

(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.