

Appendix__: Business Associate Agreement

I. Authority:

Pursuant to 45 C.F.R. § 164.502(e), the Indian Health Service (IHS), as a covered entity, is required to enter into an agreement with a “business associate,” as defined by 45 C.F.R. § 160.103, under which the business associate must agree to appropriately safeguard Protected Health Information (PHI) that it will use and disclose when performing functions, activities or services pursuant to its contract with the IHS. By signing Contract No. _____ (Contract), _____ agrees that it is a Business Associate and will comply with the terms below, in addition to other applicable Contract terms and conditions, and applicable law, relating to the safekeeping, use, and disclosure of PHI. This Appendix comprises the Business Associate Agreement (Agreement).

II. Definitions:

The following terms shall have the same meaning as those terms in 45 C.F.R. Part 160 and Part 164, which are the federal regulations implementing the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended: Breach, Designated Record Set, Disclosure, Health Care Operations, Individual, Minimum Necessary, Notice of Privacy Practices, PHI, Required by Law, Secretary, Security Incident, Subcontractor, Unsecured PHI, and Use.

- A. Business Associate. “Business Associate” shall generally have the same meaning as the term “business associate” at 45 C.F.R. § 160.103, and in reference to the party to this Agreement shall mean _____.
- B. Covered Entity. “Covered Entity” shall generally have the same meaning as the term “covered entity” at 45 C.F.R. § 160.103, and in reference to the party to this Agreement, shall mean the IHS.
- C. HIPAA Rules. “HIPAA Rules” shall mean the Privacy, Security, Breach Notification, and Enforcement Rules at 45 C.F.R. Part 160 and Part 164.
- D. Master Patient Index (MPI). The “Master Patient Index” or “MPI” is composed of a unique list of patients and a current list of medical centers where each patient has been seen. This enables the sharing of patient data between operationally and regionally diverse systems. Each record (or index entry) on the MPI contains a small amount of patient data used to identify individual entries.

The mission of the MPI is to uniquely identify a patient and to “link” that patient’s data throughout the IHS facilities using the Integration Control Number (ICN). The MPI is the authoritative source of a patient’s ICN, the enterprise-wide identifier for IHS facilities and the key to accessing a patient’s record. The

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accuracy of patient information and patient identification directly affects clinical, administrative, billing, and interdepartmental processes.

III. Obligations and Activities of Business Associate:

- A. Compliance:** Business Associate agrees not use or disclose PHI other than as authorized by the Agreement or as required by law. Business Associate acknowledges that it is directly liable under the HIPAA Rules and subject to civil and, in some cases, criminal penalties for making uses and disclosures of PHI that are not authorized by the Agreement or required by law. Business Associate agrees that it will require all of its agents, employees, subsidiaries, and affiliates, to whom Business Associate provides PHI, or who create or receive PHI on behalf of Business Associate for Covered Entity, to comply with the HIPAA Rules and to enter into written agreements with Business Associate that provide the same restrictions, terms, and conditions as set forth in the Agreement.
- B. Subcontractors:** In accordance with 45 C.F.R. §§ 164.502(e)(1)(ii) and 164.308(b)(2), which govern relations with subcontractors, Business Associate agrees to ensure that any subcontractors that create, receive, maintain, or transmit PHI on behalf of Business Associate agree to the same restrictions, terms, and conditions that apply to Business Associate with respect to such PHI.
- C. Safeguarding PHI:** Business Associate shall develop and use appropriate procedural, physical, and electronic safeguards to protect against the use or disclosure of PHI in a manner not authorized by this Agreement or required by law. Business Associate will limit any use, disclosure, or request for use or disclosure of PHI to the minimum amount necessary to accomplish the intended purpose of the use, disclosure, or request.
- D. Safeguarding Electronic PHI:** Business Associate agrees to use appropriate safeguards, as set forth in Subpart C of 45 C.F.R. Part 164 with respect to electronic PHI, to prevent use or disclosure of electronic PHI other than as authorized by this Agreement or required by law.
- E. Reporting Use or Disclosures Not Authorized By this Agreement or Required by Law:** Business Associate agrees to report to Covered Entity any use or disclosure of PHI not authorized by this Agreement or required by law within thirty (30) days of discovering the use or disclosure, or any security incident of which it becomes aware. In addition, Business Associate shall mitigate, to the extent practicable, any harmful effect that is known to Business Associate of the use, disclosure, or security incident.
- F. Reporting of Breach:** In accordance with the policy of the Department of Health and Human Services, Business Associate will report, within one hour of discovery, all suspected or confirmed breaches to Covered Entity.

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- G. Notification of Breach of Unsecured PHI:** In addition to the above, Business Associate shall notify Covered Entity of a breach, as set forth in 45 C.F.R. § 164.410, of the security of any unsecured PHI that Business Associate received from, or created or received on behalf of, Covered Entity within thirty (30) calendar days after the discovery of the breach by Business Associate, its employees, officers, and/or other agents, unless notification is specifically excepted by 45 C.F.R. § 164.412.
1. Requirements of Notice. Such notice shall include, to the extent possible, the identification of each individual whose unsecured PHI has been, or is reasonably believed by Business Associate to have been, accessed, acquired, or disclosed during such breach; a brief description of the circumstances of the breach of security, including the date of the breach and the date of Business Associate's discovery of the breach; and the type of unsecured PHI involved in the breach. Business Associate agrees to provide any other available information that Covered Entity is required to include in notification to the individual under 45 §164.404(c). In the event notification is delayed, evidence demonstrating the necessity of the delay shall accompany the notification.
- H. Individual Access to PHI:** Business Associate shall maintain a designated record set for each individual for whom it maintains PHI. In accordance with an individual's right to access his or her PHI, Business Associate shall make available all PHI in the individual's designated record set to the individual to whom that information pertains, or, upon the request of the individual, to that individual's authorized representative, as necessary to satisfy Covered Entity's obligations under 45 C.F.R. § 164.524. Availability to access PHI shall be made within five (5) calendar days of receipt of a valid request.
- I. Accounting of Disclosures:** Business Associate shall maintain records of PHI received from, or created or received on behalf of, Covered Entity and shall document subsequent uses and disclosures of such information by Business Associate. Business Associate shall, within five (5) calendar days after receiving a request from Covered Entity, provide to Covered Entity such information as Covered Entity may require to fulfill its obligations to account for disclosures of PHI pursuant to 45 C.F.R. § 164.528.
- J. Amendment of PHI:** Business Associate shall, within five (5) calendar days of a request by Covered Entity, make PHI available to Covered Entity for Covered Entity to fulfill its obligations under 45 C.F.R. § 164.526 to amend PHI and shall, as directed by Covered Entity, within five (5) calendar days of receipt of such direction, incorporate any amendments into PHI held by Business Associate. In addition, Business Associate shall ensure incorporation of any such amendments into PHI held by its agents or subcontractors within ten (10) days of such direction, and shall notify Covered Entity within five (5) calendar days of when

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those agents or subcontractors have completed the incorporation of the amendments. Business Associate shall forward to Covered Entity all requests to amend PHI that it receives directly from individuals within five (5) calendar days of its receipt of a request.

K. Carrying out Covered Entity's Obligations: To the extent Business Associate is to carry out one or more of Covered Entity's obligation(s) under Subpart E of 45 C.F.R. Part 164, Business Associate agrees to comply with the requirements of Subpart E that apply to Covered Entity in the performance of such obligation(s).

L. Disclosures for Verifying Compliance: Upon request, Business Associate shall permit access by the Secretary and Covered Entity during normal business hours to its facilities, books, records, accounts, and any other sources of information, including PHI and any agreements that it has with subcontractors, vendors, and/or other agents relating to the use and disclosure of PHI received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity, for purposes of determining both Business Associate's and Covered Entity's compliance with the HIPAA Rules.

IV. Permitted Uses and Disclosures by Business Associate:

A. Business Associate shall not use or disclose PHI except to perform functions, activities, or services on behalf of Covered Entity as provided for in the Contract, this Agreement, the HIPAA Rules, or other applicable law.

B. Business Associate agrees that it may use or disclose PHI on behalf of Covered Entity only:

1. Upon obtaining the authorization of the individual to whom the PHI pertains;
2. For the purposes of treatment, payment or health care operations unless Covered Entity has agreed to a restriction pursuant to 45 C.F.R. § 164.520(b)(iv)(A) or 45 C.F.R. § 164.522; or
3. Without an authorization or consent, if in accordance with 45 C.F.R. § 164.510, 45 C.F.R. § 164.512, 45 C.F.R. § 164.514(e), 45 C.F.R. § 164.514(f), or 45 C.F.R. § 164.514(g).

C. Business Associate shall use and disclose PHI in compliance with each applicable requirement of 45 C.F.R. § 164.504(e), which section is fully incorporated herein.

D. Business Associate agrees to make uses, disclosures, and requests for PHI consistent with Covered Entity's minimum necessary policies and procedures.

E. It is anticipated that Business Associate will have access to the MPI.

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F. Business Associate may not use or disclose PHI in a manner that would violate Subpart E of 45 C.F.R. Part 164 if done by Covered Entity, except for the specific uses and disclosures set forth below.

1. Business Associate may disclose PHI for the proper management and administration of Business Associate or to carry out the legal responsibilities of Business Associate, provided the disclosures are required by law, or Business Associate obtains reasonable assurances from the person to whom the information is disclosed that the information will remain confidential and used or further disclosed only as required by law or for the purposes for which it was disclosed to the person, and the person notifies Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached.

V. Obligations of Covered Entity:

- A. Covered Entity shall provide Business Associate with its Notice of Privacy Practices and any changes to the Notice.
- B. Covered Entity shall notify Business Associate of any limitation(s) in Covered Entity's Notice of Privacy Practices under 45 C.F.R. § 164.520, to the extent that such limitation may affect Business Associate's use or disclosure of PHI.
- C. Covered Entity shall notify Business Associate of any change in, or revocation of, the permission by an individual to use or disclose his or her PHI to the extent that such changes may affect Business Associate's use or disclosure of PHI.
- D. Covered Entity shall notify Business Associate of any restriction on the use or disclosure of PHI that Covered Entity has agreed to or is required to abide by under 45 C.F.R. § 164.522, to the extent that such restriction may affect Business Associate's use or disclosure of PHI.
- E. Covered Entity shall not request Business Associate to use or disclose PHI in any manner that would not be permissible under Subpart E of 45 C.F.R. Part 164 if done by Covered Entity, except as provided in Part IV, Subpart F, Section 1.

VI. Termination:

- A. **Term:** The Term of this Agreement shall be effective as of the date Business Associate signs the underlying Contract and shall terminate when the Contract ends or on the date covered entity terminates for cause as authorized in paragraph (b) of this Section, whichever is sooner.
- B. **Termination for Cause:** Business Associate authorizes termination of this Agreement by Covered Entity, if Covered Entity determines Business Associate

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has violated a material term of the Agreement and Business Associate has not ended the violation within the time specified by Covered Entity.

C. **Obligations of Business Associate Upon Termination:** Upon termination of this Agreement for any reason, Business Associate, with respect to PHI received from Covered Entity, or created, maintained, or received by Business Associate on behalf of Covered Entity, shall:

1. Retain only that PHI which is necessary for Business Associate to continue its proper management and administration or to carry out its legal responsibilities;
2. Return to Covered Entity, or, if agreed to by Covered Entity, destroy, the remaining PHI that Business Associate does not need to continue its proper management and administration or to carry out its legal responsibilities;
3. Continue to use appropriate safeguards, in compliance with Subpart C of 45 C.F.R. Part 164, with respect to electronic PHI to prevent use or disclosure of electronic PHI, other than as provided for in this Part, for as long as Business Associate retains the PHI;
4. Not use or disclose PHI retained by Business Associate other than for the purposes for which such PHI was retained and subject to the same conditions set out above, at Part IV, Subpart F, Section 1 of the Agreement which applied prior to termination;
5. Return to Covered Entity, or, if agreed to by Covered Entity, destroy, the PHI retained by Business Associate when it is no longer needed by Business Associate for its proper management and administration or to carry out its legal responsibilities; and
6. If Business Associate or its agent or subcontractor destroys any PHI, Business Associate will provide Covered Entity with documentation evidencing such destruction within thirty (30) days of completion of destruction.

