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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

2 CFR Part 376

45 CFR Parts 74 and 76

Department of Health and Human Services' Implementation of OMB Guidance on Nonprocurement Debarment and Suspension

AGENCY: Department of Health and Human Services.

ACTION: Interim final rule with request for comments.

SUMMARY: The Department of Health and Human Services (HHS or the Department) is issuing a new part 376 on nonprocurement debarment and suspension in Title 2 the Code of Federal Regulations (CFR). This new part is HHS's implementation of OMB's guidance provided at 2 CFR part 180. HHS is removing 45 CFR part 76, the part containing its implementation of the government-wide common rule on nonprocurement debarment and suspension. The new part in 2 CFR serves the same purpose as the common rule, but in a simpler way. This interim final rule is part of OMB's initiative to streamline and consolidate all federal regulations on nonprocurement debarment and suspension. It is an administrative simplification that would make no substantive change in HHS policy or procedures for nonprocurement debarment and suspension.

DATES: *Effective Date:* March 1, 2007.

Comment Date: April 2, 2007.

ADDRESSES: You may submit comments by any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

E-mail: to Nancy.Weisman@hhs.gov. Please state "2 CFR part 376" on the subject line or mail: Nancy Weisman, HHS Office of Grants Policy, Oversight and Evaluation, Room 336-E, 200 Independence Ave., SW., Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT:

Nancy Weisman at (202) 260-4573, or by e-mail at [Nancy.Weisman@hhs.gov].

SUPPLEMENTARY INFORMATION:

I. Background

On August 31, 2005, OMB issued interim final Guidance for Government-wide Debarment and Suspension (Nonprocurement), codified in part 180 of Title 2 of the CFR (70 FR 51862). In addition to restating and updating its guidance on nonprocurement debarment and suspension, the interim final guidance requires all Federal agencies to adopt a new approach to federal agency implementation of the guidance. OMB requires each agency to issue a brief rule that: (1) Adopts the guidance, giving it regulatory effect for that agency's activities; and (2) states any agency-specific additions, clarifications, and exceptions to the government-wide policies and procedures contained in that guidance.

That guidance also requires agencies to implement the OMB guidance by February 28, 2007. Pursuant to the requirements in OMB's guidance, the Department will: (1) Establish Chapter 3 in Subtitle B of Title 2 CFR for HHS regulations on grants and agreements; (2) remove 45 CFR part 76 containing the full text of the Department's debarment and suspension common rule; (3) replace 45 CFR part 76 with a brief new part 376 that adopts OMB's guidance at 2 CFR part 180 and adds provisions specific to HHS; (4) co-locate the Department's new part 376 with OMB's guidance in 2 CFR along with other agencies' regulations in that title; and (5) revise the reference in 45 CFR 74.13 to reflect the new citation to the Department's nonprocurement debarment and suspension regulations now located at 2 CFR part 376.

II. Invitation To Comment

This new part in 2 CFR adopts the OMB guidelines with the same additions and clarifications we made to the common rule on nonprocurement debarment and suspension in the **Federal Register** publication of

November 26, 2003 (68 FR 66630). In soliciting comments on this action, we are not seeking to revisit substantive issues that were already resolved during the preparation of that final common rule. Because we intend the new part to make no changes in current HHS policies and procedures, we specifically invite comments on any unintended changes in substantive content that the new part in Title 2 CFR would make relative to the November 2003 common rule at 45 CFR part 76.

III. Procedural Review Requirements

A. Executive Order 12866, Regulatory Planning and Review

HHS has determined that 2 CFR part 376 is not a significant regulatory action.

B. Regulatory Flexibility Act

HHS certifies this rulemaking will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act [5 U.S.C. 605(b)].

Therefore, no regulatory flexibility statement has been prepared. Since this rule relocates existing HHS nonprocurement and debarment policies or procedures and does not promulgate any new policies and procedures that would impact the public, it has been determined that this rule will not have a significant economic effect on a substantial number of small entities, and, thus, a regulatory flexibility analysis was not performed.

