

SYNOPSIS OF THE SUPPLEMENTAL STANDARDS OF ETHICAL CONDUCT FOR EMPLOYEES OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

The Supplemental Standards of Ethical Conduct for Employees of the Department of Health and Human Services (HHS Supplemental Standards) at 5 CFR Part 5501 implement a number of procedural and substantive options available under the Office of Government Ethics Standards of Ethical Conduct for Employees of the Executive Branch (OGE Standards) at 5 CFR Part 2635. The HHS Supplemental Standards became effective July 30, 1996, and replaced several provisions in the prior agency ethical conduct rules contained at 45 CFR Parts 73 and 73a that were superseded by the OGE Standards. Substantial revisions were made to the HHS Supplemental Standards in amendments effective February 3, 2005, and August 31, 2005. This synopsis incorporates those changes and is intended only to provide a general summary. Employees should refer to the text of the regulations for a more complete description and consult with their agency ethics officials if they have questions concerning the application of the rules to their particular circumstances.

This synopsis also includes a summary of 5 CFR Part 5502, which supplements the OGE Financial Disclosure rules contained at 5 CFR Part 2634.

SECTION 5501.101 GENERAL

COVERAGE. The HHS Supplemental Standards apply to all employees of the Department, including uniformed service officers in the Public Health Service Commissioned Corps on active duty. Special Government employees (SGEs) are covered except to the extent they are specifically excepted from certain provisions.

SECTION 5501.102 DESIGNATION OF SEPARATE COMPONENTS

SEPARATE AGENCIES. For purposes of determining whether an outside entity is a prohibited source of: (1) gifts, (2) invitations to engage in an outside activity, (3) invitations to teach, speak, or write for compensation, or, (4) for NIH employees, awards, the Department has been divided into separate agencies:

- (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;

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- (10) National Institutes of Health;
- (11) Program Support Center; and
- (12) Substance Abuse and Mental Health Services Administration.

For most employees, the prohibited source inquiry will focus on whether the outside entity is seeking official action from, doing or seeking to do business with, or regulated by the employing component.

EXCEPTION. For employees in the Office of the Secretary and any other individuals not specifically employed by a designated separate agency, an outside entity that has matters pending anywhere in the entire Department is a prohibited source.

SECTION 5501.103 GIFTS FROM TRIBAL ORGANIZATIONS

GIFT EXCEPTION. An employee may accept an unsolicited gift of native artwork, crafts, or commercially available items representative of traditional native culture from federally recognized Indian tribes or Alaska Native villages or regional or village corporations valued up to and including \$200 per source per calendar year. Such gifts may include art, jewelry, pottery, rugs, carvings, beadwork, and native dress.

LIMITATIONS. Notwithstanding the exception, an employee shall not accept any gift in return for being influenced in the performance of an official act or accept gifts from the same or different sources on a basis so frequent that a reasonable person would be led to believe the employee is using public office for private gain.

APPROVAL. If the donor is a tribe or village that has interests that may be substantially affected by the performance or nonperformance of the recipient's official duties, the employee may accept the gifts authorized by this section only where there is a written finding by the appropriate 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.

SECTION 5501.104 PROHIBITED FINANCIAL INTERESTS FOR FDA EMPLOYEES

BASIC PROHIBITION. An FDA employee (including the spouse and minor children of an FDA employee) may not hold a financial interest, such as stock, in any organization that is "significantly regulated" by FDA. This prohibition does not apply to special Government employees.

DEFINITION OF SIGNIFICANTLY REGULATED ORGANIZATION. The term refers to any organization that derives 10% or more of its annual gross sales from the sale of FDA-regulated products; where the organization has no record of sales, as in the case of a start-up company, it is significantly regulated if its operations are predominately in fields regulated by FDA, or if its research activities are reasonably expected to result in the development of FDA-regulated products.

EXCEPTIONS. Subject to the limitations noted below, there are exceptions which will permit an employee to hold an otherwise prohibited financial interest:

Employee Benefits. The prohibition does not apply to a financial interest, such as a pension or other employee benefit, arising from employment with a significantly regulated organization.

Holdings of Non-Filers. Employees who are not required to file either a public or a confidential financial disclosure statement may hold interests in significantly regulated organizations, subject to the following limitations: the interest did not exceed \$15,000 at the time of acquisition, it constitutes less than 1% of the outstanding equity of the organization, and the employee's total holdings in significantly regulated organizations account for less than 50% of the employee's investment portfolio.

