DEPARTMENT OF HEALTH AND HUMAN SERVICES

5 CFR Chapter XLV

RIN 3209–AA15

Supplemental Standards of Ethical Conduct for Employees of the Department of Health and Human Services

AGENCY: Department of Health and Human and Services (HHS).

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services,with the concurrence of the Office of Government Ethics (OGE), is issuing regulations for officers and employees of HHS that supplement the OGE Standards of Ethical Conduct for Employees of the Executive Branch. This final rule specifies procedural and substantive requirements that are necessary to address ethical issues unique to the Department. The rule: Designates separate agency components for purposes of the gift rules and the teaching, speaking and writing restrictions; excepts from the gift rules, subject to monetary limits, arts and crafts items received from Indian tribes or Alaska-Native organizations; prohibits the holding or acquisition of certain financial interests by employees of the Food and Drug Administration (FDA); exempts otherwise disqualifying financial interests derived from Indian or Alaska Native birthrights; prohibits certain outside employment and other outside activities; establishes HHS-wide prior approval requirements for outside employment and other outside activities, with additional rules applicable to FDA employees; authorizes certain compensated teaching, speaking and writing activities engaged in by special Government employees in the Public Health Service (PHS); and delineates restrictions on concurrent representation of tribal organizations.

EFFECTIVE DATE: July 30, 1996.

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SUPPLEMENTARY INFORMATION:

I. Background

On August 7, 1992, the Office of Government Ethics published Standards of Ethical Conduct for Employees of the Executive Branch (OGE Standards), codified at 5 CFR part 2635. See 57 FR 35006–35067, as corrected at 57 FR 48557 and 52583 and 60 FR 51667, with additional grace period extensions at 59 FR 4779–4780, 60 FR 6939–6391 and 66857–66858. Effective February 3, 1993, the OGE Standards established uniform rules applicable to all executive branch personnel.

Pursuant to 5 CFR 2635.105, executive branch agencies are authorized to publish, with the concurrence of OGE, supplemental regulations deemed necessary to implement their respective ethics programs. The Department and OGE have determined that the following supplemental regulations, which are being issued in a new chapter XLV, consisting of part 5501, of 5 CFR, are necessary to establish certain prior approval procedures, and to address gifts, financial holdings, outside employment and other outside activities, and other ethics issues arising out of the unique programs and operations of the Department.

In a separate rulemaking (which will have an effective date that is the same as the date of publication of this supplemental regulation), the Department, after consultation with OGE, will remove those provisions in its existing agency standards of conduct regulations at 45 CFR part 73 and 73a that have been superseded by the OGE Standards of Ethical Conduct, the OGE financial disclosure regulations at 5 CFR part 2634, and this final rule. The Department will then add a cross-reference to the OGE rules, as supplemented. Those portions of the HHS and FDA regulations regarding conduct that remain will preserve employee obligations unrelated to those subjects assigned to OGE for rulemaking and implementation, such as the political activity restrictions for uniformed service officers in the Public Health Service Commissioned Corps, the rules governing conduct on Federal property, and the standards for workplace courtesy, cooperation, and avoidance of sexual harassment.

II. Analysis of the Regulations

Section 5501.101 General

This section states the purpose and scope of the part, incorporates the general definitions promulgated in the OGE Standards, and defines specific terms. The section specifies that the supplemental regulations apply to all officers and employees of HHS, including special Government employees (SGEs) and uniformed service officers in the Public Health Service Commissioned Corps on active duty.

Section 5501.102 Designation of HHS Components as Separate Agencies

Section 2635.202(a) of the OGE Standards prohibits an employee from soliciting or accepting a gift offered by a prohibited source or given because of the employee's official position. A prohibited source is defined, in part, as a person who is regulated by, or has matters pending before, an employee's agency, as prescribed in 5 CFR 2635.203(d). For the purpose of identifying an employee's agency, § 2635.203(a) of the OGE Standards authorizes an executive department, by supplemental regulation, to designate as a separate agency any component of the department that exercises a distinct and separate function.

Designations made pursuant to § 2635.203(a) are used also to identify an employee's agency for purposes of applying the prohibition in 5 CFR 2635.807 on the receipt of compensation for teaching, speaking and writing that relates to an employee's official duties. In addition, under § 5501.106(d) of this part, invitations to engage in outside employment or other outside activities tendered by prohibited sources of an employee's agency, as herein defined, are subject to a prior approval requirement.

The Department has determined that each of the HHS components listed in § 5501.102 exercises distinct and separate functions. Accordingly, § 5501.102 designates the following operating divisions and components of HHS as separate agencies: (1) Administration on Aging (AOA); (2) Administration for Children and Families (ACF); (3) Agency for Health Care Policy and Research (AHCPR); (4) Agency for Toxic Substances and Disease Registry (ATSDR); (5) Centers for Disease Control and Prevention (CDC); (6) Food and Drug Administration (FDA); (7) Health Care Financing Administration (HCFA); (8) Health Resources and Services Administration (HRSA); (9) Indian Health Service (IHS); (10) National Institutes of Health (NIH); (11) Office of Consumer Affairs (OCA); (12) Program Support Center (PSC); and (13) Substance Abuse and Mental Health Services Administration (SAMHSA).

As a result of these designations, employees of a designated component have to be concerned only with the prohibited sources of their respective components when assessing the propriety of a tendered gift or invitation to teach, speak, write, or engage in outside employment or other outside

activities. Employees of a component are defined to include, in addition to employees actually within a component, employees in a division or region of the Office of the General Counsel (OGE) that principally advise or represent that component.

