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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 5

RIN 0991-AC04

Freedom of Information Regulations

AGENCY: Office of the Secretary, Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This rule amends the Department of Health and Human Services (HHS's) Freedom of Information Act (FOIA) regulations. The regulations have been revised in order to incorporate changes made to the FOIA by the Electronic FOIA Act of 1996 (E-FOIA Act), the Openness Promotes Effectiveness in our National Government Act of 2007 (OPEN Government Act), and the FOIA Improvement Act of 2016 (FOIA Improvement Act). Additionally, the regulations have been updated to reflect changes to the organization, to make the FOIA process easier for the public to navigate, to update HHS's fee schedule, and to make provisions clearer.

DATES: This rule is effective on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]

FOR FURTHER INFORMATION CONTACT: Michael Marquis, Michael Bell, Deborah Peters, and/or Brandon Lancey by e-mail to: HHS.ACFO@hhs.gov. These individuals also can be reached by telephone at 202-690-7453.

SUPPLEMENTARY INFORMATION: HHS published a proposed rule to amend its FOIA regulations for public comment in the Federal Register at *81 FR 39003* on June 15, 2016. The comment period ended on August 15, 2016. In total, we received 10 public comments in response to the proposed rule. We have given due consideration to each of the comments we received, and, in response, we have made several modifications to the proposed rule. These modifications include clarifying, revising, expanding, or adding various provisions, withdrawing provisions, and making minor technical edits. We have addressed the substantive comments that we received in narrative form below; grouped by the section the comment corresponds to, as located in the proposed rule.

Purpose (§ 5.1)

One commenter recommended removing a provision that we originally proposed in § 5.1(b)(1) concerning records that are subject to a statutorily-based fee schedule program. The commenter interpreted this provision to suggest that we would withhold records in response to a FOIA request simply because a separate statute provided for charging fees for those records. In order to help clarify the meaning of that provision, the commenter's recommendation has been accepted and the proposed provision has been removed. An additional provision relating to records that are subject to other statutes specifically providing for fees has been added at § 5.52(f). In addition to the language in § 5.1(b)(1) concerning records that are subject to a statutorily-based fee schedule program, we have also removed the language concerning §§ 5.1(b)(2), (3) and (5), as we consider

the provisions of § 5.2 to adequately address proactive disclosures and the provisions of § 5.5 and § 5.22 to adequately address the interrelationship between the FOIA and the Privacy Act and how to make a first-party request.

Presumption of openness and proactive disclosures (§ 5.2)

Three commenters suggested revising the language of this section to more closely conform to the provisions of the FOIA Improvement Act, which codified the presumption of openness into the statute. This recommended change has been made and the rule reflects the statutory language at 5 U.S.C. 552(a)(8).

Two commenters suggested that we add language concerning proactive disclosures to this section. One of these commenters provided suggested language, which included a reference to two types of records that government agencies are required to make available to the public in an electronic format pursuant to the FOIA Improvement Act and 5 U.S.C. 552(a)(2)(D). Another commenter suggested that we consider the Department of Justice's FOIA regulation and government-wide guidance when drafting language on the subject. After considering these comments, we have added additional language to this section describing the responsibility of HHS Operating and Staff Divisions to proactively make certain records available to the public under the FOIA. This includes describing the responsibility for HHS Operating and Staff Divisions to identify additional records of interest to the public that are appropriate for public disclosure and referencing frequently requested records, which the rule defines in § 5.3 to include records, regardless of form or format, that have been released to any person and have been requested three or more times. This conforms with the proactive disclosure provisions of the FOIA, as amended by the FOIA Improvement Act.

One commenter suggested that requesters who make requests for records that ultimately become frequently requested records should have the option to receive credit for their FOIA requests, or, in the event that that seems like too much work, the Department should simply always give credit. We decline to accept the commenter's suggestion. There is no provision in the FOIA requiring agencies to give "credit" to requests for records that ultimately become frequently requested records. There also does not appear to be any policy rationale behind this suggestion. The purpose of the FOIA is not to provide "credit" to individuals or entities that make requests. Rather, it is to ensure an informed citizenry and inform the public about the operations and activities of the government.

