall be in writing;
   b. The agreement shall state in reasonable detail the specific services covered by the arrangement;
   c. The agreement shall cover all of the services to be provided by the physician to the entity;
   d. The term shall be for at least one year;
   e. The compensation to be paid over the term of the arrangement shall be set in advance. [Interpreted to require that the payment methodology, not the aggregate payment, be set in advance. Example: a fee schedule for services is acceptable]; and
   f. The compensation shall not exceed fair market value, and shall not be determined based on the volume or value of referrals made by the physician or his family to HHSC.

3. **Compliance-Related Objectives.** HHSC intends to develop and establish any and all physician personal services agreements in full compliance with all federal and state statutes and regulations, including Stark and Antikickback.

4. **Stark Personal Services Exception.** Where an entity and a physician have a personal services arrangement, the remuneration paid to the physician will not trigger Stark if:
a. The arrangement is in writing, signed by the parties, and sets forth the specific services covered by the arrangement and the time of their performance;

b. The written agreement covers all of the services to be provided by the physician to the entity;

c. The term is for at least one year;

d. The compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and is not determined based on the volume or value of referrals made by the physician or his family to the hospital [interpreted to require that the payment methodology, not the aggregate payment, be set in advance. Example: a fee schedule for services is acceptable].

e. The services to be performed do not involve counseling or promotion or other business arrangements that violate federal or State law; and

f. The arrangement meets such other requirements as have been, or may be, imposed by the government.

C. Physician Recruitment Exception: A hospital may compensate a physician to cause the physician to relocate to the hospital’s service area and to become a member of the hospital’s medical staff, provided that:

1. The arrangement is in writing, and signed by the parties;

2. The physician is actually relocating from outside the hospital’s service area;

3. The physician is not required to refer patients to the hospital; and

4. The amount of remuneration is not determined in a manner that takes into account, directly or indirectly, the volume or value of referrals to the hospital;

5. **Tax Alert.** In order to protect the corporation’s tax-exempt status, any HHSC facility entering into a recruitment agreement, must be prepared to show that:
   - The recruitment is truly a relocation, not an attempt to lure a physician from a competing provider or retain a physician on the island, and,
   - There is a demonstrable need for the physician to serve the community.

D. Equipment or Space Lease Exception: A hospital may enter into an arrangement to lease equipment or office space to a physician provided that:

1. The arrangement is in writing, signed by the parties, and sets forth the specific equipment or square footage subject to the lease arrangement;

2. The written agreement covers all of the services to be provided by the physician to the entity;

3. The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement and must be used exclusively by the lessee while being used by the lessee;
4. The term is for at least one year;

5. The lease payments are for fair market value for such equipment or office space rental; and

6. Lease payments are not determined based on the volume or value of referrals made by the physician or his family to the hospital.

7. **ALERT.** In assessing compliance with Stark and Antikickback, it is vital to recognize that any failure to comply with a Stark statutory exception renders the entire arrangement in violation of Stark. In contrast, failure to fit within an Antikickback safe harbor does not result in an automatic violation but only places the arrangement in a gray area in which it may or may not be acceptable given all of the facts and circumstances.

E. **Joint Venture Arrangements:**

1. HHSC facilities from time to time enter into joint venture arrangements with physicians, usually involving the joint operation of a shared service, such as a rehabilitation unit or a diagnostic device. These arrangements require coordination from the outset between facility senior management and HHSC General Counsel or designee.

2. All joint ventures should, without exception, be structured in accordance with federal anti-kickback laws.

3. Prior to the commencement of any joint venture activity, the parties must develop a formal business plan which explains both the rationale for the venture and its capital needs. The business plan should include a detailed financial pro forma. Outside financial consultants should be involved to the extent necessary to the proper preparation of these documents.

4. Each participant in the joint venture shall receive an ownership interest in the new entity which is commensurate with the value of its contribution of assets or funding without regard to anticipated referrals.

5. The facility shall document a detailed description of why the parties’ respective ownership interests and allocation of profits and losses from the joint venture satisfies requirements that such items correspond to the fair market value of their respective contributions to the enterprise. The facility should never bear a disproportionate share of losses or receive an insufficient share of profits when compared to similar investors.