C. Unfunded Mandates Reform Act

HHS has determined that 2 CFR 376 does not contain a Federal mandate under 2 U.S.C. 1501(7) that may result in the expenditure by state, local and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any one year.

D. Paperwork Reduction Act

The Paperwork Reduction Act, 44 U.S.C. 35, does not apply because the issuance of 2 CFR part 376 does not impose any new reporting or recordkeeping requirements that require approval by OMB.

E. Executive Order 13132, Federalism

This regulation does not have federalism implications, as set forth in Executive Order 13132. This regulation does not have substantial direct effects

on the states, the relationship between the Federal Government and the states, or the distribution of power and responsibilities among the various levels of government.

List of Subjects

2 CFR Part 376

Administrative practice and procedure, Debarment and suspension, Grant programs, Reporting and recordkeeping requirements.

45 CFR Part 74

Accounting, Colleges and universities, Grant programs, Hospitals, Indians, Intergovernmental relations, Nonprofit organizations, Reporting and recordkeeping requirements.

45 CFR Part 76

Administrative practice and procedure, Debarment and suspension, Grant programs, Reporting and recordkeeping requirements.

Dated: February 26, 2007.

Michael O. Leavitt,
Secretary.

■ Accordingly, under the authority of 5 U.S.C. 301; 31 U.S.C. 6101 (note); E.O. 12689 (3 CFR, 1989 Comp., p. 235); E.O. 12549 (3 CFR, 1986 Comp., p. 189); E.O. 11738 (3 CFR, 1973 Comp., p. 799), the Department of Health and Human Services publishes the following amendments to the Code of Federal Regulations, Title 2, Subtitle B, and Title 45, Chapter I, as set forth below.

Title 2—Grants and Agreements

■ Add Chapter III in Subtitle B of Title 2 CFR where HHS grants and agreement rules will appear. With this regulatory action, Chapter III will consist of Part 376, to read as follows:

CHAPTER III—DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 376—NONPROCUREMENT DEBARMENT AND SUSPENSION

Sec.

376.10 What does this part do?

376.20 Does this part apply to me?

376.30 What policies and procedures must I follow?

Subpart A—General

376.137 Who in the Department of Health and Human Services (HHS) may grant an exception to let an excluded person participate in a covered transaction?

376.147 Does an exclusion from participation in Federal health care programs under Title XI of the Social Security Act affect a person's eligibility to participate in nonprocurement and procurement transactions?

Subpart B—Covered Transactions

376.220 What contracts and subcontracts, in addition to those listed in 2 CFR 180.220, are covered transactions?

Subpart C—Responsibilities of Participants Regarding Transactions

376.332 What methods must I use to pass requirements down to participants at lower tiers with whom I intend to do business?

376.370 What are the obligations of Medicare carriers and intermediaries?

Subpart D—Responsibilities of Federal Agency Officials Regarding Transactions

376.437 What method do I use to communicate to a participant the requirements described in the OMB guidance at 2 CFR 180.435?

Subpart E—Excluded Parties List System [Reserved]

Subpart F—General Principles Relating to Suspension and Debarment Actions [Reserved]

Subpart G—Suspension [Reserved]

Subpart H—Debarment [Reserved]

Subpart I—Definitions

376.935 Disqualified (HHS supplement to government-wide definition at 2 CFR 180.935).

376.995 Principal (HHS supplement to government-wide definition at 2 CFR 180.995).

Subpart J—[Reserved]

Authority: 5 U.S.C. 301; 31 U.S.C. 6101 (note); E.O. 12689 (3 CFR, 1989 Comp., p. 235); E.O. 12549 (3 CFR, 1986 Comp., p. 189); E.O. 11738 (3 CFR, 1973 Comp., p. 799).

§ 376.10 What does this part do?