One commenter, in connection with the requirements that we make certain records available proactively for public inspection in an electronic format and make available in an electronic format frequently requested records, suggested that we properly track and make available Public Use Files (PUFs) and ensure that they are adequately maintained. In addition, the commenter suggested we proactively track and publish score cards for PUF release reliability alongside data about FOIA performance. This comment is outside the scope of the rule. The purpose of this rule is to provide guidelines for the processing of agency records under the FOIA. The rule does not specify how we will treat specific category of records unless those categories are specifically delineated in the FOIA statute.

One commenter suggested that the Department should use the systems it has to proactively release information pursuant to 5 U.S.C. 552(a)(2) to highlight types of records that HHS is obligated to have but could not locate in response to a FOIA request. After reviewing this comment, we have decided not to accept the suggestion. The purpose of 5 U.S.C. 552(a)(2) is to make certain

categories of records available to the public automatically and without waiting for a FOIA request. Our main goal in implementing this provision of the FOIA is to determine which records we must make publicly available (including frequently requested records), to identify additional records of interest to the public that are appropriate for public disclosure, and to post and index such records.

One commenter stated that HHS should track Structured Query Languages (SQLs) used to respond to data FOIA requests. The commenter believes these should be tracked to make sure that PUF files released as a frequently requested record are consistent over time even after contractors or personnel change. The commenter also wanted the SQL and schema definitions to be provided with the response to the FOIA request/data result and if software was used, that should be provided with the data too. This comment is outside the scope of the rule. The rule does not specify how we will treat specific category of records unless those categories are specifically delineated in the FOIA statute.

Definitions (§ 5.3)

One commenter suggested revising the definition of “educational institution” to include a student who makes a request in furtherance of their coursework or other school-sponsored activities, which reflects a recent development in the case law. The suggested change has been accepted.

In order to comport with a recent development in the case law, two commenters suggested removing the following line from the definition of “representative of the news media”: “We decide whether to grant a requester media status on a case-by-case basis, based on the requester’s intended use of the requested records.” We have accepted this suggestion. Another commenter also had a concern with this language, but that comment is now moot since the language has been removed.

One commenter recommended including a comprehensive list of entities that would qualify as a “representative of the news media” instead of citing examples such as television, radio stations, and periodicals. The commenter noted that modern journalism has moved online. We have decided to reject the commenter’s suggestion to include a comprehensive list of entities that would qualify as “representatives of the news media.” Such a list would be difficult to devise and could become quickly outdated, given the ever-changing media landscape. We do note, however, that the rule acknowledges the presence of online media and makes reference to “online publications that disseminate news”.

One commenter thought that the following wording used to describe the term “representative of the news media” was unclear: “We do not consider requests for records that support the news-dissemination function of the requester to be a commercial use.” In response to this comment, we do not believe that this wording requires additional clarification. This wording was derived from the Uniform Freedom of Information Fee Schedule and Guidelines published by the Office of Management and Budget (OMB). The OMB has policy-making responsibility for issuing fee guidance, and we defer to the OMB for any further interpretation of this wording.

One commenter suggested that the rule include performance metrics to evaluate the Chief FOIA Officer and the Deputy Chief FOIA Officer and that these metrics be based on objective measures of external collaboration (e.g., number of emails answered, average response time to answer FOIA requester questions, etc.). While we believe strongly in providing good customer service and being held accountable for providing timely responses to FOIA requests, we believe the mechanisms to achieve these goals are already in place. Requesters can seek assistance with the

processing of their requests by contacting the appropriate FOIA Public Liaison at the FOIA Requester Service Center processing their request. Requesters can also seek assistance with their FOIA request through the services provided by the Office of Government Information Services (OGIS). Moreover, each year we submit to the Department of Justice and make available to the public two reports evaluating the Department's performance on FOIA: the Annual FOIA Report and the Chief FOIA Officer Report. The Annual FOIA Report contains detailed statistics on the numbers of requests received and processed by the Department, the time taken to respond, and the outcome of each request, as well as many other vital statistics regarding the administration of the FOIA at the Department. The Chief FOIA Officer Report includes detailed descriptions of the steps taken by the Department to improve FOIA compliance and transparency. Together, these reports provide the public with an accurate representation of the Department's performance on FOIA.

One commenter suggested making a grammatical change to the first sentence of the definition of the term "FOIA request" and suggested removing the second sentence of the definition because it does not enhance the reader's understanding of the meaning of the term. The commenter also thought that the second sentence of the definition might restrict the Department's ability to communicate with requesters. After considering this comment, we have made the suggested grammatical change to the first sentence of the definition and removed the second sentence.

