

description of the construct validity of the device.

- A warning that the device does not identify the presence or absence of clinical diagnoses.
- A warning that the device is not a stand-alone diagnostic.
- The intended use population and the intended use environment.
- Any instructions technicians must convey to patients regarding the administration of the test and collection of cognitive test data.

Computerized cognitive assessment aids are prescription devices restricted to patient use only upon the authorization of a practitioner licensed by law to administer or use the device; see 21 CFR 801.109 (*Prescription devices*).

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k), if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the computerized cognitive assessment aid they intend to market.

## II. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

## III. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 807, subpart E regarding premarket notification submissions have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801, regarding labeling have been approved under OMB control number 0910–0485.

## IV. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at <http://www.regulations.gov>.

1. DEN130033: De Novo Request per 513(f)(2) of the Federal Food, Drug, and Cosmetic Act from Cerebral Assessment Systems, Inc., dated June 24, 2013.

## List of Subjects in 21 CFR Part 882

Medical devices, Neurological devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 882 is amended as follows:

## PART 882—NEUROLOGICAL DEVICES

- 1. The authority citation for 21 CFR part 882 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

- 2. Add § 882.1470 to subpart B to read as follows:

### § 882.1470 Computerized cognitive assessment aid.

(a) *Identification.* The computerized cognitive assessment aid is a prescription device that uses an individual's score(s) on a battery of cognitive tasks to provide an interpretation of the current level of cognitive function. The computerized cognitive assessment aid is used only as an assessment aid to determine level of cognitive functioning for which there exists other valid methods of cognitive assessment and does not identify the presence or absence of clinical diagnoses. The computerized cognitive assessment aid is not intended as a stand-alone or adjunctive diagnostic device.

(b) *Classification.* Class II (special controls). The special control(s) for this device are:

(1) The technical parameters of the device's hardware and software must be fully characterized and be accompanied by appropriate non-clinical testing:

(i) Hardware specifications must be provided. Appropriate verification, validation, and hazard analysis must be performed.

(ii) Software, including any proprietary algorithm(s) used by the device to arrive at its interpretation of the patient's cognitive function, must be

described in detail in the software requirements specification (SRS) and software design specification (SDS). Appropriate software verification, validation, and hazard analysis must be performed.

(2) The device must be designed and tested for electrical safety.

(3) The labeling must include:

(i) A summary of any testing conducted to demonstrate how the device functions as an interpretation of the current level of cognitive function. The summary of testing must include the following, if available: Any expected or observed adverse events and complications; any performance measurements including sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) per the devices intended use; a description of the repeatability of measurements; a description of how the cut-off values for categorization of measurements were determined; and a description of the construct validity of the device.

(ii) A warning that the device does not identify the presence or absence of clinical diagnoses.

(iii) A warning that the device is not a stand-alone diagnostic.

(iv) The intended use population and the intended use environment.

(v) Any instructions technicians must convey to patients regarding the administration of the test and collection of cognitive test data.

Dated: August 11, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF STATE

### 22 CFR Part 35

[Public Notice 9220]

RIN 1400–AD85

### Program Fraud Civil Remedies

**AGENCY:** Department of State.

**ACTION:** Final rule.

**SUMMARY:** The Department of State is updating its regulations regarding its implementation of the Program Fraud Civil Remedies Act of 1986, to remove a conflict between the “reviewing official” and the “authority head” as defined by the implementing regulations.

**DATES:** This rule is effective August 17, 2015.

**FOR FURTHER INFORMATION CONTACT:** Alice Kottmyer, Attorney-Adviser,

Office of the Legal Adviser, (202) 647-2318, or [kottmyeram@state.gov](mailto:kottmyeram@state.gov).

**SUPPLEMENTARY INFORMATION:** The Program Fraud Civil Remedies Act of 1986, 31 U.S.C. 3801 *et seq.* (the Act), outlines a procedure for establishing administrative procedures for imposing civil penalties and assessments against persons who make, submit, or present, or cause to be made, submitted, or presented, false fictitious, or fraudulent claims or written statements to authorities or to their agents; and specifying the hearing and appeal rights of persons subject to allegations of liability for such penalties and assessments. In a nutshell, the “investigating official” (who is in the Office of the Inspector General) presents a case to the “reviewing official” (currently defined as the Chief Financial Officer) who, if appropriate, forwards the case to the Department of Justice. The Department of Justice will approve a “claim” if it believes further action is warranted. The reviewing official serves the claim on the respondent. There is a hearing before an administrative law judge (ALJ), and a disposition adverse to the respondent can be appealed to the “authority head,” defined in the rule as the Under Secretary for Management.

Currently, the Under Secretary for Management is designated by the President as the Chief Financial Officer for the Department of State. Therefore, he is the reviewing official as well as the authority head, which of course is unacceptable. This rule corrects that anomaly, by defining the “reviewing official” as the Assistant Legal Adviser for Buildings and Acquisitions (hereinafter, “the ALA”). The Under Secretary for Management remains the authority head.

