devices has serious public health implications.

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

(1) The device’s sensitivity and specificity performance characteristics or positive percent agreement and negative percent agreement, for each specimen type claimed in the intended use of the device, must meet one of the following two minimum clinical performance criteria:

(ii) For devices evaluated as compared to an FDA-cleared nucleic acid based-test or other currently appropriate and FDA accepted comparator method other than correctly performed viral culture method:

(A) The sensitivity result estimate for the device when testing for influenza A and influenza B must be at the point estimate of at least 80 percent with a lower bound of the 95 percent confidence interval that is greater than or equal to 70 percent.

(B) The negative percent agreement estimate for the device when testing for influenza A and influenza B must be at the point estimate of at least 95 percent with a lower bound of the 95 percent confidence interval that is greater than or equal to 90 percent.

(ii) For devices evaluated as compared to correctly performed viral culture method as the comparator method:

(A) The sensitivity result estimate for the device when testing for influenza A must be at the point estimate of at least 90 percent with a lower bound of the 95 percent confidence interval that is greater than or equal to 80 percent. The sensitivity result estimate for the device when testing for influenza B must be at the point estimate of at least 80 percent with a lower bound of the 95 percent confidence interval that is greater than or equal to 70 percent.

(B) The specificity result estimate for the device when testing for influenza A and influenza B must be at the point estimate of at least 95 percent with a lower bound of the 95 percent confidence interval that is greater than or equal to 90 percent.

(2) When performing testing to demonstrate the device meets the requirements in paragraph (b)(1) of this section, a currently appropriate and FDA accepted comparator method must be used to establish assay performance in clinical studies.

(3) Annual analytical reactivity testing of the device must be performed with contemporary influenza strains. This annual analytical reactivity testing must meet the following criteria:

(i) The appropriate strains to be tested will be identified by FDA in consultation with the Centers for Disease Control and Prevention (CDC) and sourced from CDC or an FDA-designated source. If the annual strains are not available from CDC, FDA will identify an alternative source for obtaining the requisite strains.

(ii) The testing must be conducted according to a standardized protocol considered and determined by FDA to be acceptable and appropriate.

(iii) By July 31 of each calendar year, the results of the last 3 years of annual analytical reactivity testing must be included as part of the device’s labeling. If a device has not been on the market long enough for 3 years of annual analytical reactivity testing to have been conducted since the device received marketing authorization from FDA, then the results of every annual analytical reactivity testing since the device received marketing authorization from FDA must be included. The results must be presented as part of the device’s labeling in a tabular format, which includes the labeled information for each virus tested as described in the certificate of authentication, either by:

(A) Placing the results directly in the device’s §809.10(b) of this chapter compliant labeling that physically accompanies the device in a separate section of the labeling where the analytical reactivity testing data can be found; or

(B) In the device’s label or in other labeling that physically accompanies the device, prominently providing a hyperlink to the manufacturer’s public Web site where the analytical reactivity testing data can be found. The manufacturer’s home page, as well as the primary part of the manufacturer’s Web site that discusses the device, must provide a prominently placed hyperlink to the Web page containing this information and must allow unrestricted viewing access.


Leslie Kux,
Associate Commissioner for Policy.

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 15

[Docket No. FR–5986–F–01]

RIN 2501–AD81

Revision of Freedom of Information Act Regulation

AGENCY: Office of the Secretary, HUD.

ACTION: Final rule.

SUMMARY: This final rule amends HUD’s Freedom of Information Act (FOIA) regulation to implement the FOIA Improvement Act of 2016. The FOIA Improvement Act enacted a range of procedural issues, including requirements that agencies establish a minimum of 90 days for requesters to file an administrative appeal, and codifies the foreseeable harm standard.
In addition, this final rule revises a section of HUD’s FOIA regulations to more accurately reflect statutory language.

DATES: Effective Date: February 13, 2017.

FOR FURTHER INFORMATION CONTACT: Helen Foster, Deputy Chief Administrative Officer, Office of Administration, Department of Housing and Urban Development, 451 7th Street SW., Room 1039, 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 toll-free Federal Relay Service at telephone number 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

On June 30, 2016, the President signed into law the FOIA Improvement Act of 2016 (2016 Act) (Pub. L. 114–185, 130 Stat. 538), which contains several substantive and procedural amendments to the Freedom of Information Act (FOIA). The 2016 Act addresses a range of procedural issues, including requirements that agencies establish a minimum of 90 days for requesters to file an administrative appeal, and that agencies provide dispute resolution services at various times throughout the FOIA process. The 2016 Act also codifies a “foreseeable harm” standard, amends Exemption 5 to the FOIA, creates a new Chief FOIA Officer Council within the Executive Branch, and adds two new elements to agency Annual FOIA Reports. The amendments apply to any request made after the date of enactment, which was June 30, 2016.