Any HHS employee not in one of the 13 components designated as separate agencies (including employees of the Office of the General Counsel with Department-wide responsibility) is deemed an employee of the remainder of HHS. These employees are treated as if no separate designations had been made, and, as a result, all prohibited sources of HHS are attributable to them.

Under § 5501.102, an employee of the Administration for Children and Families, for example, could receive an unsolicited gift from a hospital corporation receiving Medicare reimbursement through the Health Care Financial Administration, provided that the gift was not given because of the employee's official position. The hospital corporation would be a prohibited source of gifts as to all employees of HCFA, but likely would not be a prohibited source as to all employees of ACF or other designated agency components, unless that hospital corporation was also seeking official action from, were doing business with, were regulated by, or otherwise had a matter pending before that separate designated agency component.

A hospital corporation receiving Federal funds, however, would be a prohibited source of gifts for all employees in the Office of the Assistant Secretary for Public Affairs because such employees are deemed part of the remainder of HHS and, as such, are charged with all prohibited sources of the Department. Employees of the Business and Administrative Law Division of the Office of the General Counsel, which has Department-wide responsibilities, would be treated similarly. However, employees of the Children, Families, and Aging Division of the Office of the General Counsel, which serves ACF and AOA, would receive the benefit of the separate agency designations.

Section 5501.103 Gifts from Federally Recognized Indian Tribes or Alaska Native Villages or Regional or Village Corporations

Section 2635.204(k) of the OGE Standards permits employees to accept any gift that is specifically authorized by a supplemental agency regulation. The Office of Government Ethics is authorized by 5 U.S.C. 7353(b)(1) to permit ''such reasonable exceptions as may be appropriate'' from the general ban on gifts to Federal employees given by prohibited sources or because of their official position. Section 5501.103 permits HHS employees to accept unsolicited gifts of native artwork or crafts 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.

Indian tribes and Alaska Native villages often offer gifts of artwork and crafts as a matter of custom and tradition. Many employees throughout HHS, most notably in the Indian Health Service, the Administration for Native Americans within the Administration for Children and Families, the Centers for Disease Control and Prevention, and the Substance Abuse and Mental Health Services Administration, interact with Native Americans. Cognizant of the unique status of tribal organizations, this exception is intended to effectuate harmonious and respectful relations between HHS and the governing bodies of Indian tribes and Alaskan Native villages. The Department of the Interior concurs in this approach and plans to promulgate an identical provision for its employees.

The $200 per source per year threshold is appropriate in light of the recognized value of handcrafted artwork. The figure reflects that tribal art on occasion may be expected to exceed the current $20 maximum permitted by the gift rules, but is set low enough to exclude antiquities, collectibles, or similar items having a significant commercial value. Moreover, the $200 figure is consistent with the monetary threshold contained in § 2635.204(d) of the OGE Standards relating to receipt of gifts for meritorious public service or achievement.

This section does not authorize employees to accept such gifts from individual tribe or organization members. In addition, the limitations on the use of exceptions to the gift rules, contained in 5 CFR 2635.201 through 2635.205, apply to this section. 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 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). Gifts valued over $200 may be accepted on behalf of HHS, where appropriate, if authorized by applicable statutory gift acceptance authority, e.g., 42 U.S.C. 238.

Section 5501.104 Prohibited Financial Interests Applicable to Employees of the Food and Drug Administration and the Office of the Chief Counsel

In 1972, the Department of Health, Education and Welfare, the predecessor of the Department of Health and Human Services, determined that, because the Food and Drug Administration ''is a unique consumer protection and regulatory agency within the Department,'' the Department's standards of conduct needed ''further supplementation to reflect this role.'' 37 FR 24347, 24348 (November 16, 1972). Therefore, the Department adopted additional activities and financial interests, applicable only to employees of FDA (and later to employees of the then Food and Drug Division of the Office of the General Counsel), codified at 45 CFR part 73a. The Department amended the FDA supplemental regulations in 1978, again ''to re-enforce public confidence in the integrity of decisions rendered by FDA employees.'' 43 FR 7618, 7619 (February 24, 1978).

Over two decades since the FDA supplemental regulations were first promulgated, the work of FDA still poses unique challenges for an agency ethics program. FDA employees participate in regulatory and product approval matters that substantially affect significant sectors of the United States economy, including the food, pharmaceutical, medical device, veterinary medicine, biotechnology, and cosmetics industries. Many FDA employees have access to confidential commercial information and trade secrets, the misuse of which can have serious financial consequences. Moreover, many FDA employees participate in, or have access to information about, pending enforcement matters, such as seizures, injunctive actions, and criminal investigations and prosecutions. Unethical conduct in this context, including misuse of information, could have serious public health consequences. In sum, FDA has a compelling need to monitor, and impose reasonable restrictions on, the financial and employment ties between FDA employees and the vast number of entities regulated by FDA. Such restrictions not only serve the interests identified above, but also relieve FDA of the significant administrative burden of resolving many conflict of interest problems on a case by case basis.

Therefore, § 5501.104 will preserve the substance of FDA's historic restrictions on the acquisition and holding of financial interests in

regulated organizations. (See the explanation of § 5501.106(c)(3) and § 5501.106(d)(2) for a discussion of the provisions governing outside employment of FDA employees.) Like FDA's prior financial interest restrictions, § 5501.104 is narrowly tailored in two important respects:

First, § 5501.104, like the prior FDA rule, distinguishes between interests in organizations that are significantly regulated by FDA, and interests in organizations that are only incidentally regulated by FDA. Only interests in ''significantly regulated organizations'' are restricted. ''Significantly regulated organization'' is defined, at § 5501.101(c)(2), to include any organization that derives ten percent or more of its annual gross sales from the sale of FDA-regulated products. The new rule adds a necessary modification to FDA's prior definition: companies that have no record of sales, but which are operating solely within a field regulated by FDA, also will be deemed to be ''significantly regulated.'' This modification is necessary to cover companies that are subject to significant regulation by FDA but which do not yet have any products on the market. The rule would cover, for example, start-up biotechnology companies that may exist for several years before obtaining FDA approval to market any product.