Two commenters noted that we included a link in the definition of "Freedom of Information (FOIA)" that is no longer active and suggested that we either remove the link or update it. In response to these comments, we have updated the link. The updated link includes the current text of the FOIA.

One commenter suggested that the term “Freedom of Information Officer” be replaced with the term “Freedom of Information Act Officer” for the sake of consistency. The commenter noted that the word “act” is used in the titles of the Chief Freedom of Information Act Officer and the Deputy Chief Freedom of Information Act Officer and that the term “Freedom of Information Officer” has been shortened to “FOIA Officer” in §§ 5.27(b) and 5.28(a). After considering this comment, we have decided to accept the suggestion and have replaced the term “Freedom of Information Officer” with the term “Freedom of Information Act Officer”.

One commenter suggested that the term “frequently requested records” be modified to include records that have been released to any person under the FOIA and that have been requested 3 or more times. The FOIA Improvement Act requires federal agencies to make this category of records available to the public in an electronic format. In accordance with the FOIA Improvement Act, we have amended the term “frequently requested records” as suggested.

One commenter recommended changes to the definition of the term “submitter”. The commenter suggested clarifying that a person or entity that provides financial information qualifies as a submitter under the definition. The commenter also recommended adding language to the definition stating that a federal agency cannot be considered a submitter for the purposes of this rule. After considering this comment, the definition of the term submitter has been amended to include persons or entities that provide financial information to the agency. We have also included language in the definition stating that Federal government entities do not qualify as submitters.

Who can file a FOIA request? (§ 5.21)

One commenter noted that two of the three sentences in the section state that federal agencies may not submit FOIA requests; the commenter thought that one statement to that effect would suffice. At the recommendation of the commenter, the second sentence in this section has been removed. The revised section only has one sentence stating a federal agency may not submit FOIA requests.

How does HHS process my FOIA request? (formerly § 5.25)

One commenter noted that in § 5.25(b)(1)(iii) we referred to a “requestor” but throughout the rest of the rule, we referred to a “requester”. In order to be consistent, we will use “requester” for all references to the term.

Two commenters expressed concern with the criteria set forth in § 5.25(b)(1) for considering a request perfected and the amount of time provided in § 5.25(b)(2) for a requester to respond to a request to perfect their request. With regard to § 5.25(b)(1), both commenters noted that the FOIA statute states that the twenty-working-day statutory response period begins to run when the request is received by the responsible FOIA office, but not later than ten days after it is received by an HHS component designated to receive requests. Section 5.25(b)(1) has been amended at the recommendation of the commenters and in order to comply with the requirements of 5 U.S.C. 552(a)(6)(A). In addition, one of the commenters considered the contents of § 5.25(b)(1) to be contrary to the FOIA statute itself and recommended that the provision be removed from the rule in its entirety. In the view of the commenter, the provision added additional requirements to the FOIA that were not authorized by law. We disagree with this comment. The FOIA requires requesters to satisfy two conditions when submitting a FOIA request: that the request reasonably describes the records sought and that it is made in accordance with agency's published rule setting

forth the procedures for filing a FOIA request. If a requester fails to satisfy these conditions, § 5.25(b) requires an Operating Division or Staff Division to attempt to contact the requester and inform him or her of what additional information is needed to meet the requirements of the FOIA and this rule. This includes attempts to contact the requester in order to reformulate or modify a request in cases where we do not consider the records sought to be reasonably described. In addition, in instances where we close a request because of a failure to reasonably describe the records sought, the requester will be given administrative appeal rights to challenge the decision since this is an adverse determination. Finally, although such a requirement was legally permissible, we have decided to make it easier for requesters to perfect their requests by eliminating the requirement that, in order to perfect, a requester agree to pay all or an established amount of applicable fees or request a fee waiver. We do, however, encourage requesters to include such information in their requests and make reference to that suggestion in § 5.22.