Section 3 of the 2016 Act requires agencies to review and issue updated regulations on procedures for the disclosure of records under the FOIA, in accordance with the amendments made by the 2016 Act, within 180 days of enactment. Accordingly, HUD revises its FOIA regulation to incorporate changes enacted by the 2016 Act.

II. Changes Made in This Final Rule

The following is an overview of the changes made in this final rule.

Section 15.101 Proactive Disclosures of Department Records

The 2016 Act requires agencies to “make available for public inspection in an electronic format” records that, because of their subject matter, the agency determines “have become or are likely to become the subject of subsequent requests for substantially the same records,” or that have been requested 3 or more times. In response, HUD is amending §§ 15.101(a) and 15.101(b)(7) to comply with this requirement. The revisions mirror the language from the 2016 Act.

The 2016 Act also adds agency reporting requirements for agencies’ annual FOIA reports. The 2016 Act requires that a report covering the preceding fiscal year is to be submitted to the Attorney General of the United States and to the Director of the Office of Government Information Services (OGIS). The raw statistical data used in each report must be made available without charge, license, or registration requirement; in an aggregated, searchable format, and in a format that may be downloaded in bulk. Both the report and the raw statistical data used in the report must be made available for public inspection in an electronic format. In response to this requirement, HUD is amending § 15.101(b)(8) in conformance with these new reporting requirements.

Section 15.103 Timing of Responses to Requests

When a FOIA request involves “unusual circumstances,” agencies have long been required to provide written notice to the requester, and in those instances where an extension of time of more than ten working days is specified, agencies have been required to provide the requester with an opportunity to limit the scope of the request so that it can be processed more quickly or to arrange an alternative time to respond. The 2016 Act adds an additional requirement when unusual circumstances exist. Specifically, whenever agencies extend the time limits by more than ten additional working days, in the written notice to the requester they must notify the requester of their right to seek dispute resolution services from the OGIS. To address this requirement, HUD is revising § 15.103(c) to incorporate the change enacted by the 2016 Act.

HUD is also using this final rule to update several specific provisions of § 15.103 to more accurately reflect the statutory language in 5 U.S.C. 552(a)(6)(A)(i). First, HUD is revising § 15.103(a) to state that HUD will generally “make a determination whether to comply with a FOIA request within 20 working days.” Second, HUD is revising § 15.103(c), which addresses when HUD may extend the time periods for processing a FOIA request, to remove the sentence that limited extensions to 10 working days. HUD is revising this language as inconsistent with the plain reading of the statute, the logic of the rest of the language in § 15.103(c), and Department of Justice guidance. Finally, in accordance with 5 U.S.C. 552(a)(6)(B)(iii), HUD has updated § 15.103(c) to include the provision that HUD shall make available its FOIA Public Liaison, who shall assist in the resolution of any disputes between the requester and HUD.

Section 15.105 Responses to Requests

When an agency makes a determination regarding whether to comply with a FOIA request, the 2016 Act provides that the agency is required to immediately notify the requester of such determination and the reasons therefore, and also notify the requester that they have a right to seek assistance from the agency’s FOIA Public Liaison.

For adverse determinations, the 2016 Act requires that agencies afford the requester no less than 90 days from the date of the adverse determination on the request to file an appeal. In addition, the 2016 Act requires that agencies notify the requester that they may seek dispute resolution services from the FOIA Public Liaison or from OGIS.

Consistent with this requirement, HUD has revised § 15.105(d) to provide that, once HUD makes a determination regarding compliance within the time line provided in § 15.103(a), HUD will immediately notify the requester of such determination, the reasons therefore, and their right to seek assistance from the FOIA Public Liaison.

For adverse determinations, HUD has added § 15.105(d)(2)(iv) to provide that HUD will notify the requester of their right to file an appeal no less than 90 days after the date of receiving the adverse determination. Finally, § 15.105(d)(2)(v) has been added to provide that HUD will notify the requester of their right to seek dispute resolution services from the FOIA Public Liaison or from OGIS.