D. **Survival:** The obligations of Business Associate under this Part shall survive the termination of this Agreement.

VII. Indemnification:

In the event Business Associate is investigated and/or becomes a party to a civil or criminal cause of action in any forum relating to its failure to comply with the HIPAA Rules, Business Associate shall reimburse Covered Entity all reasonable costs and expenses Covered Entity may incur relating to such investigation and/or cause of action, and will otherwise hold Covered Entity harmless for any and all reasonable costs and expenses relating to the foregoing.

VIII. Miscellaneous:

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- A. **Incorporation:** This Agreement is attached to and fully incorporated into the Contract.
- B. **Notices:** All notices under this Agreement shall be provided by certified mailing, and shall require proof of date of receipt.
- C. **Regulatory References:** A reference in this Agreement to a section in the HIPAA Rules means the section as in effect or as amended.
- D. **Amendment:** The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for compliance with the requirements of the HIPAA Rules and any other applicable law.
- E. **Interpretation:** Any ambiguity in this Agreement shall be interpreted to permit compliance with the HIPAA Rules.
- F. **Successors and Assigns:** This Agreement shall be binding upon, inure to the benefit of and be enforceable by and against the Parties and their successors and assigns.
- G. **Severability:** If a court of competent jurisdiction deems any provision of this Agreement unenforceable, such provision shall be severed from this Agreement and every other provision of the Agreement shall remain in full force and effect.

CONTRACTORS PERFORMANCE CONDITIONS & RESPONSIBILITIES:

- 1. Contractor is responsible for reporting all taxes from wages earned under this contract to the appropriate State and Federal Agencies, provided the awardee is an individual.**
- 2. Contractor is responsible for his/her own reliable transportation in the performance of the contract.**
- 3. Contractor is responsible for Fringe Benefits and other benefits such as health, retirement, etc. for his/her employees, if other than self.**
- 4. Contractor is responsible for maintaining satisfactory standards of competence, conduct, appearance and integrity. The quality of work performance of the contractor shall be subject to review.**
- 5. Contractor is responsible for notifying the designated supervisor/director if he/she will be late, ill or unable to work for other reasons.**
- 6. Contractor earns no leave and is compensated only for hours actually worked at the agreed compensatory rate.**
- 7. Contractor is responsible for signing-in and signing-out of immediate work area, utilizing in-house system of accountability.**

Indian Health Service

Special General Memorandum 2015-03



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Indian Health Service
Rockville MD 20852

SGM No. 2015-03

September 3, 2015

TO: All Employees

FROM: Deputy Director

SUBJECT: Mandatory Seasonal Influenza Immunizations for Civilian Health Care Personnel Working in Indian Health Service Health Care Facilities

The purpose of this Special General Memorandum is to add seasonal influenza immunization to the list of required vaccinations for civilian health care personnel working in Indian Health Service (IHS) health care facilities. Influenza vaccination for health care facility staff and licensed independent practitioners is a major patient safety issue in the United States and is an important component of comprehensive infection control programs. Individuals who become infected are contagious at least one day before any signs or symptoms of influenza appear, and therefore these individuals can infect others without knowing they are contagious.

All Civil Service employees, contract staff, temporary employees, students, and volunteers, who work in an IHS health care facility, must receive a seasonal influenza vaccination by October 31 of each year or have on file a valid medical exemption for vaccination signed by a licensed independent practitioner. Commissioned Corps Officers of the United States Public Health Service (PHS) are already required to obtain their annual seasonal influenza immunization (per Manual Circular - Commissioned Corps Personnel - PHS No. 377, Subchapter CC26.1 Instruction 8, PHS Readiness Standards).

1. Individuals with a valid medical exemption for vaccination will be required to wear a mask provided by IHS during the influenza season (November 1 through March 31) and during other periods of increased influenza activity as defined by the Centers for Disease Control and Prevention and/or State public health authorities.
2. All employees, contract staff, temporary employees, students, and volunteers, must be provided access to influenza vaccinations at no charge.

I am counting on the full support of all members of the IHS community to implement this new requirement system-wide. Thank you for your continued support and cooperation to further protect the health of the patients we serve.

/Robert G. McSwain/
Robert G. McSwain



DEPARTMENT OF HEALTH & HUMAN SERVICES

MEMORANDUM

Aberdeen Area
Indian Health Service
Federal Building, Room 309
115 4th Ave. SE
Aberdeen, SD 57401

AUG - 8 2013

DATE:

TO: All Aberdeen Area Civil Service Employees and Commission Corps Officers
All Contractors, Volunteers and Other Providers

FROM: Acting Area Director

SUBJECT: Courtesy and Respect in the Workplace Policy

The single most important thing we can offer our patients, customers and coworkers is courtesy and respect in our daily interactions.

No matter what your job title, grade, duties or responsibilities are, your number one job is to perform those duties and responsibilities in a manner that is consistent with the standards of conduct outlined in the Department's Standards of Conduct, Subpart C - Conduct on the Job, 73.735-301 Courtesy and consideration for others. This Subpart reads as follows:

- (a) An employee's conduct on the job is, in all respects, of concern to the Federal Government. Courtesy, consideration, and promptness in dealing with the public must be shown in carrying out official responsibilities, and actions which deny the dignity of individuals or conduct which is disrespectful to others must recognize that inattention to matters of common courtesy can adversely affect the quality of service the Department is responsible for providing.
- (b) Of equal importance is the requirement that courtesy is shown in daily interaction with coworkers. Employees shall be polite to and considerate of other employees and shall respect their needs and concerns in the work environment.

I expect each individual who works for the Aberdeen Area IHS to adhere to these requirements. I expect each supervisor and/or manager to hold their subordinates responsible for meeting this standard and taking appropriate corrective action when individuals violate it. I also expect management to take appropriate corrective action when first line supervisors fail to exercise their supervisory responsibilities.

While I am emphasizing only one of the sections under Subpart C, I expect each supervisor and manager to become familiar with the entire subpart. I also expect each supervisor to assure that anyone over whom they exercise supervisory control is knowledgeable of and adhere to all aspects of the Standards of Conduct. You may access a copy of the HHS Standards of Conduct by following this link: <http://ethics.od.nih.gov/lawreg/hhs-resid-std.htm#301>

I am issuing this policy memorandum to demonstrate my commitment to assuring courtesy, respect and dignity in the work place. Everyone from patients, clients, customers and employees have the right to expect a professional environment when they walk through the doors of any Aberdeen Area IHS facility.

This memorandum is to be distributed "desk to desk" with supervisors assuring that each employee, officer, contractor and/or volunteer has knowledge of it and initials a copy of the memorandum. Chief Executive Officer and Division Directors are to assure that this memorandum is posted in appropriate places in plain sight of anyone entering their work area.

If you have questions or need assistance, you may contact the Regional Human Resource Office, Employee /Labor Relations staff by calling (605) 226-7553.

A handwritten signature in dark ink, appearing to read 'Ron Cornelius', with a long horizontal flourish extending to the right.

Ron Cornelius



Great Plains Area
Indian Health Service
Federal Building, Room 309
Aberdeen, SD 57401

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

**STANDARDS OF CONDUCT
STANDARDS OF ETHICAL CONDUCT
SUPPLEMENTAL STANDARDS OF ETHICAL CONDUCT**

EMPLOYEE CERTIFICATION

I have been provided a copy of the U.S. Department of Health and Human Services Standards of Conduct regulations which apply to all Indian Health Service Officers and Employees (5 CFR Part 2635). I have been advised that the Aberdeen Area Deputy Ethics Counselor is Acting HR Officer, Patricia Tomhave-Dodge who can be reached at 605-226-7553 if I have any questions.

I understand that it is my responsibility to read and familiarize myself with the regulatory contents. I understand that I may discuss questions or concerns related to my responsibilities, conduct and financial interests with this individual or his/her designated representative.

Employee Signature

Date

PLEASE PRINT OR TYPE:

Employee Name: _____

Title: _____

Location: _____

HHS Residual Standards of Conduct

These Standards were published in a booklet entitled "Standards of Conduct" on March 30, 1989 (45 CFR Part 73). Subsequently, HHS published the [Supplemental Standards of Ethical Conduct for Employees of DHHS](#) which covers ethics rules and regulations. Therefore, only the following subparts and sections of the HHS Standards of Conduct remain in effect. [Please consult with the Office of General Counsel prior to taking any action based on any of these subpart/sections. Revised by OGC, 5/2/2000.]

[§ 73.735-301 -- Courtesy and consideration for others](#)

[§ 73.735-302 -- Support of department programs](#)

[§ 73.735-305 -- Conduct in Federal buildings](#)

[§ 73.735-306 -- Sexual harassment](#)

[§ 73.735-508\(e\) -- Government decisions Outside Official channels](#)

[§ 73.735-805 -- Advice and guidance on conflicts matters](#)

[Subpart L -- Disciplinary Action \(§ 73.735-1201\)](#)

[Subpart M -- Reporting Violations \(§§ 73.735-1301 -- 73.735-1304\)](#)

[Appendix to Part 73 -- List of Some Offenses for Which Disciplinary Action May be Taken](#)

[§ 73.735-301 Courtesy and consideration for others.](#)

(a) An employee's conduct on the job is, in all respects, of concern to the Federal government. Courtesy, consideration, and promptness in dealing with the public must be shown in carrying out official responsibilities, and actions which deny the dignity of individuals or conduct which is disrespectful to others must be avoided. Employees must recognize that inattention to matters of common courtesy can adversely affect the quality of service the Department is responsible for providing. Where appropriate, courtesy to the public should be included in the standards for employee performance.

(b) Of equal importance is the requirement that courtesy be shown in day-by-day interaction with co-workers. Employees shall be polite to and considerate of other employees, and shall respect their needs and concerns in the work environment.

[§ 73.735-302 Support of department programs.](#)

(a) When a Department program is based on law, Executive Order or regulation, every employee has a positive obligation to make it function as efficiently and economically as possible and to support it as long as it is a part of recognized public policy. An employee may, therefore, properly make an

address explaining and interpreting such a program, citing its achievements, defending it against uninformed or unjust criticism, or soliciting views for improving it.

(b) An employee shall not, either directly or indirectly, use appropriated funds to influence, or attempt to influence, a Member of Congress to favor or oppose legislation. However, when authorized by his or her supervisor, an employee is not prohibited from: (1) Testifying, on request, as a representative of the Department on pending legislation or proposals before Congressional Committees; or (2) Assisting Congressional Committees in drafting bills or reports on request, when it is clear that the employee is serving solely as a technical expert under the direction of committee leadership.

(c) All employees shall be familiar with regulations and published instructions that relate to their official duties and responsibilities and shall comply with those directives. This includes carrying out proper orders from officials authorized to give them.

(d) Employees are required to assist the Inspector General and other investigative officials in the performance of their duties or functions. This requirement includes the giving of statements or evidence to investigators of the Inspector General's office or other HHS investigators authorized to conduct investigations into potential violations.

§ 73.735-305 Conduct in Federal buildings.

(a) An employee shall not participate while on Government-owned or leased property or while on duty for the Government, in any gambling activity including the operation of a gambling device, in conducting a lottery or pool, in a game for money or property, or in selling or purchasing a numbers slip or ticket.

(b) An employee shall not while in or on Government-owned or leased property or while on duty for the Government solicit alms and contributions, engage in commercial soliciting and vending, display or distribute commercial advertisements, or collect private debts.

(c) The prohibitions in paragraphs (a) and (b) of this section do not preclude: (1) Activities necessitated by an employee's law enforcement duties; (2) Participation in Federally sponsored fund-raising activities conducted pursuant to Executive Order 10927, or similar HHS approved activities; or (3) Buying a lottery ticket at an authorized State lottery outlet for a lottery authorized by State law and conducted by an agency of a State within that State.

(d) General Services Administration regulations on "Conduct on Federal Property" apply to all property under the control of the General Services Administration, and they are also applicable to all buildings and space under the control of this Department. These regulations prohibit, among other things, gambling, being intoxicated, and possession, distribution, or use of narcotic or dangerous drugs on the premises. The GSA regulations are found in Subpart 101-20.3 of the GSA Regulations, 41 CFR 101-20.3.