The Act (in 31 U.S.C. 3801(a)(8)) outlines the qualifications for the reviewing official, all of which are met by the ALA. (1) He or she must be designated by the authority head to make the determination under 31 U.S.C. 3803(a)(2) to send the case to the Department of Justice for its review and action, if appropriate. (2) He or she must be serving in a position for which the rate of basic pay is not less than the minimum rate of basic pay for grade GS-16 under the General Schedule; the ALA is a member of the Senior Executive Service, and thus has a rate of pay at least as high as GS-16, a grade which was eliminated under the provisions of the Civil Service Reform Act of 1978. (3) He or she must not be subject to supervision by, or required to report to, the investigating official, and not employed in the organizational unit of the authority in which the

investigating official is employed; the ALA is not in the Office of the Inspector General and is not (nor will he or she ever be) subject to the supervision of anyone in that office.

Accordingly, 22 CFR 35.2(r), the definition of “reviewing official,” is changed by this rulemaking.

## Regulatory Findings

### *Administrative Procedure Act*

This regulation amends a “rule of agency organization, procedure, or practice”, which is not subject to the notice-and-comment rulemaking procedures set forth in 5 U.S.C. 553. See 5 U.S.C. 553(b). Therefore, the Department is issuing this amendment as a final rule.

### *Regulatory Flexibility Act/Executive Order 13272: Small Business*

Because this final rule is exempt from notice and comment rulemaking under 5 U.S.C. 553, it is exempt from the regulatory flexibility analysis requirements set forth by the Regulatory Flexibility Act. Nonetheless, consistent with the Regulatory Flexibility Act, the Department certifies that this rule will not have a significant economic impact on a substantial number of small entities.

### *Unfunded Mandates Reform Act of 1995*

Section 202 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1532, generally requires agencies to prepare a statement before proposing any rule that may result in an annual expenditure of \$100 million or more by State, local, or tribal governments, or by the private sector. This rule will not result in any such expenditure, nor will it significantly or uniquely affect small governments.

### *Small Business Regulatory Enforcement Fairness Act of 1996*

This rule is not a major rule as defined by 5 U.S.C. 804. The Department is aware of no monetary effect on the economy that would result from this rulemaking, nor will there be any increase in costs or prices; or any effect on competition, employment, investment, productivity, innovation, or the ability of United States-based companies to compete with foreign-based companies in domestic and import markets.

### *Executive Orders 12866 and 13563*

The Department of State has reviewed this rule to ensure its consistency with the regulatory philosophy and principles set forth in Executive Orders 12866 and 13563, and has determined that the benefits of this regulation

outweigh any cost. The Department does not consider this rule to be a economically significant rulemaking action.

### *Executive Orders 12372 and 13132: Federalism*

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government. The rule will not have federalism implications warranting the application of Executive Orders 12372 and 13132.

### *Executive Order 12988: Civil Justice Reform*

The Department has reviewed the regulation in light of sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

### *Executive Order 13175*

The Department of State has determined that this rulemaking will not have tribal implications, will not impose substantial direct compliance costs on Indian tribal governments, and will not preempt tribal law. Accordingly, the requirements of Executive Order 13175 do not apply to this rulemaking.

### *Paperwork Reduction Act*

This rule does not impose or revise information collection requirements under the provisions of the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

### **List of Subjects in 22 CFR Part 35**

Administrative practice and procedure, Claims, Fraud, Penalties.

For the reasons stated in the preamble, amend part 35 of title 22 of the Code of Federal Regulations as follows:

### **PART 35—PROGRAM FRAUD CIVIL REMEDIES**

- 1. The authority citation for part 35 is revised to read as follows:

**Authority:** 22 U.S.C. 2651a; 31 U.S.C. 3801 *et seq.*

- 2. Revise § 35.2(r) to read as follows:

#### **§ 35.2 Definitions.**

\* \* \* \* \*

(r) *Reviewing official* means the Assistant Legal Adviser for Buildings and Acquisitions or her or his designee who is—

(1) Not subject to supervision by, or required to report to, the investigating official;

(2) Not employed in the organizational unit of the authority in which the investigating official is employed; and

(3) Serving in a position for which the rate of basic pay is not less than the minimum rate of basic pay for grade GS-16 under the General Schedule.

\* \* \* \* \*

Dated: August 3, 2015.

**Patrick F. Kennedy,**

*Under Secretary of State for Management,  
Department of State.*

[FR Doc. 2015-20263 Filed 8-14-15; 8:45 am]

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## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

### 24 CFR Part 15

[Docket No. FR-5624-F-02]

RIN 2501-AD57

### Revision of Freedom of Information Act Regulation

**AGENCY:** Office of the Deputy Secretary, HUD.

**ACTION:** Final rule.

**SUMMARY:** This final rule amends HUD's regulations implementing the Freedom of Information Act (FOIA) to update and streamline HUD's current FOIA regulation. Specifically, it updates HUD's regulations to reflect statutory changes to the FOIA, current HUD organizational structure, and current HUD policies and practices with respect to the FOIA. In addition, the rule uses current cost figures in calculating and charging fees. This final rule also incorporates changes made upon further evaluation of HUD's FOIA Regulation and in response to public comments received.