Mutual and Other Investment Funds. The prohibition does not apply to publicly traded or available investment funds (such as mutual funds) or widely held pension funds that do not have a written policy of concentrating investments in significantly regulated organizations, provided that the individual does not have the ability to control the interests held by the fund.

Individual Exceptions. Where FDA finds exceptional circumstances, it may grant an employee a written exception, provided that the prohibition is not necessary to avoid a violation of law or to ensure public confidence in the impartiality or objectivity of agency programs.

SECTION 5501.105 INDIAN OR ALASKA NATIVE BIRTHRIGHTS

DISQUALIFYING FINANCIAL INTERESTS. Under the criminal conflict of interest statute, 18 U.S.C. § 208, an employee is prohibited from participating in an official capacity in any particular matter in which, to the employee's knowledge, the employee or certain other persons have a financial interest, if the particular matter will have a direct and predictable effect on that interest.

EXEMPTION. This section incorporates an exemption contained in the criminal statute that permits Indian or Alaska Native employees to participate officially in particular matters that affect tribal organizations in general. Such employees may not, however, participate in particular matters that affect the specific Indian allotment trust or claims fund in which they have rights by virtue of their status or which involve their own Indian tribe or village corporation as a specific party.

SECTION 5501.106 OUTSIDE EMPLOYMENT AND OTHER OUTSIDE ACTIVITIES

APPLICABILITY. The outside employment prohibitions and the prior approval requirements do not apply to special Government employees.

PROHIBITED ASSISTANCE IN THE PREPARATION OF GRANT APPLICATIONS OR CONTRACT PROPOSALS. An employee cannot render consultative or professional services, for compensation, to prepare, or assist in the preparation of, grant applications, contract proposals, program reports, or any other matters that are intended to be the subject of dealings with HHS.

PROHIBITED EMPLOYMENT IN HHS-FUNDED ACTIVITIES. An employee cannot engage in compensated work on an HHS-funded grant, contract, cooperative agreement, cooperative research and development agreement, or other similar project or arrangement authorized by statute.

FDA EMPLOYMENT PROHIBITIONS. In addition to the HHS-wide prohibitions, there are prohibitions that apply to any FDA employee who is required to file either a public or a confidential financial disclosure statement. Such employees may not engage in employment, whether or not for compensation, with a "significantly regulated organization" (see explanation of section 5501.104 above). Such employees also may not engage in self-employed business where the sale or promotion of FDA-regulated products is expected to constitute 10% or more of annual gross sales or revenues. These prohibitions do not apply to employment of spouses or minor children of employees, although any ethical issues that may arise as a result of such employment must be handled according to the appropriate provisions of the OGE Standards.

EXCEPTIONS TO FDA EMPLOYMENT PROHIBITIONS. An FDA employee may engage in medical and related practices, provided that the employment does not involve substantial unrelated business responsibilities and does not involve employment with a medical product manufacturer in the conduct of biomedical research. An FDA employee may also engage in clerical work, retail sales, service industry jobs, building trades, maintenance, or similar services involving mainly unskilled labor or utilizing skills in areas unrelated to the substantive programmatic activities of the FDA.

OGC AND OIG OUTSIDE PRACTICE OF LAW PROHIBITIONS. An attorney in or supervised by the Office of the General Counsel or the Office of the Counsel to the Inspector General cannot practice law where the outside activity, in fact or in appearance, may require the assertion of a legal position that conflicts with the interests of the Department. OGC and OIG attorneys are also prohibited from engaging in any outside law practice that might require the interpretation of a statute, regulation, or rule administered or issued by the Department.

EXCEPTION TO OGC AND OIG LAW PRACTICE PROHIBITIONS. If appropriate approvals are obtained, an OGC or OIG attorney may represent, with or without compensation, specified relatives or an estate for which the attorney serves as a personal fiduciary; or, without compensation, a person subject to disciplinary, loyalty, or other personnel administration proceedings.

HHS PRIOR APPROVAL REQUIREMENT. Written approval is required before any HHS employee may engage, with or without compensation, in the following outside employment or activities:

Providing *consultative or professional services*, including service as an expert witness;

Engaging in *teaching, speaking, writing or editing* that relates to an employee's official duties or that is undertaken as a result of an invitation from a prohibited source; and

Providing services to a non-Federal entity as an *officer, director, or board member*, or as a member of a group, however denominated, that renders advice, counsel, or consultation.