Second, § 5501.104, like the prior FDA rule, places the most strict limitations on employees whose duties carry the greatest potential for conflict of interest. In the past, FDA used various tests to determine which employees should be covered by the most strict prohibitions on financial interests. Compare 37 FR 24349 with 43 FR 7621. Under § 5501.104, the test is simplified: The most strict prohibition applies to those employees required to file either a public financial disclosure statement or a confidential financial disclosure statement, pursuant to 5 CFR part 2634. With certain exceptions, such employees are prohibited from holding or acquiring any interest in a significantly regulated organization. All other employees are allowed, pursuant to § 5501.104(b)(2), to hold or acquire such interests, subject to essentially the same limitations contained in the prior FDA rule.

Section 5501.104 excepts interests in certain investment and pension funds from the financial interest restrictions. To qualify for this exception, the fund must not be self-directed and must not have an express policy or practice of concentrating its investments in significantly regulated organizations. For example, a widely diversified mutual fund generally would be a permissible holding, even though the fund holds some stocks of significantly regulated organizations whereas a sector fund that focused on the pharmaceutical industry would not.

The new rule also excepts pensions arising from employment with a significantly regulated organization. This exception does not appear in the prior FDA rule, but it does codify an FDA policy that has been in effect since 1976. The Food and Drug Administration has determined that such an exception is necessary to facilitate recruitment of qualified scientific and professional personnel, many of whom may have begun their careers in industry.

Furthermore, § 5501.104 provides FDA employees with the opportunity to request an individual exception in cases involving exceptional circumstances. Where the employee can demonstrate exceptional circumstances, FDA may grant an individual exception, provided that the application of the financial interest prohibition is not necessary to ensure public conference in the impartiality or objectivity with which FDA programs are administered or to avoid a violation of 5 CFR part 2635.

Finally, consistent with prior FDA policy, the prohibition relating to financial interests would continue to apply to the spouses and minor children of FDA employees. FDA has made the determination, pursuant to 5 CFR 2635.403(a), that there is a direct and appropriate nexus between this prohibition as applied to spouses and minor children and the efficiency of the service. It should be noted, however, that § 5501.104 is not intended to prohibit employment by spouses and minor children in regulated industry, although any actual or apparent conflicts of interests created as to FDA employees by such employment must be resolved under other applicable provisions of 5 CFR part 2635.

Section 5501.105 Exemption For Otherwise Disqualifying Financial Interests Derived From Indian or Alaska Native Birthrights

Section 208(a) of title 18 of the United States Code prohibits an employee of the executive branch from participating personally and substantially as a Government employee in any proceeding, application, request for a ruling or other determination, contract, claim, controversy, or other particular matter in which the employee, the employee's spouse, minor child, or organization in which the individual is employed, otherwise serving, or seeking other employment, has a financial interest.

The Ethics Reform Act of 1989 amended 18 U.S.C. 208(b)(4) to provide that the conflict of interest prohibition does not apply to a financial interest resulting solely from the interest of the employee or the employee's spouse or minor child in birthrights in a federally recognized Indian tribe or Alaska Native village corporation, in an Indian allotment held in trust by the United States, or in an Indian claims fund held in trust or administered by the United States, if the particular matter does not involve the Indian allotment or claims fund or the Indian tribe or village corporation as a specific party or parties. Section 5501.105 incorporates the statutory exemption referenced in the OGE Standards at 5 CFR 2635.402(d).

Section 5501.106 Outside Employment and Other Outside Activities

Section 5501.106 establishes supplemental regulations concerning the outside employment and other outside activities of HHS employees, other than special Government employees. The section covers both compensated and uncompensated activities and addresses traditional outside employment relationships, as well as other outside activities. The Department is authorized by §§ 2635/802(a) and 2635.803 of the OGE Standards, respectively, to prohibit its employees from engaging in certain outside employment or other outside activities and to require prior approval before engaging in other defined outside employment or activities.

(a) *Applicability*. The outside employment and activity prohibitions and the prior approval requirements imposed by paragraphs (c) and (d), respectively, do not apply to special Government employees. Nevertheless, special Government employees remain subject to other statutory and regulatory authorities governing their outside activities, including the criminal representation statutes, 18 U.S.C. 203 and 205, and other applicable provisions of 5 CFR part 2635 and this part.

(b) *Definitions*. Section 5501.106(b) sets forth definitions of the terms used in the section.

(c) *Prohibited Outside Employment and Activities*. Section 5501.106(c) prohibits certain outside employment and activities that, if engaged in by an HHS employee, would pose a conflict with the employee's official duties, would cause a reasonable person to question the impartiality with which agency programs are administered, or would otherwise compromise agency interests.

(1) *Prohibited Assistance in the Preparation of Grant Applications or Contract Proposals.* More specifically, § 5501.106(c)(1) prohibits an HHS employee from engaging in 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. Such conduct, if undertaken on an uncompensated basis, though not expressly prohibited by paragraph (c)(1), is subject to the prior approval requirement in paragraph (d). This provision carries forward longstanding policy reflected in the now superseded HHS Standards of Conduct at 45 CFR 73.735–704(a)(2).