**DATES:** *Effective:* September 16, 2015.

**FOR FURTHER INFORMATION CONTACT:** Dolores W. Cole, Director, FOIA and Executive Correspondence, Office of Administration, Department of Housing and Urban Development, 451 7th Street SW., Room 10139, Washington, DC 20410-0500; telephone number 202-402-2671 (this is not a toll-free number). Hearing- or speech-impaired individuals may access this number via TTY by calling the Federal Relay Service at telephone number 1-800-877-8339 (this is a toll-free number).

**SUPPLEMENTARY INFORMATION:**

### I. Background

HUD's regulations at 24 CFR part 15 contain the policies and procedures governing public access to HUD records under the FOIA (5 U.S.C. 552). Subject to certain statutory exceptions, the FOIA gives persons the right to request and receive a wide range of information from any Federal agency. The FOIA has been amended several times since its enactment in 1966. In 2007, significant amendments to the FOIA were made by the Openness Promotes Effectiveness in our National Government Act of 2007 (OPEN Government Act) (Pub. L. 110-175, approved December 31, 2007). The OPEN Government Act made several amendments to procedural issues affecting FOIA administration, including the protection of the fee status for news media, the time limits for agencies to act upon FOIA requests, the availability of agency records maintained by a private entity, the establishment of a FOIA Public Liaison and FOIA Requester Service Center, and the requirement to describe the exemptions authorizing the redaction of material provided under the FOIA.

In addition to these statutory changes, several policy directives have been issued that affect HUD's FOIA program. These policy directives include Presidential memoranda dated January 21, 2009, entitled "Freedom of Information Act" (74 FR 4683, January 26, 2009), which applies a presumption of disclosure in FOIA decision-making and "Transparency and Open Government" (74 FR 4685, January 26, 2009), which encourages Federal agencies to harness new technologies to proactively post online information about their operations and decisions consistent with applicable law. As required by the Presidential memoranda, on March 19, 2009, Attorney General Eric Holder issued comprehensive new FOIA guidelines (see <http://www.justice.gov/ag/foia-memo-march2009.pdf>). The Attorney General's guidance further advises that agencies should release information to the fullest extent of the law, including information that may be legally withheld, provided there is no foreseeable harm to an interest protected by an exemption or the disclosure is not prohibited by law. In addition, the Attorney General's FOIA guidelines emphasized that agencies must have effective systems in place for responding to FOIA requests.

Consistent with this law and guidance, HUD undertook a comprehensive review of its FOIA regulation. As part of this review, HUD looked to the proposed updated FOIA

regulation published by the Department of Justice (DOJ) on March 21, 2011 (76 FR 15236). DOJ intended that its regulation serve as a model for all agencies in updating their own FOIA regulations.<sup>1</sup> As a result of its review, HUD published a proposed rule on May 31, 2013 (78 FR 32595), modeled on DOJ's proposed regulation, to incorporate changes enacted by the OPEN Government Act of 2007, reflect developments in case law, include current cost figures for calculating and charging fees, and enhance the administration and operation of HUD's FOIA program by increasing the transparency and clarity of the regulation.

### II. Changes and Clarifications Made in This Final Rule

This final rule follows publication of the May 31, 2013, proposed rule and takes into consideration the public comments received on the proposed rule. In response to public comment, a discussion of which is presented in the following section of this preamble, and in further consideration of issues addressed at the proposed rule stage, the Department is making the following changes at this final rule:

- HUD is revising § 15.103(c) to state that HUD will provide written notice to requesters when the time limits for HUD's response will be delayed. HUD will also provide the requester with the date by which HUD expects to complete its processing of the request.
- HUD is revising § 15.104(c)(3) to mirror the language of the FOIA. Specifically, HUD is removing the requirement that a representative of the news media, if not a full-time member of the news media, should establish that he or she is a person whose main professional activity or occupation is information dissemination.
- HUD is revising § 15.106(c) to reduce the duplication costs that HUD will charge for a paper photocopy of a record from \$0.18 per page to \$0.10 per page.
- HUD is revising § 15.107(a) to refer to the most current Executive order regarding classified information, which is Executive Order 13526, issued December 29, 2009.
- HUD is removing proposed § 15.109 from this final rule. Upon review HUD has determined that, § 15.109, entitled "Mortgage sales," directed itself to a specific HUD program rather than establish disclosure policy applicable

<sup>1</sup> See, <http://www.justice.gov/sites/default/files/testimonies/witnesses/attachments/03/15/11/03-15-11-oip-pustay-testimony-re-the-freedom-of-information-act---ensuring-transparency-and-accountability-in-the-digital-age.pdf>.