FDA AND NIH PRIOR APPROVAL REQUIREMENT. FDA and NIH employees must obtain prior approval for outside employment with any prohibited source, within the meaning of 5 CFR 2635.203(d), of the employee's component agency.

EXCEPTIONS TO HHS, FDA, AND NIH PRIOR APPROVAL REQUIREMENTS. Prior approval is not required for participation in a political, religious, social, fraternal, or recreational organization, unless the position requires the provision of professional services or the activity is performed for compensation.

Prior approval is not required where the activity has been specifically exempted in a written determination either issued or approved by the Designated Agency Ethics Official (DAEO).

FORMS. A request for prior approval must be documented on an HHS Form 520 and submitted to the employee's supervisor a reasonable time in advance of the proposed activity. For activities involving teaching, speaking, writing, or editing, the employee must submit an outline, draft, or similar description of the subject matter and the proposed text of any disclaimer that is required by either the OGE Standards or the agency instructions or manual issuances authorized by the DAEO.

STANDARD FOR APPROVAL. Approval can be granted only if the activity is not expected to involve conduct prohibited by statute or regulation, including the OGE Standards and the agency supplemental.

DURATION OF APPROVAL. Approval is effective for one year only. Employees must renew their request for approval annually if they want to continue any long term outside activity. If the outside activity or the employee's duties change significantly, a new request must be submitted.

MANUAL ISSUANCES. With the approval of the DAEO, agency components may:

Exempt categories of employment or other activities from the prior approval requirement;

Specify internal procedures governing the submission of prior approval requests;

Designate appropriate officials to act on such requests;

Provide examples of outside employment or other outside activities that are permissible or impermissible consistent with the OGE Standards and the HHS Supplemental Standards; and

Issue policies requiring advance agency review, clearance, or approval of certain speeches, books, articles, or similar products to determine whether the material contains an appropriate disclaimer, discloses nonpublic information, or otherwise complies with the teaching, speaking and writing provisions.

SECTION 5501.107 TEACHING, SPEAKING AND WRITING BY SPECIAL GOVERNMENT EMPLOYEES IN THE PUBLIC HEALTH SERVICE

PERMITTED COMPENSATION. A special Government employee in the Public Health Service may accept compensation for teaching, speaking or writing, even when the invitation or offer of compensation is extended by a person who has interests that could be substantially affected by the SGE's official duties, as long as the SGE recuses from the official matter that could affect that person's interests.

SECTION 5501.108 REPRESENTATION OF TRIBAL ORGANIZATIONS ON AN INTERGOVERNMENTAL PERSONNEL ACT ASSIGNMENT

BASIC RULE. A criminal statute, 18 U.S.C. § 205, generally bans representational activities, whether or not for compensation, performed by any employee in claims against, or in other matters affecting, the Government.

EXCEPTION. This section permits an employee detailed or assigned to an Indian tribe or an Alaska Native village under the Intergovernmental Personnel Act to act as an

agent or attorney for, or appear on behalf of, such tribe or Alaska Native village 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.

WRITTEN NOTICE. Before representing the tribe or village, the employee must advise in writing the head of the department, agency, court, or commission before which the individual appears, of any personal and substantial involvement the individual may have had as an employee of the United States in connection with the matter.

SECTION 5501.109 PROHIBITED OUTSIDE ACTIVITIES FOR NIH EMPLOYEES

APPLICABILITY. The outside activity prohibitions do not apply to special Government employees.

EMPLOYMENT PROHIBITIONS. An employee of the NIH cannot engage in employment, whether or not for compensation, with a substantially affected organization, a supported research institution, or a health care provider or insurer. Such employees also cannot engage in any 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, the Federal Technology Transfer Act, 15 U.S.C. 3710d, or implementing regulations.

TEACHING, SPEAKING, WRITING AND EDITING PROHIBITIONS. An employee of the NIH cannot teach, speak, write, or edit for compensation for any substantially affected organization, supported research institution, or health care provider or insurer.

DEFINITIONS. Substantially affected organizations include biotechnology, pharmaceutical, and medical device companies (or any organization with a majority of such members) and any other organizations determined by the DAEO or the NIH Director to be substantially affected by NIH programs, policies, or operations. Supported research institution means any educational institution or non-profit independent research institution (or any organization with a majority of such members) that within the last year, or currently, has applied for, proposed, or received an NIH grant, cooperative agreement, research and development contract, or CRADA. Health care provider or insurer means a hospital, clinic, skilled nursing facility, rehabilitation program, health maintenance organization, or other provider of health care items and services, and any entity organized and licensed to offer health care insurance or coverage.