This part adopts the Office of Management and Budget (OMB) guidance in subparts A through I of 2 CFR part 180, as supplemented by this part, as the Department of Health and Human Services (HHS or Department) policies and procedures for nonprocurement debarment and suspension. HHS thereby gives regulatory effect to the OMB guidance as supplemented by this part. This part satisfies the requirements in 2 CFR 180.20, section 3 of Executive Order 12549, “Debarment and Suspension” (3 CFR 1986 Comp., p. 189), Executive Order 12689, “Debarment and Suspension” (3 CFR 1989 Comp., p. 235) and 31 U.S.C. 6101 note (Section 2455, Pub. L. 103–355, 108 Stat. 3327).

§ 376.20 Does this part apply to me?

This part and, through this part, pertinent portions of the OMB guidance in subparts A through I of 2 CFR part 180 (see table at 2 CFR 180.100(b)), apply to you if you are a—

(a) Participant or principal in a “covered transaction” under subpart B

of 2 CFR part 180, as supplemented by this part, and the definition of nonprocurement transaction” at 2 CFR 180.970.

(b) Respondent in HHS suspension or debarment action;

(c) HHS debarment or suspension official;

(d) HHS grants officer, agreements officer, or other HHS official authorized to enter into any type of nonprocurement transaction that is a covered transaction.

§ 376.30 What policies and procedures must I follow?

The policies and procedures that you must follow are the policies and procedures specified in each applicable section of the OMB guidance in subparts A through I of 2 CFR part 180, including the corresponding section that HHS published in 2 CFR part 376 identified by the same section number. The contracts under a nonprocurement transaction, that are covered transactions, for example, are specified by section 220 of the OMB guidance (*i.e.*, 2 CFR 180.220) as supplemented by section 220 in this part (*i.e.*, 2 CFR 376.220). For any section of OMB guidance in subparts A through I of 2 CFR part 180 that has no corresponding section in this part, HHS policies and procedures are those in the OMB guidance at 2 CFR part 180.

Subpart A—General

§ 376.137 Who in the Department of Health and Human Services may grant an exception to let an excluded person participate in a covered transaction?

The HHS Debarment/Suspension Official has the authority to grant an exception to let an excluded person participate in a covered transaction as provided at 2 CFR 180.135.

§ 376.147 Does an exclusion from participation in Federal health care programs under Title XI of the Social Security Act affect a person's eligibility to participate in nonprocurement and procurement transactions?

Any individual or entity excluded from participation in Medicare, Medicaid, and other Federal health care programs under Title XI of the Social Security Act, 42 U.S.C. 1320a–7, 1320a–7a, 1320c–5, or 1395ccc, and implementing regulation at 42 CFR part 1001, will be subject to the prohibitions against participating in covered transactions, as set forth in this part and part 180, and is prohibited from participating in all Federal government procurement programs and nonprocurement programs. For example, if an individual or entity is

excluded by the HHS Office of the Inspector General from participation in Medicare, Medicaid, and/or other Federal health care programs, in accordance with 42 U.S.C. 1320a-7, then that individual or entity is prohibited from participating in all Federal government procurement and nonprocurement programs (42 CFR part 1001).

Subpart B—Covered Transactions

§ 376.220 What contracts and subcontracts, in addition to those listed in 2 CFR 180.220, are covered transactions?

In addition to the contracts covered under 2 CFR 180.220(b), this part also applies to all lower tiers of subcontracts under covered nonprocurement transactions, as permitted under the OMB guidance at 2 CFR 180.220(c). (See optional lower tier coverage in the diagram in the Appendix to 2 CFR part 180.)

Subpart C—Responsibilities of Participants Regarding Transactions

§ 376.332 What methods must I use to pass requirements down to participants at lower tiers with whom I intend to do business?

To communicate the requirements to lower-tier participants, you must include a term or condition in the lower-tier transaction requiring the lower-tier participant's compliance with 2 CFR part 180, as supplemented by this subpart.

§ 376.370 What are the obligations of Medicare carriers and intermediaries?

