

**§ 5301.105**

**5 CFR Ch. XLIII (1–1–04 Edition)**

particular matter, as defined in 5 CFR 2635.402(b)(3).

(2) A Member of the National Science Board may not receive compensation from any award made while serving on the Board. However, unless prohibited by law, an award may be charged, and a Member may be reimbursed, for actual expenses incurred by the Member

in doing work supported by the award. If a Member was an investigator or consultant under an award before appointment to the Board, the award may be charged and the Member may continue to receive compensation to the extent established before the Member's nomination.

## CHAPTER XLV—DEPARTMENT OF HEALTH AND HUMAN SERVICES

---

<i>Part</i>		<i>Page</i>
5501	Supplemental standards of ethical conduct for employees of the Department of Health and Human Services .....	753



**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 and the Office of the Chief Counsel.
- 5501.105 Exemption for otherwise disqualifying financial interests derived from Indian or Alaska Native birthrights.
- 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.

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, 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 part 2635 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 solely in fields 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 thirteen components of HHS listed below is designated as an agency separate from each of the other twelve 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;

§ 5501.103

5 CFR Ch. XLV (1–1–04 Edition)

(2) Administration for Children and Families;

(3) Agency for Health Care Policy and Research;

(4) Agency for Toxic Substances and Disease Registry;

(5) Centers for Disease Control and Prevention;

(6) Food and Drug Administration;

(7) Health Care Financing Administration;

(8) Health Resources and Services Administration;

(9) Indian Health Service;

(10) National Institutes of Health;

(11) Office of Consumer Affairs;

(12) Program Support Center; and

(13) Substance Abuse and Mental Health Services Administration.

(b) *Definition*—(1) *Employee of a component* includes, in addition to employees actually within a component, an employee in a division or region of the Office of the General Counsel that principally advises or represents that component.

(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 13 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

(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 or crafts 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 non-performance 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 and the Office of the Chief Counsel.**

(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 or of the Office of the Chief Counsel 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 hold a pension arising from 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 was \$5,000 or less;

(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: 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. 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.

**§ 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 and the Office of the Chief Counsel.* An employee of the Food and Drug Administration or the Office of the Chief Counsel 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 is limited to clerical or similar services (such as cashier or janitorial services) in retail stores, such as supermarkets, drug stores, or department stores.

(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 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 to the extent that an employment or other activity has been exempted under paragraph (d)(5) of this section, an employee shall obtain written approval prior to engaging, with or without compensation, in the following outside employment or activities:

(i) Providing consultative or professional services, including service as an expert witness.

(ii) Engaging 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 who is a prohibited source within the meaning of 5 CFR 2635.203(d), as modified by § 5501.102.

(iii) Providing 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, unless the service is provided without compensation other than reimbursement of expenses to a political, religious, social, fraternal, or recreational organization and the position held does not require the provision of professional services within the meaning of paragraph (b)(3) of this section.

(2) *Additional approval requirement for employees of the Food and Drug Administration and the Office of the Chief Counsel.*

(i) 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 Office of the Chief Counsel shall obtain written approval prior to engaging in any outside employment, as defined in 5 CFR 2635.603(a), whether or not for compensation, or any self-employed business activity.

(ii) The requirement of paragraph (d)(2)(i) of this section does not apply to participation in the activities of a political, religious, social, fraternal, or recreational organization, unless the position held requires the provision of professional services or is performed for compensation other than the reimbursement of expenses.

(iii) The requirement of paragraph (d)(2)(i) of this section shall not apply to the extent that an employment activity has been exempted, pursuant to paragraph (d)(5) of this section.

(3) *Submission of requests for approval.* 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 should be directed to the employee's supervisor who will forward it to the official authorized to approve outside employment and activities requests for the employee's component. All requests for prior approval shall include the following information:

(i) The employee's name, organizational location, occupational title, grade, and salary;

(ii) The nature of the proposed outside employment or other outside activity, including a full description of the specific duties or services to be performed;

(iii) A description of the employee's official duties that relate in any way to the proposed activity;

(iv) The name and address of the person or organization for whom or with which the work or activity will be done, including the location where the services will be performed;

(v) 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;

(vi) 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 of absence from that will be required;

(vii) The method of basis of any compensation (e.g., fee, per diem, honorarium, royalties, stock options, travel and expenses, or other);

(viii) A statement as to whether the compensation is derived from an HHS grant, contract, cooperative agreement, or other source of HHS funding;

(ix) 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; and

(x) For activities involving teaching, speaking, writing or editing, 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)(5) of this section.

(4) *Standard for approval.* Approval shall be granted unless it is determined that the outside employment or other outside activity is 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 as-

signed 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.

(5) *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.

**§ 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.