GENERAL EXCEPTION. An employee may engage in employment with, or teaching, speaking, writing, or editing for, a political, religious, fraternal, or recreational organization.

SPECIFIC EXCEPTIONS. Subject to appropriate approvals being obtained under applicable law and regulations, NIH employees may engage in and accept compensation for the following outside employment or activities:

Teaching involving multiple presentations at academic institutions; or delivering a single class lecture unrelated to the employee's official duties if performed as part of a regularly scheduled course.

Clinical, medical or health-related professional practice involving provision of care to individual patients, provided such practice does not involve an NIH-funded project, current or recent NIH patients, referring private patients to NIH, or substantial unrelated non-professional duties.

Clerical work, retail sales, service industry jobs, building trades, maintenance, or similar services involving mainly unskilled labor.

Continuing professional education involving teaching, speaking, writing, or editorial activities that are unrelated to the employee's official duties and which are performed as part of a continuing professional education program conducted by an educational activity provider (if any funding is provided by a substantially affected organization it must be in the form of an unrestricted educational grant for this exception to apply).

Authorship of writings that are unrelated to the employee's official duties if the writing or editing activity is subject to scientific peer review or a substantially equivalent editorial review process (if a substantially affected organization funds the publishing activity it must be involved only as an unrestricted financial contributor and exercise no editorial control for this exception to apply).

Service as a member of a Data Safety and Monitoring Board, subject to certain conditions.

Teaching, speaking, writing, or editing activities that are part of "Grand Rounds" programs unrelated to official duties.

Service on a grant or scientific review committee for a supported research institution or health care provider.

WAIVER. The DAEO may grant a waiver from any prohibited outside activity provision in the regulation if the activity is not otherwise unlawful and would not cause an appearance of misuse of position or loss of impartiality.

SECTION 5501.110 PROHIBITED FINANCIAL INTERESTS FOR SENIOR NIH EMPLOYEES

APPLICABILITY. The prohibiting holdings rule does not apply to special Government employees or the spouse or minor children of a special Government employee.

DEFINITIONS. Senior employee means the Director and Deputy Director of the NIH; 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 DAEO or the NIH Director, in consultation with the DAEO.

PROHIBITION APPLICABLE TO SENIOR EMPLOYEES. A senior employee or the spouse or minor child of such senior employee shall not have a financial interest in a substantially affected organization (see definition in section 5501.109 above) unless: the total cost or value of the combined interest of the employee and the employee's spouse and minor children does not exceed \$15,000; the holding constitutes less than 1% of the outstanding equity of the organization; and the employee's total holdings in substantially affected organizations account for less than 50% of the combined investment portfolios of the employee and the employee's spouse and minor children.

EXCEPTIONS FOR CERTAIN FINANCIAL INTERESTS. Subject to the limitations noted below, there are exceptions which will permit a senior employee or spouse or minor child of a senior employee to hold an otherwise prohibited financial interest:

Employee Benefits. The prohibition does not apply to a financial interest, such as a pension or other employee benefit, arising from employment with a substantially affected organization.

Mutual and Other Investment Funds. The prohibition does not apply to publicly traded or available investment funds (such as mutual funds) or widely held pension funds that do not have a written policy or practice of concentrating investments in substantially affected organizations, provided that the employee does not have the ability to control the interests held by the fund.

Sector Mutual Funds. The prohibition does not apply to interests in substantially affected organizations contained within sector mutual funds that do not concentrate fund investments in the biomedical science, pharmaceutical, medical device, biotechnology or health industry sectors. For those sector mutual funds that concentrate their investments in substantially affected organizations, a senior employee or spouse or minor child of a senior employee may have an interest in such funds if the combined value of the holdings is \$50,000 or less, provided that the holding amount, when added to the value of

any securities in substantially affected organizations held outside the sector mutual fund, is less than 50% of the employee's investment portfolio (including investments of the spouse and minor children).

Individual Exceptions. Where NIH, with the approval of the DAEO, finds exceptional circumstances, it may grant an employee a written exception to hold a financial interest in a substantially affected organization, provided that the prohibition is not necessary to avoid a violation of law or to ensure public confidence in the impartiality or objectivity of agency programs.

Invention Rights. An 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, the Federal Technology Transfer Act, 15 U.S.C. 3710d, or implementing regulations.

