

**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.
- 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.
- 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, 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.

[61 FR 39763, July 30, 1996, as amended at 70 FR 5558, Feb. 3, 2005; 70 FR 51568, Aug. 31, 2005]