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CFR 2640.202 or from non-publicly traded securities that are not covered by the regulatory exemption. 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.

(c) *Reporting and divestiture.* For purposes of determining the divestiture period specified in 5 CFR 2635.403(d), as applied to financial interests prohibited under paragraph (a) of this section, the "date divestiture is first directed" means the date on which the new entrant public or confidential financial disclosure report required by part 2634 of this title or any report required by § 5502.106(c) of this chapter is due.

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

§ 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

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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.* An employee of the Food and Drug Administration 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 primarily involves manual or unskilled labor or utilizes talents, skills, or interests in areas unrelated to the substantive programmatic activities of the FDA, such as clerical work, retail sales, service industry jobs, building trades, maintenance, or similar services.

(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 or the Office of Counsel to the Inspector General 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 as provided in paragraph (d)(3) of this section, an employee shall obtain written approval prior to engaging, with or without compensation, in outside employment, including self-employed business activities, or other outside activities in which the employee seeks to:

(i) Provide consultative or professional services, including service as an expert witness;

(ii) Engage 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 or organization that is a prohibited source within the meaning of 5 CFR 2635.203(d), as modified by the separate HHS component agency designations in § 5501.102; or

(iii) Provide 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.

(2) *Additional approval requirement for employees of the Food and Drug Administration and the National Institutes of Health.* 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 National Institutes of Health shall obtain written approval prior to engaging, with or without compensation, in any outside employment, as defined in 5 CFR 2635.603(a), with, or any self-employed business activity involving the sale or promotion of products or services of, any person or organization that is a prohibited source of the employee's component agency.

(3) *Exceptions to prior approval requirements.* (i) Notwithstanding the requirements of paragraphs (d)(1) and (d)(2) of this section, prior approval is not required for participation in the activities of a political, religious, social, fraternal, or recreational organization unless:

(A) The activity or the position held in the organization requires the provision of professional services within the meaning of paragraph (b)(3) of this section; or

(B) The activity is performed for compensation other than the reimbursement of expenses.

(ii) Notwithstanding the requirements of paragraphs (d)(1) and (d)(2) of this section, prior approval is not required for participation in an employment or other outside activity that has been exempted under paragraph (d)(7) of this section.

(4) *Submission of requests for approval.*

(i) 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 shall be directed to the employee's supervisor. The supervisor shall submit the request and a statement addressing the extent to which the employee's duties are related to the proposed outside activity to an agency designee, who shall make a final determination with respect to the request.

(ii) All requests for prior approval shall include the following information:

(A) The employee's name, contact information, organizational location, occupational title, grade, step, salary, appointment type, and financial disclosure filing status;

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

(C) A description of the employee's official duties that relate to the proposed activity;

(D) A description of how the employee's official duties will affect the interests of the person for whom or organization with which the proposed activity will be performed;

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

(F) A statement as to whether travel is involved and, if so, whether the transportation, lodging, meals, or per diem will be at the employee's expense or provided by the person for whom or organization with which the work or activity will be done, and a description of the arrangements and an estimate of the costs of items to be furnished or reimbursed by the outside entity;

(G) 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;

(H) 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 and type of leave that will be required;

(I) The method or basis of any compensation to be received (e.g., fee, honorarium, retainer, salary, advance, royalty, stock, stock options, non-travel related expenses, or other form of remuneration tendered in cash or in-kind in connection with the proposed activity) from the person for whom or organization with which the work or activity will be done;

(J) The amount of any compensation to be received from the person for whom or organization with which the work or activity will be done;

(K) The amount and date of any compensation received, or due for services performed, within the current and previous six calendar years immediately preceding the submission of the request for approval from the person for whom or organization with which the work or activity will be done (including any amount received or due from an agent, affiliate, parent, subsidiary, or predecessor of the proposed payor);

(L) A statement as to whether the compensation is derived from an HHS grant, contract, cooperative agreement, or other source of HHS funding or attributed to services related to an activity funded by HHS, regardless of the specific source of the compensation;

(M) 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;

(N) For activities involving teaching, speaking, or writing, a syllabus, outline, summary, synopsis, draft or similar description of the content and subject matter involved in the course, speech, or written product (including, if available, a copy of the text of any speech) and 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)(6) of this section; and

(O) Such other relevant information that 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(a) determines is necessary or appropriate in order to evaluate whether a proposed activity is likely to involve conduct prohibited by statute or Federal regulations, including 5 CFR part 2635 and this part.

(5) *Standard for approval.* Approval shall be granted only upon a determination that the outside employment or other outside activity is not 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 assigned 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.

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(6) *Duration of approval.* Approval shall be effective for a period not to exceed one year from the date of approval. Upon a significant change in the nature of the outside activity or in the employee's official position or duties, the employee shall submit a revised request for approval using the procedure in paragraph (d)(4) of this section. If the outside activity is anticipated to exceed one year from the date of the most recent approval, the employee shall renew the request for approval no later than thirty days prior to the expiration of the period authorized.

(7) *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.

(e) *Waivers.* The designated agency ethics official may grant a written waiver, for an individual or class of similarly situated individuals, from any prohibited outside activity provision in this section or in § 5501.109 based on a determination that the waiver is not inconsistent with part 2635 of this title or otherwise prohibited by law and that, under the particular circumstances, application of the prohibition is not necessary to avoid the appearance of misuse of position or loss of impartiality or otherwise to ensure confidence in the impartiality and objectivity with which agency programs are administered. An individual or class waiver under this paragraph may impose appropriate conditions, such as requiring execution of a written disqualification.

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

§ 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.