**Attachment:** 1. A Primer on Principal Federal Laws Governing Financial Relationships Between HHSC and Physicians
A PRIMER ON PRINCIPAL FEDERAL LAWS GOVERNING FINANCIAL RELATIONSHIPS BETWEEN HHSC AND PHYSICIANS

A. Stark: Stark prohibits physician referrals of patients for certain services to entities in which the referring physician has a financial interest.¹

1. The Prohibitions: Stark provides that a physician (or an immediate family member) who has a financial relationship with an entity may not refer Medicare or Medicaid patients to that entity for the furnishing of designated health services (and the recipient of the referral may not bill for such services).² Referrals and billing in violation of Stark prohibitions expose both the physician and the entity to civil sanctions, including penalties and potential exclusion from the Medicare and Medicaid programs.

2. The Key Definitions:

- Financial Relationship is defined as: (i) a physician or immediate family member’s ownership or investment interest in the referral recipient; or (ii) a compensation arrangement between the physician (or immediate family member) and the entity.

- An ownership interest “may be through equity, debt or other means and includes an interest in an entity that holds an ownership or investment interest in any entity providing the designated health services”. In the case of HHSC facilities, this applies mainly to joint ventures which are co-owned by HHSC and one or more physician(s).

- A compensation arrangement is “any arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity . . .”³

- Remuneration is “anything of value in addition to cash, the term includes discounts, forgiveness of debt, or other benefits made directly or indirectly, in cash or in kind”.

- Referral by a “referring physician” includes both patient admissions and any request or order for an item or service constitutes a designated health service.

- Designated Health Services include:
  - Clinical laboratory services;
  - Physical therapy services;
  - Occupational therapy services;

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¹ The references to “Stark” include both the laws known as Stark I (which applied only with regard to clinical laboratories) and Stark II (which applied to other forms of service discussed here). “Stark” also refers to final regulations under Stark I and proposed regulations under Stark II. It is likely that the federal government will issue final Stark II regulations sometime in 2000, which may require revision of this policy.

² However, exceptions to Stark apply with regard to most common contractual relationships with physicians. In order to avoid the ban on referrals and reimbursement, an arrangement must be structured to qualify for one or more of the exceptions.

³ In the case of HHSC, this most frequently will apply to medical director contracts and other services arrangements.
Radiology services;
Radiation therapy services;
Durable medical equipment;
Parenteral and enteral nutrients, equipment, and supplies;
Prosthetics, orthotics, and prosthetic devices;
Home health services;
Outpatient prescription drugs; and
Inpatient and outpatient hospital services.

If a referral does not pertain to one or more designated health services, it is beyond the scope of Stark.

3. **Sanctions**:

   a. **Civil Monetary Penalty**: Health care providers may be subject to a civil monetary penalty of up to $15,000 per claim for a prohibited service or item. Violations may also result in denial of payment or demand for refunds of amounts collected in violation of Stark. [Arrangements designed to circumvent Stark carry penalties of $100,000.]

   b. **Exclusion**: Health care providers may be excluded from participation in the Medicare and Medicaid programs if they:

      ✓ Present or cause to be presented a claim for a Designated Health Service that the provider knows or should have known was furnished under a prohibited referral, or

      ✓ Fail to make a timely refund (60 days from the date when the prohibited amounts are collected).

4. **The Exceptions**: Stark itself provides a number of specific exceptions that permit physicians to make referrals to entities with which they have ownership or compensation arrangements if certain requirements are met:

   a. **Exception: Bona Fide Employment**

      ✓ The arrangement is in writing and describes in reasonable detail the services to be provided by the physician employee.

      ✓ The arrangement provides compensation consistent with the fair market value for the identified services and is not determined in a manner which takes into account the volume or value of any referrals made by the physician to the entity.

      ✓ The arrangement would be commercially reasonable even if no referrals were made to the employer.

   b. **Exception: Personal Services Arrangement**

      ✓ The arrangement is in writing, signed by the parties, and sets forth the specific services covered by the arrangement;
The written agreement covers all of the services to be provided by the physician to the entity;

The term is for at least one year;

The compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and is not determined based on the volume or value of referrals made by the physician or his family to the hospital [Interpreted to require that the payment methodology, not the aggregate payment, be set in advance. Example: a fee schedule for services is acceptable.]

c. Exception: Lease of Equipment or Space

A hospital may enter into an arrangement to lease equipment or office space to a physician provided that:

The arrangement is in writing, signed by the parties, and sets forth the specific equipment or square footage subject to the lease arrangement;