(2) *Prohibited Employment in HHS-Funded Activities.* Section 5501.106(c)(2) prohibits an HHS employee from engaging 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. The paragraph precludes the provision of personal services, whether as an employee, consultant, contractor, or otherwise, that are rendered in the performance of a particular grant, contract, or agreement for which the project derives funding from HHS. This provision does not *per se* bar employment with an entity that receives HHS funds, but rather if focuses on discrete matters for which the employee's services and attendant compensation can be attributed to a defined HHS-funded project or contractual arrangement.

This provision codifies prior HHS policy, as implemented by the HHS Form 520, ''Request for Approval of Outside Activity.'' The prohibition was deemed necessary to preclude the appearance that a compensated employment or business opportunity may have been obtained through the use of the employee's official position and to address a number of other potential ethics concerns. Given that millions of dollars in HHS grants and contracts are awarded annually, the Department has determined that maintaining the policy against compensated outside employment in grant or contract implementation is critical to protect against questions arising regarding the impartiality and objectivity of its employees and the administration of the Department's programs. In fulfilling its mission, the Department would be hindered if members of the public were to question whether HHS employees were using their public position or workplace connections for private remunerative gain attributable, directly or indirectly, to appropriated funds.

(3) *Prohibited Outside Activities Applicable to Employees of the Food and Drug Administration and the Office of the Chief Counsel.*

Under FDA's prior rule, originally adopted in 1972, those employees whose duties pose the greatest potential for conflict of interest generally could not engage in employment with significantly regulated organizations. 45 CFR 73a.735–401(b). The basis for this rule was essentially the same as the basis for the rule restricting financial interests in significantly regulated organizations (see discussion of § 5501.104 above). Not only are such employees in a position to affect the financial interests of these organizations through the performance of their official duties, but the employees may have access to nonpublic information that could be used to the advantage of the organizations. Therefore, § 5501.106(c)(3) will substantially preserve this prohibition, with respect to employees who are required to file public or confidential financial disclosure reports.

The new rule provides two exceptions to the prohibition on employment with a significantly regulated organization. The first exception, at paragraph (c)(3)(ii)(A), essentially continues an exception found in FDA's prior rule. The purpose of the exception is to allow employees who are licensed to practice various medical professions to remain current in their professions, including the maintenance of licenses or certifications. The list of practices in the exception (medicine, dentistry, veterinary medicine, pharmacy, nursing) is not exclusive, but illustrative. The practice of the various medical professions usually is precisely defined and highly regulated by State law, and FDA cannot give a definition of each practice that is covered by the exemption. However, the exception is intended to cover only employment that involves the provision of medical professional services. Thus, for example, the exception would not cover the practice of law or accounting. Moreover the exception is not intended to allow FDA employees to be employed by a medical product manufacturer in the conduct of biomedical research.

The second exception, in paragraph (c)(3)(ii)(B), will allow clerical or similar employment (such as cashier or janitorial work) with retail stores that are significantly regulated by FDA. Normally, such positions would pose little risk for abuse of nonpublic information obtained from FDA, and any potential conflicts of interest can be dealt with on a case by case basis.

In addition to employment with a significantly regulated organization, the new rule also prohibits certain self-employed business activities. Certain sole proprietorships in fields subject to significant FDA regulation may not constitute ''employment,'' within the meaning of 5 CFR 2635.603(a), but such activities pose the same, if not greater, risks. Therefore, public and confidential disclosure report filers would be prohibited from engaging in self-employed business activities where the sale or promotion of FDA-regulated products is expected to constitute ten percent or more of annual gross sales or revenues.

(4) *Prohibited Outside Practice of Law Applicable to Attorneys in the Office of the General Counsel.*

Summary. Section 5501.106(c)(4) prohibits attorneys in or supervised by the Office of the General Counsel from practicing law outside their official positions where the activity, in fact or in appearance, may require the assertion of a legal position that conflicts with the interests of the Department. Office of the General Counsel 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.

Exceptions. Consistent with Federal policy embodied in the exceptions to the representational bans contained in 18 U.S.C. 203 and 205, nothing in the section precludes representation or advice, if approved by the appropriate official or supervisor, that is: (1) Rendered, with or without compensation, to specified relatives or an estate for which an employee serves as a fiduciary; or (2) provided, without compensation, to an employee subject to disciplinary, loyalty, or other personnel administration proceedings.

In order to take advantage of the exceptions to 18 U.S.C. 203 and 205 or representing family members or an estate, both statutes expressly require the approval of the Government official responsible for the employee's appointment. See 18 U.S.C. 203(d) and 205(e). The parallel provision in 18 U.S.C. 205(d) that permits an employee to provide uncompensated legal assistance to another employee in disciplinary, loyalty, or other personnel administration proceedings does not explicitly contain an authorization requirement, but specifies that the activity must not be ''inconsistent with the faithful performance of [the employee's] duties.'' The Office of Government Ethics has issued an

opinion concluding that an employee may not unilaterally make this finding; as a result, supervisory approval is required. OGE Informal Advisory Letter 82 X 19 (December 9, 1982), as published in ''The Informal Advisory Letters and Memoranda and Formal Opinions of the United States Office of Government Ethics,'' (the ''OGE Advisory Publication''), 313 (1979–1988), which is available for purchase from the Government Printing Office. As an outside professional activity, such representation would be subject, in any event, to the prior approval procedures in § 5501.106(d) of this part.

Paragraph (c)(4)(ii)(C) makes explicit that neither the ban on asserting contrary positions nor the prohibition on interpreting agency statutes is intended to proscribe the giving of testimony under oath.