Section 15.106 Fees

The 2016 Act contains several new provisions regarding agencies’ ability to assess search and duplication fees. First, the 2016 Act provides that an agency shall not assess any search fees, or in some cases, duplication fees, if the agency has failed to comply with any time limit described in § 15.103, with limited exceptions. Second, if an agency determines that unusual circumstances apply to the processing of a FOIA request, and the agency has provided timely written notice to the requester, then a delayed response time is excused for an additional ten days; if the agency fails to comply with the extended time limit, it may not charge fees, or, in some cases, duplication fees, with limited exceptions. Third, the 2016 Act
provides an exception allowing agencies to charge search fees, or in some cases, duplication fees, if unusual circumstances apply, more than 5,000 pages are necessary to respond to the request, timely written notice has been made to the requester, and the agency has discussed with the requester via written mail, electronic mail, or telephone (or made not less than 3 good-faith attempts to do so) how the requester could effectively limit the scope of the request. Fourth, the 2016 Act maintains that if a court determines that “exceptional circumstances” exist, as defined in 5 U.S.C. 552(a)(6)(C), the agency’s failure to comply with a time limit “shall be excused for the length of time provided by the court order.”

In accordance with the first change, HUD is updating § 15.106(d) to provide that HUD will not assess search fees or, for requesters that are educational or noncommercial scientific institutions or representatives of the news media requesting records not sought for commercial use, duplication fees, if it fails to comply with the extended time limits as described in § 15.103. To comply with the second change, HUD is adding § 15.106(d)(5) to grant HUD an additional ten days when unusual circumstances apply and timely written notice has been provided to the requester and to terminate HUD’s ability to assess search fees or duplication fees, as applicable, if HUD does not comply with the additional ten days. Regarding the third change, HUD is adding § 15.106(d)(6) to allow HUD to charge search fees when unusual circumstances apply and more than 5,000 pages are necessary to respond to the FOIA request. Regarding the fourth amendment, HUD is adding § 15.106(d)(7)(i) to excuse a failure to comply with any time limit if a court determines that exceptional circumstances exist; and § 15.106(d)(7)(ii), which provides the definition of “exceptional circumstances” as defined in 5 U.S.C. 552(a)(6)(C), has also been added for clarifying purposes.

Section 15.107 Documents Generally Protected From Disclosure

The 2016 Act requires that agencies withhold information under FOIA “only if the agency reasonably foresees that disclosure would harm an interest protected by an exemption.” If disclosure is prohibited by law. The 2016 Act further directs agencies to consider whether partial disclosure of information is possible whenever the agency determines that a full disclosure of a requested record is not possible, and to take reasonable steps necessary to segregate and release nonexempt information. The 2016 Act does not require disclosure of information that is otherwise prohibited from disclosure by law, or otherwise exempted from disclosure under Exemption 3.

Consistent with these changes, HUD is restructuring § 15.107 and adding paragraph (a) to provide that HUD shall withhold information only if it is reasonably foreseeable that disclosure would harm an interest protected by an exemption, or if disclosure is prohibited by law. Paragraph (a) also emphasizes that HUD will consider whether partial disclosure of information is possible if it determines that a full disclosure of a requested record is not possible, and that HUD will take reasonable steps necessary to segregate and release nonexempt information.

In addition, the 2016 Act sunsets the deliberative process privilege, as protected from disclosure under Exemption 5 of the FOIA. Specifically, the 2016 Act amends Exemption 5 to provide that the deliberative process privilege does not apply to records created 25 years or more before the date on which the records were requested. In accordance with the 2016 Act, HUD is revising § 15.107(b)(5) to state that the deliberative process privilege “shall not apply to records created 25 years or more before the date on which the records were requested.”

III. Justification for Final Rulemaking

In general, HUD publishes a rule for public comment before issuing a rule for effect, in accordance with HUD’s regulations on rulemaking at 24 CFR part 10. Part 10, however, provides in § 10.1 for exceptions from that general rule where HUD finds good cause to omit advance notice and public participation. The good cause requirement is satisfied when the prior public procedure is “impracticable, unnecessary or contrary to the public interest.”