§ 73.735-306 Sexual harassment.

Sexual harassment is deliberate unsolicited verbal comments, gestures, or physical contact of a sexual nature which are unwelcome. Sexual harassment is unacceptable conduct and is expressly prohibited. In addition, supervisors and managers are prohibited from taking or promising personnel actions in exchange for sexual favors, or failing to take an action because an employee or applicant for employment, refuses to engage in sexual conduct. This same prohibition applies to relationships

between Department personnel who take or recommend action on a grant or contract and the grantee or contractor. Those employees who wish to file a complaint of sexual harassment should contact the Office of Equal Employment Opportunity (EEO) within their respective agencies for guidance. (Time frames for pursuing a charge alleging sexual harassment are the same as for any other complaint based on allegations of sex discrimination.)

§ 73.735-508(e) Other prohibitions.

Employees shall avoid any action whether or not specifically prohibited by this part, which might result in or create the appearance of:

(e) Making a Government decision outside official channels

§ 73.735-805 Advice and guidance on conflicts matters.

(a) Whenever an employee has a question about the appropriate course of conduct to be followed in a matter that may involve an actual or apparent conflict of interest, he or she should immediately consult with his or her supervisor or a deputy ethics counselor, or both. If a supervisor who is consulted determines that the matter warrants further consideration, he or she may, in conjunction with the employee, submit the details of the matter, in writing, to the appropriate deputy ethics counselor. These details should include a description of:

- (1) The activity, relationship, or interest giving rise to the question posed by the employee;
- (2) The duties or official responsibilities of the employee(s) involved;
- (3) The nature of the actual or apparent conflict of interest; and
- (4) Any other information that may be helpful in reviewing the problem.

(b) Upon receiving the submission of an employee or a supervisor, the deputy ethics counselor will develop any additional information about the matter as necessary, and will confer with the Department Ethics Counselor as appropriate. The Department Ethics Counselor and the head of the principal operating component or his or her designee will be informed of any serious violation of the standards of this subpart or any other conflict of interest law. Questions of first impression or other unusual matters shall be brought to the attention of the Department Ethics Counselor and the head of the principal operating component or his or her designee.

(c) On the basis of all information gathered including, where appropriate, the advice of the Department Ethics Counselor, the deputy ethics counselor will:

- (1) Decide that there is no violation or potential violation of the standards of this subpart or any other law and so notify the employee and his or her supervisor in writing; or
- (2) Decide that a violation or potential violation of the standards of this subpart or other law has occurred or may occur, and that the employee involved shall take one or more of the steps set forth in § 73.735-904 to resolve the problem and notify the employee and his or her supervisor in writing; or
- (3) Decide that, although no violation of this subpart or other law has occurred, the nature of the matter is such that the employee should periodically report any additional information that would require reconsideration of the initial submission.

Subpart L -- Disciplinary Action (§ 73.735-1201)

§ 73.735-1201 General provisions.

(a) Violations of the regulations contained in the Part may be cause for disciplinary action which could be in addition to any penalty prescribed by law. (For a list of some offenses for which disciplinary action may be taken and "The Code of Ethics for Government Service," the violation of which may also result in disciplinary action, see Appendixes A and B of this Part).

(b) The type of disciplinary action to be taken must be determined in relation to the specific violation. Those responsible for recommending and for taking disciplinary action must apply judgment to each case, taking into account the general objectives of meeting any requirements of law, deterring similar offenses by the employee and other employees, and maintaining high standards of employee conduct and public confidence. Some types of disciplinary action which may be considered are:

- (1) Admonishment
- (2) Written reprimand
- (3) Reassignment
- (4) Suspension
- (5) Demotion
- (6) Removal

(c) Suspension, demotion, and removal are adverse actions; and when such actions are taken, applicable laws, regulations, and policies must be followed. [46 FR 7369, Jan. 23, 1981, as amended at 53 FR 4409, Feb. 16, 1988]

Subpart M--Reporting Violations

§ 73.735-1301 Responsibility for reporting possible criminal violations. An employee who has information which he or she reasonably believes indicates a possible offense against the United States by an employee of the Department, or any other individual working on behalf of the Department, shall immediately report such information to his or her supervisor, any management official, or directly to the Office of the Inspector General. Offenses covered by the preceding sentence include, but are not limited to, bribery, fraud, perjury, conflict of interest, misuse of funds, equipment, or facilities, and other conduct by a government officer or employee, grantee, contractor or other person which is prohibited by title 18 of the United States Code. Employees and supervisors should refer to chapter 5-10 of the Department's General Administration Manual for procedures regarding the reporting and handling of such information.

APPENDIX A TO PART 73--LIST OF SOME OFFENSES FOR WHICH DISCIPLINARY ACTION MAY BE TAKEN

Following is a list of some offenses for which disciplinary action may be taken under this Part. When a statute applies specifically to a particular offense, either wholly or in part, the statute is cited. Neither the list of offenses nor the statutory citations are all-inclusive. The "Code of Ethics for Government Service" is not cited because of its general applicability but is published in its entirety in Appendix B.

A. Concerning Efficiency of Operations in General.

1. Engaging in wasteful actions or behavior in the performance of assigned duties; conducting non-Government business during official work hours; or participating in a strike (18 U.S.C. 1918), work stoppage, slowdown, sickout, or other similar action.
2. Absence without leave, failure to adhere to the rules and regulations for requesting and obtaining leave, or improper use of sick leave.

3. Deliberate insubordination or refusal to carry out lawful orders or assignments given.
4. Disruptive behavior, such as:
 - a. Inflicting or threatening or attempting to inflict bodily injury on another (except for necessary defense of self or others) while on the job or on Federal premises.
 - b. Discourtesy, disreputable conduct, or use of insulting, abusive or obscene language to or about other individuals while on the job.
5. Sexual harassment of employees or members of the public.
6. Failure to observe precautions for safety, such as failure to use safety equipment when it is provided or ignoring signs, posted rules or regulations, or written or verbal safety instructions.
7. Unauthorized use, possession, or distribution of alcoholic beverages (5 U.S.C. 7352) or controlled substances (e.g., hallucinogens, such as LSD; stimulants, such as cocaine and amphetamines; sedatives, such as barbiturates; narcotics and other drugs or substances, such as hashish and other cannabis substances).
8. Unauthorized gambling; or canvassing, soliciting, or peddling on Government premises.
9. Failure to carry or show proper identification or credentials as required by competent authority; misuse of identification cards or investigative or identification credentials or badges.
10. Failure to disclose (i.e., report) information, when such disclosure is not specifically prohibited by law or Executive Order, that involves (a) violation of law, rule, or regulation, (b) mismanagement or gross waste of funds or abuse of authority, or (c) posing a substantial and specific danger to public health or safety; failure to cooperate in an official Department inquiry.
11. Failure to pay just debts, including taxes to and loans from governmental sources.
12. Deceit or interference in a Civil Service examination (18 U.S.C. 1917) or in connection with a Government personnel action.
13. Fraud or false statements in a Government matter. (18 U.S.C. 1001 through 1003.)
14. Supervisory failure to initiate disciplinary or corrective action when the facts are known and disciplinary or corrective action is warranted.
15. Employment of a member of an organization that advocates the overthrow of our constitutional form of government. (5 U.S.C. 7311; 50 U.S.C. 784.)

B. Concerning Government Funds, Property, Documents, and Records.

1. Actual or attempted embezzlement or theft of Government or personal money or property either directly or through use of Government documents, automated equipment, or other means; actual or attempted embezzlement or theft of the money or property of another person in the possession of an employee by reason of his or her employment. (18 U.S.C. 641 and 654.)
2. Failure to account for public money. (18 U.S.C. 643.)
3. Deliberate falsifying of official time and attendance records; improper use of official travel or forging, counterfeiting, or otherwise falsifying official Government travel records or documents. (18 U.S.C. 508.)
4. False record entries or false reports of money or securities. (18 U.S.C. 2073.)
5. Loss or misuse of or damage to Government property or endangering persons or Government property through carelessness or by willful malicious conduct.
6. Mutilating, destroying, or concealing public records. (18 U.S.C. 2071.)
7. Misuse of penalty (postal) privilege. (18 U.S.C. 1719.)
8. Failure to safeguard administratively confidential, financial, and trade secrets information.

9. Unauthorized use of documents presented or used to procure the payment of money from or by the Government. (18 U.S.C. 285.)
10. Unauthorized use of a Government vehicle; serious or repeated violations of traffic regulations while driving a Government vehicle or a vehicle rented or leased for official Government purposes; reckless driving or improper operation of any Government owned, rented, or leased motor vehicle. (31 U.S.C. 1349[b].)
11. Violations of the Privacy Act, including:
 - a. Willful prohibited disclosure of individually identifiable information in violation of 5 U.S.C. 552a.
 - b. Willfully maintaining a system of records without meeting the notice requirements of the Privacy Act as required by 5 U.S.C. 552a.
12. Violation of regulations concerning the release of classified information, confidential, or security and investigative information. (18 U.S.C. 798 and 1905; 21 U.S.C. 331j; and 50 U.S.C. 783.)

C. Concerning Conflicts of Interest and Related Unethical Conduct:

1. Violations of 18 U.S.C. Chapter 11: Bribery, Graft, and Conflicts of Interest, including:
 - a. Having a direct or indirect financial interest (includes employee ownership of stocks, bonds, or partnership interests in an entity or employment of the employee, his or her spouse, or dependent child) that conflicts with one's Government duties because such entity is either regulated by, has or seeks to do business with the agency, or has any other particular matter with or pending before the agency that may give rise to either an actual conflict or the appearance thereof. (18 U.S.C. 208.)
 - b. Bribery of a public official; soliciting or accepting directly or indirectly anything of monetary value, including gifts, gratuities, favors, entertainment, or loans either as compensation for governmental services or from individuals who are seeking contractual or other business or financial relations with the Department, are conducting operations or activities that are regulated by the Department, or have interests that may be substantially affected by the performance or nonperformance of the employee's official duties; receiving salary or any contribution to or supplementation of salary from a private source as compensation for services for the Government. (18 U.S.C. 201 and 209.)
 - c. Acting as the agent of a foreign principal registered under the Foreign Agents Registration Act. (18 U.S.C. 219.)
2. Engaging, directly or indirectly, in a financial transaction as a result of or primarily relying on information that is obtained through one's official duties and would not be available were the employee not an employee of the Federal Government.
3. Soliciting a contribution from another employee for a gift to an official superior, making a donation as a gift to an official superior, or accepting a gift from an employee receiving less pay than oneself. (5 U.S.C. 7351.)
4. Engaging, without required permission, in outside activities that result in or create the appearance of a conflict of interest.
5. Teaching, lecturing, or writing that depends in specific information obtained as a result of one's Government employment when that information is not otherwise available to the public.
6. Failure to obtain required clearance of an official speech or article.
7. Lobbying with appropriated funds. (18 U.S.C. 1913.)
8. Representation before a Federal agency (other than in the proper discharge of one's official duties) as an agent or attorney in a claim against the United States (or receiving any

gratuity or share in any such claim in consideration for assistance given) or as an agent or attorney for anyone before any department, agency, court, or otherwise in connection with any proceeding, application, request for a ruling, or claim on any other particular matter in which the United States is a party or has a direct and substantial interest. (18 U.S.C. 205.) (Note: This section notwithstanding, an employee may, if not in-consistent with the performance of his or her official duties, act without compensation as an agent or attorney for another person who is the subject of any disciplinary or other administrative proceeding or as an agent or attorney for one's parent, spouse, child, or any person or estate for whom or which he or she serves as personal fiduciary except in those matters in which the employee has participated personally and substantially.)