Asseting Contrary Legal Positions. Paragraph (c)(4)(i)(A) is consistent with the rules of professional conduct governing the attorney-client relationship. Precluding outside law practice that may require the assertion of legal positions adverse to the Department derives from the unique and sensitive relationship between an attorney and a client, which for attorneys in the Office of the General Counsel, is the Department of Health and Human Services.

Morever, the Department has a legitimate interest in maintaining the consistency and credibility of the Department's position before the Federal courts. For the most part, the representational bans contained in 18 U.S.C. 203 and 205 would preclude outside practice by Department attorneys in the Federal courts because nondiversity cases within the Federal jurisdiction generally involve controversies in which the United States is a party or has a direct and substantial interest. However, cases may arise involving the interpretation or application of Federal statutes or regulations that do not necessarily implicate the direct and substantial interests of the United States.

The Office of Government Ethics and the Office of Legal Counsel at the Department of Justice have opined that the combined involvement of a Federal statute and a Federal forum in and of itself does not create a direct and substantial interest on the part of the United States for purposes of sections 203 and 205. OGE 94 X 7 (February 7, 1994), as published in the 1994 Supplement to the ''OGE Advisory Publication''; 14 Op. O.L.C. 139 (June 7, 1990). As a consequence, Department attorneys representing private clients might appear in front of the same judges before whom they appear in their official capacities and argue different interpretations of Federal statutes or regulations. Depending upon the visibility of the issues and any attendant controversy, asserting conflicting legal positions may diminish the persuasiveness of the advocate and undermine the credibility of both clients. Paragraph (c)(4)(i)(A) is intended, therefore, to safeguard the interests of the Department as the primary client to which the attorney employee owes a professional responsibility.

Concededly, while representing a private client, a Department attorney might take legal positions on a myriad of issues not directly related to Federal interests or agency programs—such as jurisdiction, service of process, standing, evidence, or statutory construction—that differ from those the attorney might have asserted while acting in a governmental capacity. The section is not intended to proscribe instances of outside practice merely because such issues would have been handled differently if the matters arose in the prosecution or defense of an agency case. Advocacy with respect to ancillary issues unrelated to substantive legal positions or agency administered statutes would only rarely have an impact sufficiently adverse to agency interests to be proscribed by the regulation.

Interpreting Agency Administered Statutes. Paragraph (c)(4)(i)(B) is intended to effectuate the prohibition on the use of public office for private gain, to preclude inconsistent legal positions on core issues affecting the interests of the Department, and to protect the public interest by preventing any lay perception that an attorney's employment with the Department signifies extraordinary competency on agency related issues, or that an agency attorney's interpretation implicitly is sanctioned or approved by the Department.

For the most part, outside practice involving agency administered statutes would be precluded as a conflicting activity. If the subject matter of the proposed representation and the assigned duties of the attorney correlate, the outside activity potentially would require, under the standards set forth in 5 CFR 2635.402 and 2635.502, the employee's disqualification from matters so central or critical to the performance of the employee's official duties that the employee's ability to perform the duties of the employee's position would be materially impaired. Similarly, representation on matters involving the application of agency statutes may implicate direct and substantial interests of the United States, thus contravening the representational bans in 18 U.S.C. 203 and 205.

Although the regulation to some extent covers areas that are subject to existing prohibitions, paragraph (c)(4)(i)(B) reaches situations not specifically addressed in the existing standards. Absent the prohibition contained in this section, a Department attorney principally engaged in advising a client component conceivably could obtain outside employment advising, as opposed to representing, a private client on areas of agency law to which the attorney is not assigned. In these circumstances, there is considerable risk that the employment position held by the individual may convey an impression of authoritativeness or access to agency experts that may not necessarily be warranted. Moreover, private clients, and those aware of the agency attorney's involvement, may assume incorrectly that the agency attorney's interpretation has been vetted through the Department and is effectively a Departmental interpretation as well. Rendering legal services that may require the interpretation of any statute, regulation, or rule administered or issued by the Department creates an appearance that the employee has used the employee's official position to obtain an outside business opportunity. Further, if counsel were engaged in law practice that involved agency statutes, the potential for asserting legal positions adverse to the interests of the Department would be heightened.

Other Prohibitions and Procedures. As a professional activity within the meaning of 5 CFR 2636.305(b)(1), the outside practice of law must be authorized in advance under the prior approval provisions contained in section 5501.106(d). If an outside activity is expected to involve conduct prohibited by a statute or Federal regulation, including 5 CFR part 2635 and this part, approval must be denied.

The prohibitions contained in the criminal law, the OGE Standards and this supplement constitute considerable impediments to outside law practice. Subject to such exceptions as are contained in the cited authorities, permission cannot be granted, for example, if the activity:

(1) Creates an actual or apparent conflict with the employee's official duties under the criminal conflict of interest provisions in 18 U.S.C. 208 or the standards set forth in 5 CFR 2635.402 and 2635.502;

(2) Involves compensated representational services before any

department, agency, or court, in relation to any proceeding or other particular matter in which the United States is a party or has a direct and substantial interest, as proscribed by 18 U.S.C. 203; or

(3) Entails, irrespective of compensation, prosecution of claims against the Government or service as an agent or attorney before any department, agency, or court, in connection with any covered matter in which the United States is a party or has a direct and substantial interest, in contravention of 18 U.S.C. 205.

Further, if the proposed outside activity would reflect adversely upon the Department so as to constitute conduct prejudicial to the Government within the meaning of 5 CFR 735.203, approval would be denied. In addition, any approved outside activity requiring absence from duty is subject to the denial or cancellation of leave due to exigencies of staffing and workload.