HUD finds that good cause exists to publish this rule for effect without first soliciting public comment because prior public comment is unnecessary. This final rule follows the statutory directive in Section 3 of the 2016 Act, which requires agencies to review and issue updated regulations on procedures for the disclosure of records under the FOIA, in accordance with the amendments made by the 2016 Act, within 180 days of enactment. The 2016 Act codifies a number of transparency and openness principles and enacts a number of procedural requirements, including requiring that agencies establish a minimum of 90 days for requesters to file an administrative appeal and that they provide dispute resolution services at various times throughout the FOIA process. This final rule reflects the changes required by the 2016 Act. Finally, the rule revises provisions § 15.103 to more accurately reflect the statutory language in 5 U.S.C. 552(a)(6)(A)(i).

IV. Findings and Certifications

Executive Order 12866 and Executive Order 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if the regulation is necessary, to select the regulatory approach that maximizes net benefits. Because this final rule incorporates changes enacted by the 2016 Act, this rule was determined to not be a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and therefore was not reviewed by OMB.

Environmental Impact

This rule is categorically excluded from environmental review under the National Environmental Policy Act (42 U.S.C. 4321). The revision of the FOIA-related provisions § 15.103 to more accurately reflect the statutory language in 5 U.S.C. 552(a)(6)(A)(i).
Executive Order 13132, Federalism

Executive Order 13132 (entitled "Federalism") prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial direct compliance costs on state and local governments and is not required by statute, or the rule preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. This final rule does not have federalism implications and does not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the Executive Order.

Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) establishes requirements for federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments, and on the private sector. This final rule does not impose any federal mandates on any state, local, or tribal governments, or on the private sector, within the meaning of the Unfunded Mandates Reform Act of 1995.

List of Subjects in 24 CFR Part 15

Classification: Information, Courts, Freedom of information, Government employees, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, HUD amends 24 CFR part 15 as follows:

PART 15—PUBLIC ACCESS TO HUD RECORDS UNDER THE FREEDOM OF INFORMATION ACT AND TESTIMONY AND PRODUCTION OF INFORMATION BY HUD EMPLOYEES

1. The authority for 24 CFR part 15 is revised to read as follows:


2. Amend § 15.101 by removing in paragraph (a) “and copying” and adding in its place “in an electronic format”, and by adding paragraphs (b)(7) and (b)(8), to read as follows:

§ 15.101 Proactive disclosures of departmental records.

(b) * * * *

(7) Copies of all records, regardless of form or format that have been released to any person under § 15.105; and

(i) Because of the nature of their subject matter, the agency determines that the records have become or are likely to become the subject of subsequent requests for substantially the same records; or

(ii) Have been requested three or more times.

8. Report for the preceding fiscal year submitted to the U.S. Attorney General and the Director of the Office of Government Information Services (OGIS) as required by 5 U.S.C. 552(e) and the raw statistical data used in each report. This report will be made available:

(i) Without charge, license, or registration requirement;

(ii) In an aggregated, searchable format; and

(iii) In a format that may be downloaded in bulk.

§ 15.103 Timing of responses to requests.

(c) Extension of time periods for processing a request. In unusual circumstances, as defined in this paragraph, HUD may extend the time period for processing a FOIA request. In such circumstances, HUD will provide the requester with written notice setting forth the unusual circumstances for the extension and the date on which a determination is expected to be dispatched. If processing a request would require more than 10 working days beyond the general time limit established in paragraph (a) of this section, HUD will offer the requester an opportunity to limit the scope of the request so that HUD may process it within the extra 10-day working period or arrange an alternative time period within which the FOIA request will be processed. To aid the requester, HUD shall make available its FOIA Public Liaison, who shall assist in the resolution of any disputes between the requester and HUD, and notify the requester of the right of the requester to seek dispute resolution services from the Office of Government Information Services. For purposes of this section, unusual circumstances include:

§ 15.104 [Amended]

4. Amend paragraph (b) by adding “the” between “contacting” and “FOIA”.

5. Amend § 15.105 as follows:

a. Add paragraph (d) introductory text:

b. In paragraph (d)(1) remove “Once” and replace it with “If”.

c. Redesignate paragraph (d)(2)(iv) as (d)(2)(vi); and

§ 15.105 Responses to requests.

(d) Forms of response. Once HUD makes a determination regarding whether to comply with a request pursuant to time limits established in § 15.103(a), HUD shall immediately notify the requester of such determination and the reasons therefor, and the requester’s right to seek assistance from the FOIA Public Liaison.