D. Concerning Prohibited Political and Election Activities.

1. Activities prohibited by 5 U.S.C. Chapter 73, Subchapter III, including:
 - a. Section 7323, "Political contributions; prohibition."
 - b. Section 7324, "Influencing elections; taking part in political campaigns; prohibitions; exceptions."
2. Activities prohibited by 18 U.S.C. Chapter 29, including:
 - a. Section 594, "Intimidation of voters."
 - b. Section 597, "Expenditures to influence voting."
 - c. Section 598, "Coercion by means of relief appropriations."
 - d. Section 600, "Promise of employment or other benefit for political activity."
 - e. Section 601, "Deprivation of employment or other benefit for political contribution."
 - f. Section 602, "Solicitation of political contributions."
 - g. Section 604, "Solicitation from persons on relief."
 - h. Section 606, "Intimidation to secure political contributions."

E. Concerning Prohibited Personnel Practices.

1. Commission of a prohibited personnel practice (as defined in 5 U.S.C. 2302[b] [1-11]); that is, any employee who has authority to take, direct others to take, recommend, or approve any personnel action, shall not, with respect to such authority, commit any of the following practices:
 - a. Discriminate for or against any employee or applicant for employment on the basis of race, color, religion, sex, national origin, age, handicapping condition, marital status, or political affiliation.
 - b. Solicit or consider any recommendation or statement, oral or written, with respect to any individual who requests or is under consideration for any personnel action unless such recommendation or statement is based on the personal knowledge or records of the person furnishing it and consists of (1) an evaluation of the work performance ability, aptitude, or general qualifications of such individual or (2) an evaluation of the character, loyalty, or suitability of such individual.
 - c. Coerce the political activity of any person (including the providing of any political contribution or service) or take any action against any employee or applicant for employment as a reprisal for the refusal of any person to engage in such political activity.
 - d. Deceive or willfully obstruct any person with respect to such person's right to compete for employment.
 - e. Influence any person to withdraw from competition for any position for the purpose of improving or injuring the prospects of any other person for employment.

- f. Grant any preference or advantage not authorized by law, rule, or regulation to any employee or applicant for employment (including defining the scope or manner of competition or the requirements for any position) for the purpose of improving or injuring the prospects of any particular person for employment.
- g. Appoint, employ, promote, advance, or advocate for appointment, employment, promotion, or advancement, in or to a civilian position any individual who is a relative (as defined in 5 U.S.C. 3110) when the civilian position is in the Department or under his or her jurisdiction or control.
- h. Take or fail to take a personnel action with respect to any employee or applicant for employment as a reprisal for the lawful disclosure of information.
- i. Take or fail to take any personnel action against an employee or applicant for employment as a reprisal for the exercise of any appeal right granted by any law, rule, or regulation (including HHS Instructions and issuances).
- j. Discriminate for or against any employee or applicant for employment on the basis of conduct that does not adversely affect the performance of the employee or applicant or the performance of others (except criminal conviction in determining suitability or fitness).
- k. Take or fail to take any personnel action when the taking of or failure to take such action violates any law, rule, or regulation implementing, or directly concerning the merit system principles (as set forth in 5 U.S.C. 2301).

[53 FR 4410, Feb. 16, 1988]

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STANDARDS OF ETHICAL CONDUCT

2635.101 Basic obligation of public service.

(a) *Public service is a public trust.* Each employee has a responsibility to the United States Government and its citizens to place loyalty to the Constitution, laws and ethical principles above private gain. To ensure that every citizen can have complete confidence in the integrity of the Federal Government, each employee shall respect and adhere to the principles of ethical conduct set forth in this section, as well as the implementing standards contained in this part and in supplemental agency regulations.

(b) *General principles.* The following general principles apply to every employee and may form the basis for the standards contained in this part. Where a situation is not covered by the standards set forth in this part, employees shall apply the principles set forth in this section in determining whether their conduct is proper.

(1) Public service is a public trust, requiring employees to place loyalty to the Constitution, the laws and ethical principles above private gain.

(2) Employees shall not hold financial interests that conflict with the conscientious performance of duty.

(3) Employees shall not engage in financial transactions using nonpublic Government information or allow the improper use of such information to further any private interest.

(4) An employee shall not, except as permitted by subpart B of this part, solicit or accept any gift or other item of monetary value from any person or entity seeking official action from, doing business with, or conducting activities regulated by the employee's agency, or whose interests may be substantially affected by the performance or nonperformance of the employee's duties.

(5) Employees shall put forth honest effort in the performance of their duties.

(6) Employees shall not knowingly make unauthorized commitments or promises of any kind purporting to bind the Government.

(7) Employees shall not use public office for private gain.

(8) Employees shall act impartially and not give preferential treatment to any private organization or individual.

(9) Employees shall protect and conserve Federal property and shall not use it for other than authorized activities.

(10) Employees shall not engage in outside employment or activities, including seeking or negotiating for employment, that conflict with official Government duties and responsibilities.

(11) Employees shall disclose waste, fraud, abuse, and corruption to appropriate authorities.

(12) Employees shall satisfy in good faith their obligations as citizens, including all just financial obligations, especially those—such as Federal, State, or local taxes—that are imposed by law.

(13) Employees shall adhere to all laws and regulations that provide equal opportunity for all Americans regardless of race, color, religion, sex, national origin, age, or handicap.

(14) Employees shall endeavor to avoid any actions creating the appearance that they are violating the law or the ethical standards set forth in this part. Whether particular circumstances create an appearance that the law or these standards have been violated shall be determined from the perspective of a reasonable person with knowledge of the relevant facts.

(c) *Related statutes.* In addition to the standards of ethical conduct set forth in this part, there are conflict of interest statutes that prohibit certain conduct. Criminal conflict of interest statutes of general applicability to all employees, 18

U.S.C. 201, 203, 205, 208, and 209, are summarized in the appropriate subparts of this part and must be taken into consideration in determining whether conduct is proper. Citations to other generally applicable statutes relating to employee conduct are set forth in subpart I and employees are further cautioned that there may be additional statutory and regulatory restrictions applicable to them generally or as employees of their specific agencies. Because an employee is considered to be on notice of the requirements of any statute, an employee should not rely upon any description or synopsis of a statutory restriction, but should refer to the statute itself and obtain the advice of an agency ethics official as needed.

CODE OF FEDERAL REGULATIONS

TITLE 5

CHAPTER XLV – DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 5501 -- SUPPLEMENTAL STANDARDS OF ETHICAL CONDUCT FOR EMPLOYEES OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

Sec.

- 5501.101 General.
- 5501.102 Designation of HHS components as separate agencies.
- 5501.103 Gifts from federally recognized Indian tribes or Alaska Native villages or regional or village corporations.
- 5501.104 Prohibited financial interests applicable to employees of the Food and Drug Administration.
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- 5501.106 Outside employment and other outside activities.
- 5501.107 Teaching, speaking and writing by special Government employees in the Public Health Service.
- 5501.108 Exception to the prohibition against assisting in the prosecution of claims against, or acting as an agent or attorney before, the Government, applicable only to employees assigned to federally recognized Indian tribes or Alaska Native villages or regional or village corporations pursuant to the Intergovernmental Personnel Act.
- 5501.109 Prohibited outside activities applicable to employees of the National Institutes of Health.
- 5501.110 Prohibited financial interests applicable to senior employees of the National Institutes of Health.
- 5501.111 Awards tendered to employees of the National Institutes of Health.
- 5501.112 One-year disqualification of employees of the National Institutes of Health from certain matters involving an award donor.

AUTHORITY: 5 U.S.C. 301, 7301, 7353; 5 U.S.C. App. (Ethics in Government Act of 1978); 25 U.S.C. 450i(f); 42 U.S.C. 216; E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306; 5 CFR 2635.105, 2635.203, 2635.403, 2635.802, 2635.803.

SOURCE: 61 FR 39763, July 30, 1996; 70 FR 5543, February 3, 2005; and 70 FR 51559, August 31, 2005; unless otherwise noted.

§ 5501.101 General.

- (a) *Purpose.* The regulations in this part apply to employees of the Department of Health and Human Services (HHS) and supplement the Standards of Ethical Conduct for Employees of the Executive Branch contained in 5 CFR part 2635. In addition to 5 CFR part 2635 and this part, employees are required to comply with implementing guidance and procedures issued by HHS components in accordance with 5 CFR 2635.105(c). Employees are also subject to the executive branch-wide financial disclosure regulations at 5 CFR part 2634, the Employee Responsibilities and Conduct regulations at 5 CFR part 735, and the HHS regulations regarding conduct at 45 CFR part 73.
- (b) *Applicability.* The regulations in this part apply to individuals who are “employees” within the meaning of 5 CFR 2635.102(h). The regulations thus apply to special Government employees, except to the extent they are specifically excluded from certain provisions, and to uniformed service officers in the Public Health Service Commissioned Corps on active duty.

- (c) **Definitions.** Unless a term is otherwise defined in this part, the definitions set forth in 5 CFR parts 2635 and 2640 apply to terms in this part. In addition, for purposes of this part:
- (1) **Federally recognized Indian tribe or Alaska Native village or regional or village corporation** means any Indian tribe, band, nation, or other organized group or community, including any Alaska Native village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act, 43 U.S.C. 1601 *et seq.*, which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.
 - (2) **Significantly regulated organization** means an organization for which the sales of products regulated by the Food and Drug Administration (FDA) constitute ten percent or more of annual gross sales in the organization's previous fiscal year; where an organization does not have a record of sales of FDA-regulated products, it will be deemed to be significantly regulated if its operations are predominately in fields regulated by FDA, or if its research, development, or other business activities are reasonably expected to result in the development of products that are regulated by FDA.

§ 5501.102 Designation of HHS components as separate agencies.

- (a) **Separate agency components of HHS.** Pursuant to 5 CFR 2635.203(a), each of the twelve components of HHS listed below is designated as an agency separate from each of the other eleven listed components and, for employees of that component, as an agency distinct from the remainder of HHS. However, the components listed below are not deemed to be separate agencies for purposes of applying any provision of 5 CFR part 2635 or this part to employees of the remainder of HHS:
- (1) Administration on Aging;
 - (2) Administration for Children and Families;
 - (3) Agency for Healthcare Research and Quality;
 - (4) Agency for Toxic Substances and Disease Registry;
 - (5) Centers for Disease Control and Prevention;
 - (6) Centers for Medicare and Medicaid Services;
 - (7) Food and Drug Administration;
 - (8) Health Resources and Services Administration;
 - (9) Indian Health Service;
 - (10) National Institutes of Health;
 - (11) Program Support Center; and
 - (12) Substance Abuse and Mental Health Services Administration.
- (b) **Definitions—**
- (1) **Employee of a component** includes, in addition to employees actually within a component, an employee of the Office of the General Counsel whose regularly assigned duties and responsibilities principally involve the provision of legal services to the relevant component with respect to substantive programmatic issues.
 - (2) **Remainder of HHS** means employees in the Office of the Secretary and Staff Divisions, employees of the Office of the General Counsel with Department-wide responsibility, and any HHS employee not in one of the 12 components designated as separate agencies in paragraph (a) of this section.
- (c) **Applicability of separate agency designations.** The designations in paragraph (a) of this section identify an employee's "agency" for purposes of:
- (1) Determining when a person is a prohibited source within the meaning of 5 CFR 2635.203(d) for purposes of applying:

- (i) The regulations at subpart B of 5 CFR part 2635 governing gifts from outside sources; and
 - (ii) The regulations at § 5501.106 requiring prior approval of outside employment and other outside activities; and
 - (iii) The regulations at § 5501.111 governing the receipt of awards by employees of the National Institutes of Health; and
- (2) Determining whether teaching, speaking or writing relates to the employee's official duties within the meaning of 5 CFR 2635.807(a)(2)(i).

§ 5501.103 Gifts from federally recognized Indian tribes or Alaska Native villages or regional or village corporations.

- (a) *Tribal or Alaska Native gifts.* In addition to the gifts which come within the exceptions set forth in 5 CFR 2635.204, and subject to all provisions of 5 CFR 2635.201 through 2635.205, an employee may accept unsolicited gifts of native artwork, crafts, or other items representative of traditional native culture from federally recognized Indian tribes or Alaska Native villages or regional or village corporations, provided that the aggregate market value of individual gifts received from any one tribe or village under the authority of this paragraph shall not exceed \$200 in a calendar year.
- (b) *Limitations on use of exception.* If the donor is a tribe or village that has interests that may be substantially affected by the performance or nonperformance of an employee's official duties, the employee may accept the gifts authorized by paragraph (a) of this section only where there is a written finding by the agency designee that acceptance of the gift is in the agency's interest and will not violate any of the limitations on the use of exceptions contained in 5 CFR 2635.202(c).