Alternatives Considered. In developing this regulation, the Department considered several options. The confluence of the many restrictions outlined above point in the direction of banning all outside practice of law. However, public interest considerations require rejection of such a policy. Attorneys in the Federal government can play a significant role in providing legal assistance to those in need without running afoul of these provisions. In keeping with their ethical obligation to the system of justice, Department attorneys may provide legal services *pro bono publico* in areas such as landlord-tenant disputes, State criminal defense work, and State workers' compensation claims, that are unlikely to pose a conflict or other ethical concern. Indeed, the Department encourages such volunteer activities, if not inconsistent with the laws and regulations described above. Executive Order 12988 specifically directs that all Federal agencies ''develop appropriate programs to encourage and facilitate pro bono legal and other volunteer service by government employees to be performed on their own time, including attorneys, as permitted by statute, regulation, or other rule or guideline.''

The Department considered a proposal to ban compensated practice of law. The availability of pecuniary gain could increase instances of outside representation or induce the continuous practice of law with concomitant administrative, management, and conflicts avoidance burdens that are not implicated by the infrequent or occasional uncompensated activities currently permitted on behalf of indigent clients, specified relatives and estates, and individuals subject to disciplinary, loyalty, or other personnel administration proceedings. On the other hand, the Department recognizes that many compensated activities—such as preparing a will, drafting Subchapter S incorporation documents, searching real estate titles, advising on State law contract disputes, or representing a client in traffic court—can generally be undertaken without detriment to the agency's interests, provided that the employee adheres to the limitations of this rule. The Department, therefore, opted for the less restrictive approach embodied in this regulation.

(d) *Prior Approval for Outside Employment and Other Outside Activities.* Section 2635.803 of the OGE Standards provides that an agency, by supplemental regulation, may require its employees to obtain advance administrative approval before engaging in certain types of outside employment or other outside activities, where the agency has determined that such a requirement is necessary or desirable for the purpose of administering its ethics program. Provisions in the HHS Standards of Conduct and the FDA Supplement, 45 CFR parts 73 and 73a (which are superseded by this rule), have long required employees to obtain written approval prior to engaging in certain outside employment or other outside activities. Section 5501.106(d) continues this requirement.

The prior approval requirement has been an integral part of the HHS ethics program. Its continuance is deemed necessary to ensure that an employee's participation in outside employment or other outside activities does not adversely affect operations within the employing component or place the employee at risk of violating applicable statutes and regulations governing employee conduct.

(1) *General Approval Requirement.* Section 5501.106(d)(1) enumerates the employment or activities, with or without compensation, for which prior approval is required: (i) Providing consultative or professional services, including service as an expert witness; (ii) 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 (iii) 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.

Paragraph (d)(1)(iii), however, does not require prior approval for uncompensated (other than reimbursement of expenses) service as an officer, director, board member, or advisory group member in a political, religious, social, fraternal or recreational organization, unless the position held by the employee requires the provision of professional services. For example, an HHS employee trained as an accountant may serve, without prior approval, on a church board and keep the church's books. Providing accounting services is not a requirement of service on the board. However, if the church were to hire the employee, with or without compensation, as its accountant, prior approval would be required.

Prior approval is required for service as an officer, director, board member, or advisory group member in a professional association or similar organization. Officeholding in a professional association may raise ''representation'' issues and other ethics concerns not usually encountered in the context of political, religious, social, fraternal or recreational organizations.

(2) *Additional approval requirement applicable to employees of the Food and Drug Administration and the Office of the Chief Counsel.*

Under FDA's prior rule, adopted in 1972, all FDA employees have been required to obtain prior approval for all outside employment, with limited exceptions. 45 CFR 73a.735–401. This requirement proved to be an effective mechanism for preventing inadvertent conflicts of interest among FDA employees. Section 5501.106(d)(2) will continue this requirement.

FDA estimates that approximately 25% of all consumer spending in the United States is on products regulated by FDA. FDA can take actions that affect enterprises as diverse as grocery retailers, home appliance manufacturers, cosmetics distributors, and dairy farmers. Even non-profit organizations, such as patient advocacy groups or blood banks, can have an interest in FDA actions. In light of the pervasiveness and variety of FDA-regulated and FDA-affected organizations in the United States, there is a significant risk that employees engaged in outside employment or self-employed business activity may confront actual or apparent conflicts of interest.

The prior approval requirement in § 5501.106(d)(2) will allow FDA to assist employees in identifying organizations that are regulated by FDA or significantly involved in FDA issues. Ultimately, prior approval helps FDA employees to avoid conflicting activities with such organizations.

Section 5501.106(d)(2) codifies existing practice by applying the prior approval requirement to employees of

the FDA Office of the Chief Counsel. The rule also codifies current practice by requiring prior approval for self-employed business activity.

Consistent with the other prior approval provisions applicable to all HHS employees, § 5501.106(d)(2) will not require approval for participation in the activities of a political, religious, social, fraternal, or recreational organization, unless the position requires the provision of professional services, or is rendered for compensation (other than reimbursement of expenses). Moreover, the prior approval requirement will not apply to those categories of employment that have been exempted, pursuant to § 5501.106(d)(5), based on a determination that such employment activities generally would be approved and are not likely to involve conduct prohibited by statute or regulation.

(3) *Submission of Requests for Prior Approval.* This paragraph specifies that requests for approval of outside activities must be submitted to the employee's supervisor a reasonable time in advance of the proposed activity. Prior approval requests must include information sufficient to assess the activity, such as: the employee's name, organizational location, position title, and grade or rank; the name of the person or organization for whom the outside work is to be performed; a description of the type and location of such work; the method of compensation; the duration of the activity, and the number of hours the employee expects to be engaged in such work.