Because Medicare carriers, intermediaries and other Medicare contractors undertake responsibilities on behalf of the Medicare program (Title XVIII of the Social Security Act), these entities assume the same obligations and responsibilities as the HHS Medicare officials responsible for the Medicare Program with respect to actions under 2 CFR part 376. This would include the requirement for these entities to check the Excluded Parties List System (EPLS) and take necessary steps to effect this part.

Subpart D—Responsibilities of Federal Agency Officials Regarding Transactions

§ 376.437 What method do I use to communicate to a participant the requirements described in the OMB guidance at 2 CFR 180.435?

To communicate to a participant the requirements described in 2 CFR 180.435, you must include a term or condition in the transaction that requires the participant's compliance

with subpart C of 2 CFR part 180, as supplemented by Subpart C of this part, and require the participant to include a similar term or condition in lower-tier covered transactions.

Subpart E—Excluded Parties List System [Reserved]

Subpart F—General Principles Relating to Suspension and Debarment Actions [Reserved]

Subpart G—Suspension [Reserved]

Subpart H—Debarment [Reserved]

Subpart I—Definitions

§ 376.935 Disqualified. (HHS supplement to government-wide definition at 2 CFR 180.935).

Disqualified means persons prohibited from participating in specified federal procurement and nonprocurement transactions pursuant to the statutes listed in 2 CFR 180.935, and pursuant to Title XI of the Social Security Act (42 U.S.C. 1320a-7, 1320a-7a, 1320c-5, and 1395ccc) as enforced by the HHS Office of the Inspector General.

§ 376.995 Principal (HHS supplement to government-wide definition at 2 CFR 180.995).

Principal means individuals, in addition to those listed at 2 CFR 180.995, who participate in HHS covered transactions including:

- (a) Providers of federally required audit services; and
- (b) Researchers.

Subpart J—[Reserved]

Title 45—Public Welfare

CHAPTER I—DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 74—[AMENDED]

- 1. The authority citation for part 74 continues to read as follows:

Authority: 5 U.S.C. 301.

§ 74.13 [Amended]

- 2. Section 74.13 is amended by revising the citation “45 CFR part 76” to read “2 CFR part 376.”

PART 76—[REMOVED]

- 3. Remove part 76 from Title 45 CFR.

[FR Doc. 07-946 Filed 2-27-07; 12:05 pm]
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NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

2 CFR Part 3369

45 CFR Part 1169

RIN 3136-AA29

Office of the General Counsel; National Endowment for the Humanities Implementation of OMB Guidance on Nonprocurement Debarment and Suspension

AGENCY: National Endowment for the Humanities.

ACTION: Direct final rule.

SUMMARY: The National Endowment for the Humanities (NEH) implements Office of Management and Budget (OMB) guidance on nonprocurement suspension and debarment, issued on August 31, 2005 [70 FR 51863], by adopting the guidelines in a new part in title 2 of the CFR, the Government-wide title recently established for OMB guidance on grants and agreements, and removing 45 CFR part 1169, the part containing the NEH implementation of the government-wide common rule on nonprocurement debarment and suspension. This regulatory action would make no substantive change in NEH policy or procedures for nonprocurement debarment and suspension.

DATES: The effective date for this final rule is April 2, 2007.

FOR FURTHER INFORMATION CONTACT: National Endowment for the Humanities, ATTN: Office of the General Counsel, 1100 Pennsylvania Avenue, NW., Room 529, Washington, DC 20506; or Heather Gottry, (202) 606-8322. Hearing-impaired individuals are advised that information on this matter may be obtained by contacting the Endowment's TDD terminal on (202) 606-8282.

SUPPLEMENTARY INFORMATION: This final rule implements the OMB guidance and does not make any changes in current policies and procedures. NEH is not soliciting public comment on this rule and is instead issuing this rule as a direct final rule. Under 5 U.S.C. 553(b)(3)(A) agencies are not required to undergo notice and comment procedure for “interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice.” Because this rule adopts OMB’s published guidelines, which followed notice and comment procedures, and collocates NEH’s specific nonprocurement suspension and debarment rules to title 2 of the CFR, we