

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

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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;

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- (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