In order to implement the prohibitions contained in paragraphs (c)(1) and (2) of this section relating to HHS grant and contract activities, the employee must provide additional information as currently required on the HHS Form 520, ''Request for Approval of Outside Activity.'' An employee who renders consultative or professional services must state whether the client or outside employer is a current or prospective HHS grantee or contractor. And, an employee, irrespective of the type of services to be provided, must identify any HHS funding sources for the specific activity in which the employee proposes to engage.

For activities involving teaching, speaking, writing, or editing, the employee must submit the proposed text of any disclaimer that is required by either the OGE Standards or the agency instructions or manual issuances authorized by paragraph (d)(5) of § 5501.106. Section 2635.807(b)(2) of the OGE Standards permits an employee who is engaged in outside teaching, speaking or writing, to use, or permit the use of, the employee's title or position in connection with an article published in a scientific or professional journal, provided that the title or position is accompanied by a reasonably prominent disclaimer satisfactory to the agency. The disclaimer must indicate that the views expressed in the article do not necessarily represent the views of the agency or the United States.

(4) *Standard for Approval.* Paragraph (d)(4) specifies the standard for approval of outside employment or other activities. An activity that is not expected to involve conduct prohibited by statute or regulation, including part 2635 and the agency supplemental, shall be approved. However, a note following the paragraph cautions that during the course of an otherwise approvable activity, situations may arise, or actions may be contemplated, that, nevertheless, pose ethical concerns.

(5) *Responsibilities of the Designated Agency Ethics Official and Component Agencies.* Section 5501.106(d)(5) authorizes the Designated Agency Ethics Official (DAEO) or the separate agency components, with the concurrence of the DAEO, to issue instructions or manual issuances exempting categories of employment or other activities from the prior approval requirement 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 regulation, including the OGE Standards and this supplemental regulation.

Through these instructions or manual issuances, agency components may specify internal procedures governing the submission of prior approval requests, designate appropriate officials to act on such requests, and include examples of outside employment or other outside activities that are permissible or impermissible consistent with the OGE Standards and this part.

The OGE Standards also recognize that agencies may have 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 of 5 CFR 2635.807. Because the need for preclearance and/or disclaimers may differ depending upon the activities and missions of the various components of the Department, the rule authorizes inclusion of such policies within the instructions or manual issuances.

The Department will continue to employ HHS Form 520 as both a prior approval request form and a record of the disposition by the approval official. Paragraph (d)(5)(iii) of the section requires officials responsible for the administrative aspects of these regulations to make provisions for the filing and retention of these forms.

No provision is made in these regulations, however, for an annual reporting of outside activities submitted on HHS Form 521, as previously required by 45 CFR 73.735–709. That section elicited an annual written verification whether the work or activity described in the original request was actually performed and required the employee to specify the amount of time spent and whether the activity would continue unchanged. Because the HHS Form 520 contains a blank for specifying duration and any substantive change in the scope of the approved activity would constitute a new activity requiring submission of another HHS Form 520, the annual report appears to be unnecessarily duplicative. Moreover, the information requested would, in any event, form the basis of a responsible dialogue between employees and supervisors concerning workload allocation and the avoidance of conflicts. The minimal benefit to be derived from an annual report does not outweigh the considerable burden involved in collecting, tracking, and reviewing the forms. Accordingly, the requirement for filing an annual HHS Form 521 expires upon the effective date of this rule.

Section 5501.107 Teaching, Speaking and Writing by Special Government Employees in the Public Health Service

Section 5501.107 is intended to deal with a common situation presented by special Government employees in the health agencies of the Department who participate as speakers in continuing medical education (CME) courses and similar activities. These health agencies must rely on special Government employees who are experts in various biomedical fields. Such individuals tend to be active in private CME programs, which frequently are sponsored or underwritten by the medical product industry. At FDA, in particular, it is very common to find that advisory committee members, in their private capacity as recognized experts in various biomedical fields, receive regular requests to participate in CME courses from medical product manufacturers. Sometimes these manufacturers will have interests that

may be affected substantially by official matters to which the special Government employee already has been assigned. This provision makes clear that such employees may accept offers of compensation to participate in CME courses and similar events only when the employee recuses from the particular matter that would affect the interests of the manufacturer.

Section 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

Section 2635.902 of the OGE Standards contains a list of statutory provisions to which an employee's conduct must conform. Among these provisions is the criminal prohibition of 18 U.S.C. 205, which generally bans representational activities, whether or not for compensation, performed by any employee in claims against, or in other matters affecting, the Government.

The Indian Self-Determination Act (25 U.S.C. 450i(f)), however, permits Federal employees detailed or assigned to Indian tribes or Alaska Native villages or regional or village corporations, pursuant to the Intergovernmental Personnel Act (5 U.S.C. 3372), to act as agents or attorneys for, or appear on behalf of, such tribes or Alaska Native villages or corporations 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; provided that each such employee advises 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 5501.108 is added, therefore, to make explicit this exception to 18 U.S.C. 205, as referenced in §§ 2635.801(d)(4) and 2635.902(d) of the OGE Standards.

III. Matters of Regulatory Procedure

Administrative Procedure Act

The Department of Health and Human Services has found that good cause exists under 5 U.S.C. 553(b) and (d) for waiving, as unnecessary and contrary to the public interest, the general notice of proposed rulemaking and the 30-day delay in effectiveness as to this final rule. Similar regulations have been applicable to Department employees under the now superseded HHS Standards of Conduct and FDA Supplement contained at 45 CFR parts 73 and 73a. An immediate effective date is necessary to effect a smooth regulatory transition and to avoid a lapse in applicable procedural and substantive rules relating to prior approval of outside activities and prohibited financial interests that could otherwise occur due to the expiration of ''grandfathering'' provisions contained in the OGE Standards. See 60 FR 66857.