§ 5501.104 Prohibited financial interests applicable to employees of the Food and Drug Administration.

- (a) *General prohibition.* Except as permitted by paragraph (b) of this section, no employee or spouse or minor child of an employee, other than a special Government employee or the spouse or minor child of a special Government employee, of the Food and Drug Administration shall have a financial interest in a significantly regulated organization.
- (b) *Exceptions.* Notwithstanding the prohibition in paragraph (a) of this section:
- (1) An employee or spouse or minor child of an employee may have a financial interest, such as a pension or other employee benefit, arising from employment with a significantly regulated organization.

NOTE TO PARAGRAPH(b)(1): FDA employees who file public or confidential financial disclosure reports pursuant to 5 CFR part 2634, as opposed to spouses and minor children of such employees, are generally prohibited under § 5501.106(c)(3) from engaging in current employment with a significantly regulated organization.

- (2) An employee who is not required to file a public or confidential financial disclosure report pursuant to 5 CFR part 2634, or the spouse or minor child of such employee, may hold a financial interest in a significantly regulated organization if:
- (i) The total cost or value, measured at the time of acquisition, of the combined interests of the employee and the employee's spouse and minor children in the regulated organization is equal to or less than the *de minimis* exemption limit for matters involving parties established by 5 CFR 2640.202(a) or \$15,000, whichever is greater (the phrase "time of acquisition" shall mean the date on which the employee actually acquired the financial

interest—or on which the financial interest became imputed to the employee under 18 U.S.C. 208—whether by purchase, gift, bequest, marriage, or otherwise, except that with respect to a financial interest that was acquired prior to the employee's entrance on duty as an employee of the Food and Drug Administration, the "time of acquisition" shall be deemed to be the date on which the employee entered on duty);

- (ii) The holding, if it represents an equity interest, constitutes less than 1 percent of the total outstanding equity of the organization; and
 - (iii) The total holdings in significantly regulated organizations account for less than 50 percent of the total value of the combined investment portfolios of the employee and the employee's spouse and minor children.
- (3) An employee or spouse or minor child of an employee may have an interest in a significantly regulated organization that constitutes any interest in a publicly traded or publicly available investment fund (e.g., a mutual fund), or a widely held pension or similar fund, which, in the literature it distributes to prospective and current investors or participants, does not indicate the objective or practice of concentrating its investments in significantly regulated organizations, if the employee neither exercises control nor has the ability to exercise control over the financial interests held in the fund.
- (4) In cases involving exceptional circumstances, the Commissioner or the Commissioner's designee may grant a written exception to permit an employee, or the spouse or minor child of an employee, to hold a financial interest in a significantly regulated organization based upon a determination that the application of the prohibition in paragraph (a) of this section is not necessary to ensure public confidence in the impartiality or objectivity with which HHS programs are administered or to avoid a violation of part 2635 of this title.

NOTE TO PARAGRAPH (b): With respect to any excepted financial interest, employees are reminded of their obligations under 5 CFR part 2635, and specifically their obligation under subpart D of part 2635 to disqualify themselves from participating in any particular matter in which they, their spouses or minor children have a financial interest arising from publicly traded securities that exceeds the *de minimis* thresholds specified in the regulatory exemption at 5 CFR 2640.202 or from non-publicly traded securities that are not covered by the regulatory exemption. Furthermore, the agency may prohibit or restrict an individual employee from acquiring or holding any financial interest or a class of financial interests based on the agency's determination that the interest creates a substantial conflict with the employee's duties, within the meaning of 5 CFR 2635.403.

- (c) *Reporting and divestiture.* For purposes of determining the divestiture period specified in 5 CFR 2635.403(d), as applied to financial interests prohibited under paragraph (a) of this section, the "date divestiture is first directed" means the date on which the new entrant public or confidential financial disclosure report required by part 2634 of this title or any report required by § 5502.106(c) of this chapter is due.

§ 5501.105 Exemption for otherwise disqualifying financial interests derived from Indian or Alaska Native birthrights.

- (a) Under 18 U.S.C. 208(b)(4), an employee who otherwise would be disqualified may participate in a particular matter where the otherwise disqualifying financial interest that would be affected results solely from the interest of the employee, or the employee's spouse or minor child, in birthrights:
- (1) In an Indian tribe, band, nation, or other organized group or community, including any Alaska Native village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act, which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians;

- (2) In an Indian allotment the title to which is held in trust by the United States or which is inalienable by the allottee without the consent of the United States; or
 - (3) In an Indian claims fund held in trust or administered by the United States.
- (b) The exemption described in paragraph (a) of this section applies only if the particular matter does not involve the Indian allotment or claims fund or the Indian tribe, band, nation, organized group or community, or Alaska Native village corporation as a specific party or parties.

§ 5501.106 Outside employment and other outside activities.

- (a) *Applicability.* This section does not apply to special Government employees.
- (b) *Definitions.* For purposes of this section:
- (1) *Compensation* has the meaning set forth in 5 CFR 2635.807(a)(2)(iii).
 - (2) *Consultative services* means the provision of personal services by an employee, including the rendering of advice or consultation, which requires advanced knowledge in a field of science or learning customarily acquired by a course of specialized instruction and study in an institution of higher education, hospital, or other similar facility.
 - (3) *Professional services* means the provision of personal services by an employee, including the rendering of advice or consultation, which involves the skills of a profession as defined in 5 CFR 2636.305(b)(1).
- (c) *Prohibited outside employment and activities—*
- (1) *Prohibited assistance in the preparation of grant applications or contract proposals.* An employee shall not provide consultative or professional services, for compensation, to or on behalf of any other person to prepare, or assist in the preparation of, any grant application, contract proposal, program report, or other document intended for submission to HHS.
 - (2) *Prohibited employment in HHS-funded activities.* An employee shall not, for compensation, engage in employment, as defined in 5 CFR 2635.603(a), with respect to a particular activity funded by an HHS grant, contract, cooperative agreement, cooperative research and development agreement, or other funding mechanism authorized by statute.
 - (3) *Prohibited outside activities applicable to employees of the Food and Drug Administration.* An employee of the Food and Drug Administration who is required to file a public or confidential financial disclosure report pursuant to 5 CFR part 2634 shall not:
 - (i) Engage in any self-employed business activity for which the sale or promotion of FDA-regulated products is expected to constitute ten percent or more of annual gross sales or revenues; or
 - (ii) Engage in employment, as defined in 5 CFR 2635.603(a), whether or not for compensation, with a significantly regulated organization, as defined in § 5501.101(c)(2), unless the employment meets either of the following exceptions:
 - (A) The employment consists of the practice of medicine, dentistry, veterinary medicine, pharmacy, nursing, or similar practices, provided that the employment does not involve substantial unrelated non-professional duties, such as personnel management, contracting and purchasing responsibilities (other than normal "out-of-stock" requisitioning), and does not involve employment by a medical product manufacturer in the conduct of biomedical research; or
 - (B) The employment primarily involves manual or unskilled labor or utilizes talents, skills, or interests in areas unrelated to the substantive programmatic activities of the FDA, such as clerical work, retail sales, service industry jobs, building trades, maintenance, or similar services.
 - (4) *Prohibited outside practice of law applicable to attorneys in the Office of the General Counsel.*

- (i) An employee who serves as an attorney in or under the supervision of the Office of the General Counsel or the Office of Counsel to the Inspector General shall not engage in any outside practice of law that might require the attorney to:
 - (A) Assert a legal position that is or appears to be in conflict with the interests of the Department of Health and Human Services, the client to which the attorney owes a professional responsibility; or
 - (B) Interpret any statute, regulation or rule administered or issued by the Department.
 - (ii) *Exceptions.* Nothing in this section prevents an employee from:
 - (A) Acting, with or without compensation, as an agent or attorney for, or otherwise representing, the employee's parents, spouse, child, or any person for whom, or for any estate for which, the employee is serving as guardian, executor, administrator, trustee, or other personal fiduciary to the extent permitted by 18 U.S.C. 203 and 205, or from providing advice or counsel to such persons or estate; or
 - (B) Acting, without compensation, as an agent or attorney for, or otherwise representing, any person who is the subject of disciplinary, loyalty, or other personnel administration proceedings in connection with those proceedings to the extent permitted by 18 U.S.C. 205, or from providing uncompensated advice or counsel to such person; or
 - (C) Giving testimony under oath or from making statements required to be made under penalty for perjury or contempt.
 - (iii) *Specific approval procedures.*
 - (A) The exceptions to 18 U.S.C. 203 and 205 described in paragraph (c)(4)(ii)(A) of this section do not apply unless the employee obtained the approval of the Government official responsible for the appointment of the employee to a Federal position.
 - (B) The exception to 18 U.S.C. 205 described in paragraph (c)(4)(ii)(B) of this section does not apply unless the employee has obtained the approval of a supervisory official who has authority to determine whether the employee's proposed representation of another person in a personnel administration matter is consistent with the faithful performance of the employee's duties.
- (d) *Prior approval for outside employment and other outside activities—*
- (1) *General approval requirement.* Except as provided in paragraph (d)(3) of this section, an employee shall obtain written approval prior to engaging, with or without compensation, in outside employment, including self-employed business activities, or other outside activities in which the employee seeks to:
 - (i) Provide consultative or professional services, including service as an expert witness;
 - (ii) Engage in teaching, speaking, writing, or editing that:
 - (A) Relates to the employee's official duties within the meaning of 5 CFR 2635.807(a)(2)(i)(B) through (E); or
 - (B) Would be undertaken as a result of an invitation to engage in the activity that was extended to the employee by a person or organization that is a prohibited source within the meaning of 5 CFR 2635.203(d), as modified by the separate HHS component agency designations in § 5501.102; or
 - (iii) Provide services to a non-Federal entity as an officer, director, or board member, or as a member of a group, such as a planning commission, advisory council, editorial board, or scientific or technical advisory board or panel, which requires the provision of advice, counsel, or consultation.
 - (2) *Additional approval requirement for employees of the Food and Drug Administration and the National Institutes of Health.* In addition to the general approval requirements set forth in paragraph (d)(1) of this section, an employee of the Food and Drug Administration or the National Institutes of Health shall obtain written approval prior to engaging, with or without compensation, in any outside employment, as defined in 5 CFR 2635.603(a), with, or any self-

employed business activity involving the sale or promotion of products or services of, any person or organization that is a prohibited source of the employee's component agency.

(3) *Exceptions to prior approval requirements.*

- (i) Notwithstanding the requirements of paragraphs (d)(1) and (d)(2) of this section, prior approval is not required for participation in the activities of a political, religious, social, fraternal, or recreational organization unless:
 - (A) The activity or the position held in the organization requires the provision of professional services within the meaning of paragraph (b)(3) of this section; or
 - (B) The activity is performed for compensation other than the reimbursement of expenses.
- (ii) Notwithstanding the requirements of paragraphs (d)(1) and (d)(2) of this section, prior approval is not required for participation in an employment or other outside activity that has been exempted under paragraph (d)(7) of this section.