The written agreement covers all of the equipment or space to be provided by the physician to the entity;

The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement and must be used exclusively by the lessee while being used by the lessee;

The term is for at least one year;

The lease payments are for fair market value for such equipment or office space rental; and

Lease payments are not determined based on the volume or value of referrals made by the physician or his family to the entity.

d. Exception: Physician Recruitment

A hospital may pay remuneration to a physician to induce the physician to relocate to the hospital’s service area and to become a member of the hospital’s medical staff, provided that:

The arrangement is in writing, and signed by the parties;

The physician is actually relocating from outside the hospital’s service area;

The physician is not required to refer patients to the hospital; and

The amount of remuneration is not determined in a manner that takes into account, directly or indirectly, the volume or value of referrals to the hospital.

B. “Antikickback” Statute: The Antikickback Statute is a criminal statute that prohibits transactions that are intended to induce patient referrals, or to compensate a party for
making those referrals. The Statute prohibits anyone from paying or accepting a payment in exchange for the referral of a patient for services that might be covered by the Medicare and Medicaid programs or any other federal health care program.

1. **The Prohibitions.** The Antikickback Statute prohibits the *knowing and willful* solicitation or receipt of any kind of remuneration or the knowing and willful offer to pay, or payment of, any remuneration, whether direct or indirect, over or covert, *in cash or in kind*, in return for:
   
a. Referring a patient for the furnishing of any item or service; or
   
b. Purchasing, leasing, ordering or arranging for, or recommending or arranging for the purchase, lease or ordering of any item or service paid for (in whole or in part) under a federal health care program.

2. **Key Definitions:**
   - *Knowing and willful*, according to the legal decisions affecting Hawaii, means knowing that the statute prohibits the above described conduct and engaging in that conduct with the intent to disobey the law. (Although, merely engaging in the prohibited conduct is not sufficient to violate the law, it is highly advisable to avoid all conduct which could lead to questions on this point.)
   - *Remuneration* is payment of any economic benefit for referral.
   - “*In cash or in kind*” clarifies that a prohibited payment may be made, not only through payment of money, but in many other ways, including such monetary equivalents as reduced rent, compensation guarantees, equipment loans, administrative and billing services, and participation in ventures offering the opportunity to generate fees. “*Directly or indirectly*”, and “*overtly or covertly*” also demonstrate the breadth of this law.

3. **Single Purpose Standard.** The relevant courts have also confirmed that the Antikickback Statute is violated if only *one purpose* of a payment is to induce future referrals, even if another purpose was to compensate for services rendered, or some other completely legitimate purpose.

4. **Sanctions.**
   
a. **Criminal Penalties:**
      - *Felony conviction*: 
      - *Fine and/or Imprisonment*: Upon conviction, up to $25,000 or five years imprisonment or both.
      - *Notice to licensing board and professional societies*
   
b. **Exclusion.** Health care providers may be excluded from participation in the Medicare and Medicaid programs if they: 
Present or cause to be presented a claim for a designated health service that the provider knows or should have known was furnished under a prohibited referral, or

Fail to make a timely refund (60 days from the date when the prohibited amounts are collected).

5. **Safe Harbors**: Thirteen Safe Harbors published in the final regulations to the Antikickback Statute provide protection from potential violation of the Statute.

a. **Effect of Safe Harbors**:

- If a transaction falls squarely within a safe harbor, it is fully protected against violation of the Antikickback Statute.

- If a transaction does not fall squarely within a safe harbor, one of the following may be applicable:
  - The arrangement did not violate the statute because it is not intended to induce reimbursable referrals;
  - The arrangement clearly violates the statute; or
  - The arrangement falls in a gray area in which it may violate the statute in a less serious manner, and the risk is difficult to predict. However, good faith intentions to comply with the regulations are relevant to the assessment of penalties, and sham transactions that comply only superficially will not protect against penalties.

Those Safe Harbors which most commonly apply to financial/contractual relationships with physicians are as follows:

- Space Rental
- Equipment Rental
- Personal Services and Management Contracts
- Employment

b. **Comparison/Contrast**: Antikickback Statute Safe Harbors and Stark Exceptions relevant to financial relationships with physicians have essentially the same requirements, except that the Stark Personal Services Exception requirement of establishing payment methodology to determine physician compensation (i.e., remuneration) does not comply with safe harbor requirements which require that the aggregate compensation to be paid over the term of the agreement must be set in advance.