Moreover, the proposed rulemaking requirements of the Administrative Procedure Act are not applicable because this rule deals with agency organization, procedure, or practice, 5 U.S.C. 553(b), and relates to matters of agency management and personnel, 5 U.S.C. 553(a)(2). The rule also contains several substantive provisions that grant or recognize an exemption or relieve a restriction such that an immediate effective date is permitted under 5 U.S.C.(d)(1).

Executive Order 12866, Regulatory Planning and Review

In issuing this rule, the Department of Health and Human Services has adhered to the regulatory philosophy and the applicable principles of regulations set forth in section 1 of Executive Order 12866 of September 30, 1993. This rule is limited to agency organization, management, or personnel matters, and thus is not a ''significant regulatory action,'' as defined in sections 3(d) through (f) of the Executive order.

Regulatory Flexibility Act

The Department of Health and Human Services has determined under the Regulatory Flexibility Act (5 U.S.C. chapter 6) that this regulation will not have a significant economic impact on a substantial number of small business entities because it affects only HHS employees.

Paperwork Reduction Act

The Department of Health and Human Services has determined that the Paperwork Reduction Act (44 U.S.C. chapter 35) does not apply because this regulation does not impose any new information collection requirements that require the approval of the Office of Management and Budget.

List of Subjects in 5 CFR Part 5501

Conflict of interests, Government employees.

Dated: July 17, 1996.

Donna E. Shalala,

Secretary, Department of Health and Human Services.

Approved: July 22, 1996.

Stephen D. Potts,

Director, Office of Government Ethics.

For the reasons set forth in the preamble, the Department of Health and Human Services, with the concurrence of the Office of Government Ethics, is amending title 5 of the Code of Federal Regulations by adding a new chapter XLV, consisting of part 5501, to read as follows:

5 CFR CHAPTER XLV—DEPARTMENT OF HEALTH AND HUMAN SERVICES

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 and the Office of the Chief Counsel.
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.

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.

§ 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;

(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 nonperformance 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 specialize 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 and the Office of the Chief Counsel.* An employee of the Food and Drug Administration or the Office of the Chief Counsel 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 is limited to clerical or similar services (such as cashier or janitorial services) in retail stores, such as supermarkets, drug stores, or department stores.

(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 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 to the extent that an employment or other activity has been exempted under paragraph (d)(5) of this section, an employee shall obtain written approval prior to engaging, with or without compensation, in the following outside employment or activities:

(i) Providing consultative or professional services, including service as an expert witness.

(ii) Engaging 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 who is a prohibited source within the meaning of 5 CFR 2635.203(d), as modified by § 5501.102.

(iii) Providing 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, unless the service is provided without compensation other than reimbursement of expenses to a political, religious, social, fraternal, or recreational organization and the position held does not require the provision of professional services within the meaning of paragraph (b)(3) of this section.

(2) *Additional approval requirement for employees of the Food and Drug Administration and the Office of the Chief Counsel.*

(i) 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 Office of the Chief Counsel shall obtain written approval prior to engaging in any outside employment, as defined in 5 CFR 2635.603(a), whether or not for compensation, or any self-employed business activity.

(ii) The requirement of paragraph (d)(2)(i) of this section does not apply to participation in the activities of a political, religious, social, fraternal, or recreational organization, unless the position held requires the provision of professional services or is performed for compensation other than the reimbursement of expenses.

(iii) The requirement of paragraph (d)(2)(i) of this section shall not apply to the extent that an employment activity has been exempted, pursuant to paragraph (d)(5) of this section.

(3) *Submission of requests for approval.* 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 should be directed to the employee's supervisor who will forward it to the official authorized to approve outside employment and activities requests for the employee's component. All requests for prior approval shall include the following information:

(i) The employee's name, organizational location, occupational title, grade, and salary;

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

(iii) A description of the employee's official duties that relate in any way to the proposed activity;

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

(v) 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;

(vi) 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 of absence from that will be required;

(vii) The method of basis of any compensation (e.g., fee, per diem, honorarium, royalties, stock options, travel and expenses, or other);

(viii) A statement as to whether the compensation is derived from an HHS grant, contract, cooperative agreement, or other source of HHS funding;

(ix) 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; and

(x) For activities involving teaching, speaking, writing or editing, 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)(5) of this section.

(4) *Standard for approval.* Approval shall be granted unless it is determined that the outside employment or other outside activity is expected to involve conduct prohibited by statute or Federal regulation, including 5 CFR part 2635 and this part.

Note: The granting of 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.

(5) *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.

§ 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.

§ 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.

(a) *18 U.S.C. 205.* Section 205 of title 18 of the United States Code prohibits an employee, whether or not for compensation, from acting as an agent or attorney for anyone in a claim against the United States, or from acting in such capacity on behalf of another before any department, agency, or other specified entity, in any particular matter in which the United States is a party or has a direct and substantial interest.

(b) *Exception 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.* Notwithstanding the provisions of 18 U.S.C. 205, the Indian Self-Determination Act (25 U.S.C. 450i(f)) authorizes Federal employees detailed or assigned to Indian tribes or Alaska Native villages or regional or village corporations, pursuant to the Intergovernmental Personnel Act (5 U.S.C. 3372), to act as agents or attorneys for, or appear on behalf of, such tribes or Alaska Native villages or corporations 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. Such employees must advise, in writing, the head of the agency, with which they are dealing on behalf of an Indian tribe or Alaska Native village or corporation, of any personal and substantial involvement they may have had as an officer or employee of the United States in connection with the matter concerned.

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