(4) *Submission of requests for approval.*

- (i) An employee seeking to engage in any of the activities for which advance approval is required shall make a written request for approval a reasonable time before beginning the activity. This request shall be directed to the employee's supervisor. The supervisor shall submit the request and a statement addressing the extent to which the employee's duties are related to the proposed outside activity to an agency designee, who shall make a final determination with respect to the request.
- (ii) All requests for prior approval shall include the following information:
 - (A) The employee's name, contact information, organizational location, occupational title, grade, step, salary, appointment type, and financial disclosure filing status;
 - (B) The nature of the proposed outside employment or other outside activity, including a full description of the specific duties or services to be performed;
 - (C) A description of the employee's official duties that relate to the proposed activity;
 - (D) A description of how the employee's official duties will affect the interests of the person for whom or organization with which the proposed activity will be performed;
 - (E) The name and address of the person for whom or organization with which the work or activity will be done, including the location where the services will be performed;
 - (F) A statement as to whether travel is involved and, if so, whether the transportation, lodging, meals, or per diem will be at the employee's expense or provided by the person for whom or organization with which the work or activity will be done, and a description of the arrangements and an estimate of the costs of items to be furnished or reimbursed by the outside entity;
 - (G) The estimated total time that will be devoted to the activity. If the proposed outside activity is to be performed on a continuing basis, a statement of the estimated number of hours per year; for other employment, a statement of the anticipated beginning and ending date;
 - (H) A statement as to whether the work can be performed entirely outside of the employee's regular duty hours and, if not, the estimated number of hours and type of leave that will be required;
 - (I) The method or basis of any compensation to be received (e.g., fee, honorarium, retainer, salary, advance, royalty, stock, stock options, non-travel related expenses, or other form of remuneration tendered in cash or in-kind in connection with the proposed activity) from the person for whom or organization with which the work or activity will be done;
 - (J) The amount of any compensation to be received from the person for whom or organization with which the work or activity will be done;
 - (K) The amount and date of any compensation received, or due for services performed, within the current and previous six calendar years immediately preceding the submission of the request for approval from the person for whom or organization

- with which the work or activity will be done (including any amount received or due from an agent, affiliate, parent, subsidiary, or predecessor of the proposed payor);
- (L) A statement as to whether the compensation is derived from an HHS grant, contract, cooperative agreement, or other source of HHS funding or attributed to services related to an activity funded by HHS, regardless of the specific source of the compensation;
 - (M) For activities involving the provision of consultative or professional services, a statement indicating whether the client, employer, or other person on whose behalf the services are performed is receiving, or intends to seek, an HHS grant, contract, cooperative agreement, or other funding relationship;
 - (N) For activities involving teaching, speaking, or writing, a syllabus, outline, summary, synopsis, draft or similar description of the content and subject matter involved in the course, speech, or written product (including, if available, a copy of the text of any speech) and the proposed text of any disclaimer required by 5 CFR 2635.807(b)(2) or by the instructions or manual issuances authorized under paragraph (d)(6) of this section; and
 - (O) Such other relevant information that the designated agency ethics official or, with the concurrence of the designated agency ethics official, each of the separate agency components of HHS listed in § 5501.102(a) determines is necessary or appropriate in order to evaluate whether a proposed activity is likely to involve conduct prohibited by statute or Federal regulations, including 5 CFR part 2635 and this part.
- (5) **Standard for approval.** Approval shall be granted only upon a determination that the outside employment or other outside activity is not expected to involve conduct prohibited by statute or Federal regulation, including 5 CFR part 2635 and this part.

NOTE: The granting of approval for an outside activity does not relieve the employee of the obligation to abide by all applicable laws governing employee conduct nor does approval constitute a sanction of any violation. Approval involves an assessment that the general activity as described on the submission does not appear likely to violate any criminal statutes or other ethics rules. Employees are reminded that during the course of an otherwise approvable activity, situations may arise, or actions may be contemplated, that, nevertheless, pose ethical concerns.

Example 1: A clerical employee with a degree in library science volunteers to work on the acquisitions committee at a local public library. Serving on a panel that renders advice to a non-Federal entity is subject to prior approval. Because recommending books for the library collection normally would not pose a conflict with the typing duties assigned the employee, the request would be approved.

Example 2: While serving on the library acquisitions committee, the clerical employee in the preceding example is asked to help the library business office locate a missing book order. Shipment of the order is delayed because the publisher has declared bankruptcy and its assets, including inventory in the warehouse, have been frozen to satisfy the claims of the Internal Revenue Service and other creditors. The employee may not contact the Federal bankruptcy trustee to seek, on behalf of the public library, the release of the books. Even though the employee's service on the acquisitions committee had been approved, a criminal statute, 18 U.S.C. 205, would preclude any representation by a Federal employee of an outside entity before a Federal court or agency with respect to a matter in which the United States is a party or has a direct and substantial interest.

- (6) **Duration of approval.** Approval shall be effective for a period not to exceed one year from the date of approval. Upon a significant change in the nature of the outside activity or in the employee's official position or duties, the employee shall submit a revised request for approval using the procedure in paragraph (d)(4) of this section. If the outside activity is anticipated to

exceed one year from the date of the most recent approval, the employee shall renew the request for approval no later than thirty days prior to the expiration of the period authorized.

(7) *Responsibilities of the designated agency ethics official and component agencies.*

- (i) The designated agency ethics official or, with the concurrence of the designated agency ethics official, each of the separate agency components of HHS listed in § 5501.102 may issue an instruction or manual issuance exempting categories of employment or other outside activities from a requirement of prior written approval based on a determination that the employment or activities within those categories would generally be approved and are not likely to involve conduct prohibited by statute or Federal regulations, including 5 CFR part 2635 and this part.
- (ii) HHS components may specify internal procedures governing the submission of prior approval requests and designate appropriate officials to act on such requests. The instructions or manual issuances may include examples of outside employment and other outside activities that are permissible or impermissible consistent with 5 CFR part 2635 and this part. With respect to teaching, speaking, writing, or editing activities, the instructions or manual issuances may specify preclearance procedures and/or require disclaimers indicating that the views expressed do not necessarily represent the views of the agency or the United States.
- (iii) The officials within the respective HHS components who are responsible for the administrative aspects of these regulations and the maintenance of records shall make provisions for the filing and retention of requests for approval of outside employment and other outside activities and copies of the notification of approval or disapproval.

- (e) *Waivers.* The designated agency ethics official may grant a written waiver, for an individual or class of similarly situated individuals, from any prohibited outside activity provision in this section or in § 5501.109 based on a determination that the waiver is not inconsistent with part 2635 of this title or otherwise prohibited by law and that, under the particular circumstances, application of the prohibition is not necessary to avoid the appearance of misuse of position or loss of impartiality or otherwise to ensure confidence in the impartiality and objectivity with which agency programs are administered. An individual or class waiver under this paragraph may impose appropriate conditions, such as requiring execution of a written disqualification.

§ 5501.107 Teaching, speaking and writing by special Government employees in the Public Health Service.

- (a) *Applicability.* This section applies to special Government employees in the Public Health Service who otherwise are prohibited from accepting compensation for teaching, speaking or writing that is related to their official duties, within the meaning of 5 CFR 2635.807(a)(2)(i)(C), because the invitation or the offer of compensation for the activity was extended at a time when the special Government employee was assigned to perform official duties that may substantially affect the interests of the inviter or offeror.
- (b) *Permissible compensation.* A special Government employee may accept compensation for teaching, speaking or writing in circumstances described in paragraph (a) of this section only where the special Government employee recuses from the official assignment that may substantially affect the interests of the person who extended the invitation to engage in the activity or the offer of compensation.

§ 5501.108 Exception to the prohibition against assisting in the prosecution of claims against, or acting as an agent or attorney before, the Government, applicable only to employees assigned to federally recognized Indian tribes or Alaska Native villages or regional or village corporations pursuant to the Intergovernmental Personnel Act.

- (a) *18 U.S.C. 205.* Section 205 of title 18 of the United States Code prohibits an employee, whether or not for compensation, from acting as an agent or attorney for anyone in a claim against the United States, or from acting in such capacity on behalf of another before any department, agency, or other specified entity, in any particular matter in which the United States is a party or has a direct and substantial interest.
- (b) *Exception applicable only to employees assigned to federally recognized Indian tribes or Alaska Native villages or regional or village corporations pursuant to the Intergovernmental Personnel Act.* Notwithstanding the provisions of 18 U.S.C. 205, the Indian Self-Determination Act (25 U.S.C. 450i(f)) authorizes Federal employees detailed or assigned to Indian tribes or Alaska Native villages or regional or village corporations, pursuant to the Intergovernmental Personnel Act (5 U.S.C. 3372), to act as agents or attorneys for, or appear on behalf of, such tribes or Alaska Native villages or corporations in connection with any matter pending before any department, agency, court, or commission, in which the United States is a party or has a direct and substantial interest. Such employees must advise, in writing, the head of the agency, with which they are dealing on behalf of an Indian tribe or Alaska Native village or corporation, of any personal and substantial involvement they may have had as an officer or employee of the United States in connection with the matter concerned.

§ 5501.109 Prohibited outside activities applicable to employees of the National Institutes of Health.

- (a) *Applicability.* This section does not apply to special Government employees.
- (b) *Definitions.* For purposes of this section:
 - (1) *Compensation* has the meaning set forth in 5 CFR 2635.807(a)(2)(iii).
 - (2) *Continuing professional education* means a course, a program, a series of courses or programs, or other educational activity provided to members of a profession, as defined in 5 CFR 2636.305(b)(1), or academic discipline and designed principally to maintain or advance the skills and competence of practitioners in a field of specialized knowledge and to expand an appreciation and understanding of the professional responsibilities, fiduciary obligations, or ethical aspirations incumbent upon members of the group. For those members of a profession or academic discipline that does not subject its members to licensure or continuing education requirements, the term continuing professional education includes those educational activities that exemplify a purpose and content similar to those offered to or required of members of a licensed profession.
 - (3) *Data and safety monitoring board (DSMB)* means a board, committee, or panel constituted in connection with an ongoing clinical study and comprised of individuals, other than the study sponsors, organizers, and investigators, who possess expertise in relevant specialties and disciplines, such as trial design, biostatistics, and bioethics, and who review accumulating safety and outcome data in order to ensure the continuing safety of the participating human subjects and of those yet to be recruited, and to assess the continuing validity and scientific merit of the investigation.
 - (4) *Educational activity provider* means a supported research institution or a health care provider or insurer that presents Grand Rounds or offers accredited continuing professional education (or, in the case of a profession or academic discipline whose members are not subject to

licensure and which does not have program accreditation requirements, an education program determined by the designated agency ethics official or his designee or, in consultation with the designated agency ethics official or his designee, the NIH Director or the NIH Director's designee to be substantially equivalent to an accredited continuing professional education program), but does not include a substantially affected organization.

- (5) *Employment* has the meaning specified in 5 CFR 2635.603(a).
- (6) *Grand Rounds* means a regularly scheduled, interactive presentation or series of educational seminars that focus on clinical cases, recent biomedical or behavioral research results, or a review of scientific research methods and findings in a specific field, with supporting basic and clinical science information, that are conducted in an accredited medical school or an affiliated teaching hospital setting that provides practicing physicians, faculty, fellows, resident physician trainees, medical students, graduate students, and post-doctoral fellows, as well as allied and associated health professionals, and other staff, an opportunity to evaluate outcomes of patient treatment decisions, a forum to discuss clinical decision making, and a means to impart updates in diagnosis, treatment, therapy, and research as indicated by the context of the cases presented.
- (7) *Grant or scientific review committee* means a board, committee, or panel of qualified experts assembled by an external grant-making entity or other funding institution for the purpose of making a funding decision, the members of which review, evaluate, rate, rank, or otherwise assess a proposed or ongoing project or program for which grant support is sought on the basis of various factors, such as scientific merit, feasibility, significance, approach, and originality (and scientific progress in any previous period of funding), and gauge the ability of the applicant(s), principal and associate investigators, and scientific team members to complete successfully the project or program, and then recommend to the grantor whether to fund or continue to fund a particular proposal or ongoing program.
- (8) *Health care provider or insurer* means a hospital, clinic, skilled nursing facility, rehabilitation facility, durable medical equipment supplier, home health agency, hospice program, health maintenance organization, managed care organization, or other provider of health care items and services as defined in sections 1877(h)(6) or 1903(w)(7) of the Social Security Act (42 U.S.C. 1395nn(h)(6) or 1396b(w)(7)) and any entity organized and licensed as a risk-bearing entity eligible to offer health insurance or health benefits coverage.
- (9) *Scientific peer review* is the evaluation of scientific research findings for competence, significance, and originality by qualified experts who research and submit work for publication in the same field and which provides systematized accountability for adherence to ethical guidelines commonly accepted within the relevant research community for disseminating scientific information.
- (10) *Substantially affected organization* means:
 - (i) A biotechnology or pharmaceutical company; a medical device manufacturer; or a corporation, partnership, or other enterprise or entity significantly involved, directly or through subsidiaries, in the research, development, or manufacture of biotechnological, biostatistical, pharmaceutical, or medical devices, equipment, preparations, treatments, or products;
 - (ii) Any organization a majority of whose members are described in paragraph (b)(10)(i) of this section; and
 - (iii) Any other organization determined by the designated agency ethics official or, in consultation with the designated agency ethics official, by the NIH Director or the NIH Director's designee that is substantially affected by the programs, policies, or operations of the NIH.
- (11) *Supported research institution* means any educational institution or non-profit independent research institute that:
 - (i) Is, or within the last year has been, an applicant for or recipient of an NIH grant, cooperative agreement, or research and development contract;