6. In § 15.106 revise paragraph (d)(1) and add paragraphs (d)(5), (6) and (7) to read as follows:

§ 15.106 Fees.

(d) Restrictions on charging fees. (1) No search fee will be charged for requests by educational institutions, noncommercial scientific institutions, or representatives of the news media. In addition, except as provided in paragraphs (d)(5), (d)(6), and (d)(7) of this section, HUD shall not assess any search fees (or, for requesters that are educational institutions, noncommercial scientific institutions or representatives of the news media requesting records not sought for commercial use, duplication fees) if HUD has failed to comply with any time limit described in § 15.103.

5. If HUD determines that unusual circumstances apply and HUD provides timely written notice to the requester pursuant to requirements provided in § 15.103(c), a failure to comply with any time limit as described in § 15.103 is excused for an additional 10 days. If HUD fails to comply with the extended time limit, HUD may not assess any search fees (or for requesters that are educational or noncommercial scientific institutions or representatives of the news media requesting records not sought for commercial use, duplication fees).
(6) If unusual circumstances apply and more than 5000 pages are necessary to respond to the request, HUD may charge search fees or, for requesters that are educational or noncommercial scientific institutions or representatives of the news media requesting records not sought for commercial use, duplication fees, if timely written notice has been made to the requester pursuant to requirements provided in §15.103(c) and HUD has discussed with the requester through written mail, electronic mail, or telephone (or made not less than 3 good-faith attempts to do so) how the requester could effectively limit the scope of the request as stipulated in § 15.103(c).

(7)(i) If a court has determined that exceptional circumstances exist, a failure to comply with any time limit as described in §15.103 shall be excused for the length of time provided by the court order.

(ii) For purposes of this section, the term “exceptional circumstances” does not include a delay that results from a predictable workload of requests, unless HUD demonstrates reasonable progress in reducing its backlog of pending requests. However, refusal by the requester to reasonably modify the scope of a request or arrange an alternative time frame for processing a request (or a modified request) after HUD gives them an opportunity to do so shall be considered a factor in determining whether exceptional circumstances exist.

* * * * * * 

7. Amend §15.107 as follows:

(a) Remove paragraph (b);

(b) Redesignate the introductory text as new paragraph (b);

(c) Redesignate paragraphs (c) through (i) as (b)(1) through (b)(9), respectively, and

(d) Redesignate paragraph (b)(5);

Revisions and addition to read as follows:

§15.107 Documents generally protected from disclosure.

(a) HUD shall withhold information only if HUD reasonably foresees that disclosure would harm an interest protected by an exemption as provided in paragraph (b) of this section, or disclosure is prohibited by law. HUD will consider whether partial disclosure of information is possible whenever HUD determines that a full disclosure of a requested record is not possible, and will take reasonable steps necessary to segregate and release nonexempt information. Nothing in this section requires disclosure of information that is otherwise prohibited from disclosure by law, or otherwise exempted from disclosure as provided in paragraph (b)(3) of this section.

* * * * * * 

(b)(5) Certain interagency or intra-agency communications. Exemption 5 (5 U.S.C. 552(b)(5)) protects interagency or intra-agency communications that are protected by legal privileges, such as the attorney-client privilege, attorney work-product privilege, or communications reflecting the agency’s deliberative process. The deliberative process privilege shall not apply to records created 25 years or more before the date on which the records were requested.

* * * * * *

Dated: December 27, 2016.

Nani A. Coloretti, Assistant General Counsel for Regulations.

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 891

[Docket No. FR 5890–C–03]

RIN 2501–AD75

Narrowing the Digital Divide Through Installation of Broadband Infrastructure in HUD-Funded New Construction and Substantial Rehabilitation of Multifamily Rental Housing; Correction

AGENCY: Office of General Counsel, HUD.

ACTION: Final rule; correction.

SUMMARY: On December 20, 2016, HUD published a final rule requiring the installation of broadband infrastructure at the time of new construction or substantial rehabilitation of multifamily rental housing that is funded or supported by HUD, the point at which such installation is generally easier and less costly when undertaken as a stand-alone effort. This document corrects incorrect paragraph designations in one section of the regulatory text. The effective date for HUD’s final rule of January 19, 2017 is unchanged.

DATES: This rule is effective January 12, 2017 and is applicable beginning December 12, 2016.