SECTION 5501.111 AWARDS TO NIH EMPLOYEES

APPLICABILITY. This section does not apply to special Government employees.

LIMITATIONS APPLICABLE TO EMPLOYEES HAVING OFFICIAL RESPONSIBILITY FOR MATTERS AFFECTING AN AWARD DONOR. In addition to the requirements applicable to the acceptance of an award pursuant to 5 CFR 2635.204(d), an employee shall not accept a gift with an aggregate 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: is seeking official action from the employee; does or seeks business from the agency; conducts activities substantially affected by the programs, policies, or operations of the agency; or is an organization with a majority of such members.

PRIOR APPROVAL OF AWARDS. No employee shall accept an award under 5 CFR 2635.204(d) or this section unless there is advance written approval in accordance with procedures specified by the DAEO or, with the DAEO's concurrence, the Director of NIH.

EXCEPTION. The NIH Director, with the approval of the DAEO, may grant a written exception to permit an employee to accept an award conferring an exceptionally high honor, if otherwise permitted by the Government-wide Standards of Ethical Conduct regulations.

IMPROPERLY ACCEPTED OR PROHIBITED AWARDS. Employees who accept awards without the required approval or that are prohibited are subject to disposal and forfeiture procedures.

SECTION 5501.112 ONE YEAR DISQUALIFICATION OF NIH EMPLOYEES FROM MATTERS INVOLVING AWARD DONOR

APPLICABILITY. This section does not apply to special Government employees.

DISQUALIFICATION. An employee of the NIH who has, within the last year, accepted a permitted award cannot participate in any particular matter involving specific parties in which the award donor is or represents a party unless authorized to do so.

PART 5502 SUPPLEMENTAL FINANCIAL DISCLOSURE REQUIREMENTS FOR HHS EMPLOYEES

SECTION 5502.101 GENERAL

COVERAGE. The regulations in part 5502 apply to employees of HHS and supplement the Executive Branch Financial Disclosure Regulations in 5 CFR part 2634.

SECTION 5502.102 ANNUAL SUPPLEMENTAL REPORT OF OUTSIDE ACTIVITIES AND EMPLOYMENT

FILING OF REPORT. Any employee, other than a special Government employee, for whom an outside employment or activity has been approved, or who has participated in any outside employment or activity for which prior approval is required, must file by February 28 of each year a report concerning all such activities that were approved or undertaken in the previous calendar year. The annual report shall be filed with the employee's supervisor who shall review the form, in consultation with an agency ethics official, and determine whether the employee has complied with applicable laws and regulations and whether approval of any ongoing outside activity should be cancelled.

SECTION 5502.103 CONTENT OF REPORTS

REPORT CONTENTS. The annual report of outside employment or activities must include, among other information, the type and amount of any income and/or reimbursements received in connection with the outside activity. The report must describe any change with respect to information supplied in the original activity request; any change in the nature, scope, or subject matter of any approved activity; and any change in jobs or in the duties and responsibilities of the employee's position that occurred after the outside activity was approved.

SECTION 5502.104 CONFIDENTIALITY OF REPORTS

CONFIDENTIALITY. Each report filed is confidential and cannot be disclosed to the public except as authorized.

SECTION 5502.105 AGENCY PROCEDURES

PRESCRIBING PROCEDURES. The DAEO, or separate agency components with DAEO concurrence, may prescribe procedures for the submission and review of each report, including the provision for filing extensions not to exceed 90 days.

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**SECTION 5502.106 SUPPLEMENTAL DISCLOSURE OF PROHIBITED
FINANCIAL INTERESTS OF FDA EMPLOYEES**

REPORT. Within 30 days of being hired, reassigned, or acquiring a prohibited financial interest (for example, through marriage, gift, or inheritance) an employee, other than a special Government employee, must file a report describing any prohibited financial interests and indicating the type and value of the investments.

**SECTION 5502.107 SUPPLEMENTAL DISCLOSURE BY NIH EMPLOYEES OF
FINANCIAL INTERESTS IN SUBSTANTIALLY AFFECTED ORGANIZATIONS**

REPORT. A report of financial interests in substantially affected organizations (drug companies, biotechnology firms, and medical device manufacturers) shall be filed within 30 days of entering on duty by new entrant and reassigned clinical investigators and employees who file public (SF 278) or confidential (OGE 450) financial disclosure statements. Incumbent clinical investigators and public and confidential report filers shall file a report within 30 days of acquiring a financial interest in a substantially affected organization.