- (ii) Is, or within the last year has been, a proposer of or party to a cooperative research and development agreement (CRADA) with the NIH; or
 - (iii) Any organization a majority of whose members are described in paragraphs (b)(11)(i) or (ii) of this section.
- (12) *Unrestricted educational grant* means funds received by or available to an educational activity provider from another source that are granted without stipulated conditions for their use other than the limitation that the funds shall be used to advance an educational program of the grant recipient. For purposes of this section, an educational grant shall not be considered unrestricted if the funding source for a continuing professional education program directly or indirectly:
- (i) Selects or recommends the moderators, speakers, or presenters at the sponsored event;
 - (ii) Independently provides additional funding to the moderators, speakers, or presenters in connection with the educational activity;
 - (iii) Determines or recommends the audience composition;
 - (iv) Specifies or recommends the topics to be addressed, or
 - (v) Controls or recommends the planning, content, or implementation of the program in a manner inconsistent with guidelines established by a relevant professional association or accrediting organization that are designed to ensure that such activities are accurate, balanced, educational, free from commercial bias, nonpromotional, and independent of the influence of the funding source.
- (13) *Unrestricted financial contribution* means funds received by or available to a publisher, academic press, editorial board, or other entity affiliated with or operated by a supported research institution or a health care provider or insurer from another source that are provided without stipulated conditions for their use other than the limitation that the funds shall be used to advance peer-reviewed writing or editing by the funds recipient. For purposes of this section, a financial contribution shall not be considered unrestricted if the funding source for peer-reviewed writing or editing directly or indirectly:
- (i) Selects or recommends the author, reviewer, referee, or editor;
 - (ii) Independently provides additional funding to the author, reviewer, referee, or editor in connection with the writing or editing activity;
 - (iii) Determines or recommends the targeted audience of the writing or editing activity;
 - (iv) Specifies or recommends the topics to be addressed, or
 - (v) Controls or recommends the planning, content, or distribution of the written or edited product in a manner inconsistent with ethical guidelines commonly accepted within the relevant research community for disseminating scientific information which are designed to ensure that such writing or editing is accurate, unbiased, nonpromotional, transparent with respect to disclosure of potential conflicts, and independent of the influence of the funding source.

(c) *Prohibitions—*

- (1) *Prohibited outside activities with substantially affected organizations, supported research institutions, and health care providers or insurers.* Except as permitted by paragraph (c)(3) of this section, an employee of the NIH shall not:
- (i) Engage in employment with a substantially affected organization, a supported research institution, or a health care provider or insurer;
 - (ii) Teach, speak, write, or edit for compensation for any substantially affected organization, supported research institution, or health care provider or insurer; or
 - (iii) Engage in any employment or self-employed business activity that involves the sale or promotion of products or services of a substantially affected organization or a health care provider or insurer, except for the purpose of commercializing invention rights obtained by the employee pursuant to Executive Order 10096, 15 U.S.C. 3710d, or implementing regulations.

- (2) *General exception.* Nothing in paragraph (c)(1) of this section prevents an employee from engaging in employment with, or teaching, speaking, writing, or editing for, a political, religious, social, fraternal, or recreational organization.
- (3) *Specific exceptions.* Notwithstanding the prohibitions in paragraph (c)(1) of this section:
- (i) *Teaching.* An employee may engage in and accept compensation for:
 - (A) Teaching a course requiring multiple presentations as permitted under 5 CFR 2635.807(a)(3); or
 - (B) Delivering a class lecture that is unrelated to the employee's official duties within the meaning of 5 CFR 2635.807 if the activity is performed as part of a regularly scheduled course offered under the established curriculum of an institution of higher education as defined at 20 U.S.C. 1001.
 - (ii) *Clinical, medical, or health-related professional practice.* An employee may engage in and accept compensation for the outside practice of medicine, dentistry, pharmacy, nursing, or similar health-related professional practice that involves the personal provision of care, treatment, or other health-related professional services to or in connection with individual patients, provided that:
 - (A) The provision of health-related professional services to such individuals is not part of any ongoing research project conducted or funded by the NIH;
 - (B) The employee does not establish a private practice relationship with a current or recently discharged NIH patient or subject of an NIH-conducted or NIH-funded clinical trial or protocol;
 - (C) The employee does not personally refer private practice patients to the NIH; and
 - (D) The professional practice does not involve substantial unrelated non-professional duties, such as personnel management, contracting and purchasing responsibilities (other than "out-of-stock" requisitioning), and does not involve employment by a medical product manufacturer in the conduct of biomedical research.
 - (iii) *Clerical, retail, service industry, building trades, maintenance, or similar services.* An employee may engage in and accept compensation for any outside employment or self-employed business activity that primarily involves manual or unskilled labor or utilizes talents, skills, or interests in areas unrelated to the health and scientific research activities of the NIH, such as clerical work, retail sales, service industry jobs, building trades, maintenance, or similar services.
 - (iv) *Continuing professional education.* An employee may engage in and accept compensation for a teaching, speaking, writing, or editing activity that is unrelated to the employee's official duties within the meaning of 5 CFR 2635.807 if the activity is performed as part of a continuing professional education program conducted by an educational activity provider. If a substantially affected organization provides financial support for a continuing professional education program conducted by an educational activity provider, this exception is inapplicable unless the substantially affected organization is involved only as the funding source for an unrestricted educational grant.
 - (v) *Authorship of writings subjected to scientific peer review or a substantially equivalent editorial review process.* An employee may engage in and accept compensation for a writing or editing activity that is unrelated to the employee's official duties within the meaning of 5 CFR 2635.807 if the resulting article, chapter, essay, report, text, or other writing is submitted to a publisher, academic press, editorial board, or other entity affiliated with or operated by a supported research institution or a health care provider or insurer for publication in a scientific journal, textbook, or similar publication that subjects manuscripts to scientific peer review or a substantially equivalent editorial review process. If a substantially affected organization funds the publishing activities of a supported research institution or a health care provider or insurer, this exception is inapplicable unless the substantially affected organization is involved only as an unrestricted financial contributor and exercises no editorial control.

- (vi) *Data and safety monitoring boards.* An employee may serve as a member of a data and safety monitoring board for a clinical study conducted by a supported research institution or health care provider or insurer, provided that:
 - (A) The members of the DSMB are not selected or paid for their service by a substantially affected organization;
 - (B) The clinical study is not funded under a grant, cooperative agreement, or research and development contract from, or conducted pursuant to a cooperative research and development agreement (CRADA) with, or aided under another funding mechanism by, the NIH; and
 - (C) If the service is performed for compensation, the service does not entail prohibited assistance in the preparation of documents intended for submission to HHS within the meaning of § 5501.106(c)(1), and the clinical study is not an HHS-funded activity described in § 5501.106(c)(2).
- (vii) *Grand Rounds.* An employee may engage in and accept compensation for a teaching, speaking, writing, or editing activity that is unrelated to the employee's official duties within the meaning of 5 CFR 2635.807 if the activity is performed as part of a Grand Rounds program conducted by an accredited educational institution offering instruction in the life sciences, such as a medical school or school of public health, or by an affiliated teaching hospital, provided that:
 - (A) The employee's presentation includes an interactive component, such as visiting patients or discussing individual clinical cases, or interacting for educational purposes with undergraduates, graduates, or post-graduate students and fellows, in addition to any lecture;
 - (B) The audience is composed primarily of faculty and students or trainees registered in a biomedical or health-related program of studies; and
 - (C) A substantially affected organization or a speakers' bureau affiliated with a substantially affected organization does not sponsor or underwrite the costs of the Grand Rounds program or the employee's presentation, except pursuant to an unrestricted educational grant.
- (viii) *Grant or scientific review committee.* An employee may serve on a grant or scientific review committee for a supported research institution or a health care provider or insurer, provided that:
 - (A) The members of the grant or scientific review committee are not selected or paid for their service by a substantially affected organization;
 - (B) The grant award or program in relation to which the recommendation of the grant or scientific review committee is sought is not funded under a grant, cooperative agreement, or research and development contract from, conducted pursuant to a cooperative research and development agreement (CRADA) with, or aided under another funding mechanism by, the NIH; and
 - (C) If the service is performed for compensation, the service does not entail prohibited assistance in the preparation of documents intended for submission to HHS within the meaning of § 5501.106(c)(1), and the grant award or program in relation to which the recommendation of the grant or scientific review committee is sought is not an HHS-funded activity described in § 5501.106(c)(2).

§ 5501.110 Prohibited financial interests applicable to senior employees of the National Institutes of Health.

- (a) *Applicability.* This section does not apply to special Government employees or the spouse or minor children of a special Government employee.

(b) **Definitions.** For purposes of this section:

- (1) **Senior employee** means the Director and the Deputy Director of the National Institutes of Health; members of the senior staff within the Office of the Director who report directly to the NIH Director; the Directors, the Deputy Directors, Scientific Directors, and Clinical Directors of each Institute and Center within NIH; Extramural Program Officials who report directly to an Institute or Center Director; and any employee of equivalent levels of decision-making responsibility who is designated as a senior employee by the designated agency ethics official or the NIH Director, in consultation with the designated agency ethics official.
- (2) **Substantially affected organization** has the meaning set forth in § 5501.109(b)(10).

(c) **Prohibition applicable to senior employees.** Except as permitted by paragraph (d) of this section, a senior employee or the spouse or minor child of such senior employee shall not have a financial interest in a substantially affected organization.

(d) **Exceptions for certain financial interests.** Notwithstanding the prohibition in paragraph (c) of this section:

- (1) **Pension or other employee benefit.** A senior employee or spouse or minor child of a senior employee may have a financial interest, such as a pension or other employee benefit, arising from employment with a substantially affected organization.

NOTE TO PARAGRAPH (d)(1): NIH employees, as opposed to spouses and minor children of employees, are generally prohibited under § 5501.109 from engaging in current employment with a substantially affected organization.

- (2) **De minimis holdings.** A senior employee or spouse or minor child of a senior employee may have a financial interest in a substantially affected organization if:
 - (i) The aggregate market value of the combined interests of the senior employee and the senior employee's spouse and minor children in any one substantially affected organization is equal to or less than the *de minimis* exemption limit for matters involving parties established by 5 CFR 2640.202(a) or \$15,000, whichever is greater;
 - (ii) The holding, if it represents an equity interest, constitutes less than 1 percent of the total outstanding equity of the organization; and
 - (iii) The total holdings in substantially affected organizations and sector mutual funds that, in the literature they distribute to prospective and current investors or participants, state the objective or practice of concentrating their investments in the securities of substantially affected organizations account for less than 50 percent of the total value of the combined investment portfolios of the senior employee and the senior employee's spouse and minor children.
- (3) **Diversified mutual funds.** A senior employee or spouse or minor child of a senior employee may have an interest in a substantially affected organization that constitutes any interest in a publicly traded or publicly available investment fund (e.g., a mutual fund), or a widely held pension or similar fund, which, in the literature it distributes to prospective and current investors or participants, does not indicate the objective or practice of concentrating its investments in substantially affected organizations, if the employee neither exercises control nor has the ability to exercise control over the financial interests held in the fund.
- (4) **Exceptional circumstances.** In cases involving exceptional circumstances, the NIH Director or the NIH Director's designee, with the approval of the designated agency ethics official or his designee, may grant a written exception to permit a senior employee, or the spouse or minor child of a senior employee, or a class of such individuals, to hold a financial interest in a substantially affected organization based upon a determination that the application of the prohibition in paragraph (c) of this section is not necessary to ensure public confidence in the

impartiality or objectivity with which HHS programs are administered or to avoid a violation of part 2635 of this title.

- (5) *Technology transfer.* A senior employee may have a financial interest in connection with the development and commercialization of invention rights obtained by the employee pursuant to Executive Order 10096, 15 U.S.C. 3710d, or implementing regulations.
- (6) *Sector mutual funds.*
 - (i) A senior employee or spouse or minor child of a senior employee may have an interest in a substantially affected organization that constitutes any interest in a sector mutual fund that, in the literature it distributes to prospective and current investors or participants, does not indicate the objective or practice of concentrating its investments in the biomedical science, pharmaceutical, medical device, biotechnology, or health industry sectors.
 - (ii) A senior employee or spouse or minor child of a senior employee may have an interest in a substantially affected organization that constitutes any interest in a sector mutual fund that, in the literature it distributes to prospective and current investors or participants, states the objective or practice of concentrating its investments in the securities of substantially affected organizations provided that:
 - (A) The aggregate market value of the combined ownership interests of the senior employee and the senior employee's spouse and minor children in such sector funds is equal to or less than the *de minimis* exemption limit for sector mutual funds established by 5 CFR 2640.201(b)(2)(i) or \$50,000, whichever is greater; and
 - (B) The total holdings in substantially affected organizations and in sector mutual funds that, in the literature they distribute to prospective and current investors or participants, state the objective or practice of concentrating their investments in the securities of substantially affected organizations account for less than 50 percent of the total value of the combined investment portfolios of the senior employee and the senior employee's spouse and minor children.

NOTE TO PARAGRAPH (d): With respect to any excepted financial interest, employees are reminded of their obligations under 5 CFR part 2635, and specifically their obligation under subpart D to disqualify themselves from participating in any particular matter in which they, their spouses or minor children have a financial interest arising from publicly traded securities that exceeds the *de minimis* thresholds specified in the regulatory exemption at 5 CFR 2640.202 or from non-publicly traded securities that are not covered by the regulatory exemption. Furthermore, the agency may prohibit or restrict an individual employee from acquiring or holding any financial interest or a class of financial interests based on the agency's determination that the interest creates a substantial conflict with the employee's duties, within the meaning of 5 CFR 2635.403.

- (e) *Reporting and divestiture.* For purposes of determining the divestiture period specified in 5 CFR 2635.403(d), as applied to financial interests prohibited under paragraph (c) of this section, the "date divestiture is first directed" means the date on which the new entrant public or confidential financial disclosure report required by part 2634 of this title or any report required by § 5502.107(c) of this chapter is due.

§ 5501.111 Awards tendered to employees of the National Institutes of Health.

- (a) *Applicability.* This section does not apply to special Government employees.
- (b) *Definitions.* For purposes of this section, *official responsibility* has the meaning set forth in 18 U.S.C. 202(b).

- (c) *Additional limitations on awards to employees of the National Institutes of Health.* The following limitations shall apply to the acceptance by an employee of an award pursuant to 5 CFR 2635.204(d):
- (1) *Limitations applicable to employees with official responsibility for matters affecting an award donor.* An employee shall not accept a gift with an aggregate market value of more than \$200, or that is cash or an investment interest, that is an award or incident to an award from a person, organization, or other donor that:
 - (i) Is seeking official action from the employee, any subordinate of the employee, or any agency component or subcomponent under the employee's official responsibility;
 - (ii) Does business or seeks to do business with any agency component or subcomponent under the employee's official responsibility;
 - (iii) Conducts activities substantially affected by the programs, policies, or operations of any agency component or subcomponent under the employee's official responsibility; or
 - (iv) Is an organization a majority of whose members are described in paragraphs (c)(1)(i) through (iii) of this section.
 - (2) *Prior approval of awards.—*
 - (i) No employee shall accept an award under 5 CFR 2635.204(d) or this section unless the receipt thereof has been approved in writing in advance in accordance with procedures specified by the designated agency ethics official, or with the concurrence of the designated agency ethics official, the NIH Director or the NIH Director's designee.
 - (ii) Approval shall be granted only upon a determination that acceptance of the award is not prohibited by statute or Federal regulation, including 5 CFR part 2635 and this part.

NOTE TO PARAGRAPH (c): In some circumstances cash and other things of value provided in connection with the provision of personal services, including speaking or writing, may be compensation, not a gift. Other ethics rules governing outside activities may restrict receipt of such compensation. See, for example, 5 CFR 2635.807.

- (d) *Exception.* Notwithstanding the prohibition in paragraph (c)(1) of this section, the NIH Director (or the Secretary, with respect to awards tendered to the NIH Director), with the approval of the designated agency ethics official, may grant a written exception to permit an employee to accept an award otherwise prohibited by this section under the following conditions:
- (1) There is a determination by the NIH Director (or the Secretary, with respect to awards tendered to the NIH Director) that acceptance of the gift will further an agency interest because it confers an exceptionally high honor in the fields of medicine or scientific research. The following criteria will be considered in making such a determination:
 - (i) The identity of the awarding organization;
 - (ii) The longevity of the awards program;
 - (iii) The source of award funds;
 - (iv) The size of the monetary component of the award recognition;
 - (v) The identity and credentials of past award recipients;
 - (vi) The degree of publicity attendant to receipt of the award; and
 - (vii) The impact of the substantive contribution being recognized;
 - (2) Absent the prohibition in paragraph (c)(1) of this section, the gift would be permitted under part 2635 of this title; and
 - (3) The designated agency ethics official shall have determined that the application of the prohibition in paragraph (c)(1) of this section is not necessary to ensure public confidence in the impartiality or objectivity with which NIH programs are administered or to avoid a violation of part 2635 of this title.
- (e) *Disposition of improperly accepted awards—*
- (1) *Failure to obtain prior approval.* If an employee accepts an award for which approval is required under paragraph (c)(2) of this section without obtaining such approval, the employee may be

required, in addition to any penalty provided by law and applicable regulations, to forfeit the award by returning it to the donor.

- (2) *Receipt of prohibited award.* If an employee accepts an award prohibited by paragraph (c)(1) of this section, the employee shall be required, in addition to any penalty provided by law and applicable regulations, to:
- (i) Reject the award and instruct the donor to strike the honoree's name from any list of award recipients;
 - (ii) Remove the recognition from the employee's résumé or curriculum vitae;
 - (iii) Return any tangible indicia of the recognition to the donor; and
 - (iv) Forfeit the award by returning it to the donor.

§ 5501.112 One-year disqualification of employees of the National Institutes of Health from certain matters involving an award donor.

An employee, other than a special Government employee, of the National Institutes of Health who has, within the last year, accepted an award permitted under 5 CFR 2635.204(d) or § 5501.111 shall not participate in any particular matter involving specific parties in which the donor is or represents a party unless authorized to do so under 5 CFR 2635.502(d).

Prepared by HHS/OGC/ED; 8/31/05
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Special General Memorandum 95-4



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Indian Health Service
Rockville MD 20857

SGM 95-4

JUN 1, 1995

TO: Indian Health Service Employees
FROM: Director
SUBJECT: Workplace Violence

I am fully committed to ensuring that the work environment for all Indian Health Service (IHS) employees is healthy, safe, and secure from acts or threats of violence. To accomplish this, I am establishing a zero tolerance policy on Workplace Violence (WPV) that applies equally to the behavior of all employees, contractors and others with whom we work.

Our work environment must be free from all forms of violence and acts of intimidation, including harassment, threats, altercations, or assault. You are reminded that such conduct by IHS employees will not be tolerated and known incidents should be reported immediately to management officials. I expect all employees to act in a manner that is respectful and courteous to the public, as well as to fellow employees.

The IHS is not a high-risk environment for WPV, but this Agency is not immune. Many of us work in environments where the risks for violence may be higher than in the traditional office setting. I have taken this position to heighten awareness and to assist in the prevention of violent incidents at all IHS facilities. To enforce this policy through Agency management officials, staff who commit or threaten violent acts or acts of intimidation in the workplace will be subject to governing policies and procedures for addressing employee misconduct. In addition, if warranted, misconduct will be referred to local police and legal authorities for possible action.

Agency collective bargaining officials (CBO) must provide a copy of this memorandum to unions and meet existing bargaining unit obligations before implementing WPV policy. I encourage CBOs to meet with existing bargaining unit representatives to develop a strong labor-management partnership to prevent WPV.

I urge you to join me and your co-workers in actively creating and supporting a work environment that is safe, supportive, and free from WPV. These are difficult and stressful times for many of us, so awareness and early intervention are critical steps in the prevention process. If you have any questions or need assistance, please contact your local human resources staff.

/Michael Trujillo, MD, MPH/
Michael H. Trujillo, M.D., M.P.H.
Assistant Surgeon General



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health
Service

Memorandum

Received
JUN 16 1995

JUN 12, 1995

FROM: Assistant Secretary for Health
SUBJECT: Violence in the Workplace
TO: PHS Agency Heads
Acting Surgeon General
Deputy Assistant Secretaries for Health
PHS Agency Executive Officers
PHS Staff Office Directors
PHS Regional Health Administrators

The news media remind us almost daily that we live in an environment that is becoming increasingly more violent. Many of our employees have been exposed to violence or threats of violence in their daily lives, and a significant number are concerned about the potential for violence in the workplace. For these reasons, I believe it is important to set forth PHS policy on this subject.

Employees shall be protected as fully as possible from assaults, threats, intimidation, and harassment while at the work site. Thus, it is essential that we make clear to all PHS employees that violence, threats of violence, intimidating and otherwise similar disruptive behavior are unacceptable conduct that will not be tolerated. This policy also applies to contractors who are not employees but who work in PHS facilities.

In order to minimize the potential for violence in the workplace and to ensure that prompt corrective action can be taken when it does occur, anyone working in PHS facilities, who witnesses or becomes aware of threats or acts of violence from any source must immediately report what he/she has observed or learned to appropriate agency officials, as set forth below, and/or law enforcement authorities. Employees are also expected to cooperate fully in any subsequent investigations. We do not want employees to place themselves at unnecessary personal risk in dangerous situations; however, we expect them to make immediate contact with an agency official who can respond appropriately, such as a supervisor, security officer, EEO or human resource officials.

In turn, officials receiving these reports are required to immediately and appropriately act upon them.

If anyone observes a violent act or a threat posing imminent danger, his/her immediate response should be to call 911. Immediately thereafter, he/she should inform his/her supervisor and the appropriate security office.

Please distribute the attached policy statement to all employees in your organization and ensure that the issue of workplace violence and this policy are discussed in staff meetings so that any questions or concerns about implementation of the policy can be promptly addressed. The implementation of a comprehensive PHS Workplace Violence Prevention Program is a priority for me, and all employees, supervisors and managers are expected to support this initiative on a continuing basis. A PHS task

force, comprised of representatives of a variety of disciplines from all PHS agencies, has been convened for this purpose. The task force will develop a plan of action to address this critical issue in detail.

Our intention is to make the workplace safe where dignity, respect, and fairness are basic human rights. PHS employees, who commit or threaten to commit violent acts or acts of intimidation against anyone in the workplace, will be disciplined in accordance with governing policies and procedures for addressing employee misconduct and/or referred for action as appropriate under local and state law.

Collective Bargaining Officials should provide a copy of the PHS policy statement and this memorandum to recognized unions. Any obligation to negotiate must be satisfied before distributing or implementing the policy within existing bargaining units.

/Phillip R. Lee/
Phillip R. Lee, M.D.

Attachment

U.S. PUBLIC HEALTH SERVICE POLICY STATEMENT ON VIOLENCE IN THE WORKPLACE

Threatening, intimidating, violent or similar disruptive behavior in the workplace is unacceptable conduct. It is the policy of the Public Health Service (PHS) that there will be zero tolerance for such acts. PHS will take appropriate action necessary to ensure that every employee has a work environment: free from threatening behavior and violence.

Date: JUN 12 1995

/Phillip R. Lee/
Phillip R. Lee, M.D.
Assistant Secretary for Health

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