As it relates to § 5.25(b)(2), the two commenters expressed concern with the amount of time requesters were provided with to respond to a request to perfect their requests. One commenter claimed that there was no authorization in the FOIA for an agency to unilaterally “administratively close” a FOIA request; that an agency can only grant a request in full or in part or deny it; and that § 5.25(b)(2) should be removed in its entirety. In the alternative, the commenter suggested affording the requester no less than 30 days to respond to a request to perfect their request in order to ensure that they have sufficient time to respond. The second commenter thought that requesters should be given at least 20 working days to respond to communications from the agency, and if the agency takes more than twenty working days from the date of the request to initiate communication with the requester, the requester should receive the same amount of time to respond to the agency. The second commenter also thought the

agency should be required to make at least three good-faith efforts to contact a requester by various forms of communication (mail, e-mail, telephone), if a communication goes unanswered because it is returned as undeliverable. In response to these comments, we have increased the amount of time requesters are provided with to respond to a request to perfect their request from “at least 10 working days” to “at least 20 working days”. We believe that this provides requesters with a reasonable amount of time to review the request to perfect, conduct any necessary research, and respond to the agency. In instances where a communication goes unanswered because it is returned as undeliverable, we will attempt to reach the requester using any alternative contact information provided before administratively closing the request. However, we do not think it is necessary to state the number of times we will attempt to contact a requester before administratively closing the request. Finally, we disagree with the comment suggesting that agencies do not have a right to administratively close a request. The FOIA specified two requirements for an access request: It must reasonably describe the records being sought and it must be made in accordance with published rules stating the time, place, fees (if any), and procedures to be followed. If a requester fails to satisfy these conditions, the rule requires HHS to attempt to contact the requester to seek clarification and provides the requester with a reasonable amount of time to respond. If a requester does not respond to communication within the specified timeframe, it is reasonable to deny the request and administratively close it because of a failure to reasonably describe the records sought or make the request in accordance with the published rules. Such a provision is found in a number of agency FOIA regulations throughout the government including the regulations of four other cabinet-level departments. Therefore, we decline to accept the comment.

The same two commenters expressed concern with the amount of time requesters were provided

with in § 5.25(c) to respond to a request to respond to requests for additional information or clarification regarding the specifics of a request or fee assessment. In response to these comments and in order to provide requesters with a reasonable amount of time to respond, we have increased the amount of time to respond to a request for additional information or clarification regarding the specifics of a request or fee assessment from “at least 10 working days” to “at least 20 working days”. The commenters also expressed concern with the language in § 5.25(c) stating “[s]hould you not answer any correspondence, or should the correspondence be returned undeliverable, we reserve the right to administratively close the FOIA request.” The concerns expressed about this provision were the same as those stated for § 5.25(b)(2), namely that the agency should be required to make at least three good-faith efforts to contact a requester by various forms of communication (mail, e-mail, telephone), if a communication goes unanswered because it is returned as undeliverable, and that there is no authorization in the FOIA for an agency to unilaterally administratively close a FOIA request. For the same reasons stated with regard to § 5.25(b)(2), we decline to accept the comment concerning undeliverable communications. With respect to whether the agency has the authority to administratively close requests when a communication goes unanswered, we again disagree with the comment. If a requester does not respond to communication within a reasonable amount of time, we have legitimate reason to believe that the requester is no longer interested in pursuing their request. Moreover, a provision allowing for the administrative closure of requests where a request for additional information or clarification goes unanswered is commonly included in a number of agency FOIA regulations throughout the government including the regulations of four other cabinet-level departments.

Multiple commenters provided input on §§ 5.25(e), (f), and (h), which describe the Department’s procedures for multitrack processing and handling requests that involve unusual circumstances.

One commenter expressed a concern that § 5.25(h) could be read to provide the agency with the authority to provide itself with unlimited time to respond to complex FOIA requests. Another commenter requested that §§ 5.25(e) and (f) be modified to include a commitment to provide requesters with an estimated completion date if their request is placed in the complex processing queue or if unusual circumstances exist. Additionally, the commenter recommended that § 5.25(h) be modified to require an agency to notify a requester of an expected delay because of unusual circumstances and that such a notice should provide requesters with an explanation of the unusual circumstances and an estimated completion date. The commenter recommended providing such a notice prior to having any conversations regarding the scope of the request. After considering these comments, the contents of §§ 5.25(e), (f), and (h) have been modified to distinguish requests that are placed in the complex processing queue from requests involving unusual circumstances and to align these sections with the FOIA statute. In cases where unusual circumstances require us to extend the processing time by more than 10 working days, we have clarified that requesters will have an opportunity to modify the request or arrange an alternative time period for processing the original or modified request. Finally, with regard to estimated completion dates, we have clarified the language of the rule indicating that we will provide requesters with an estimated completion date when we notify them of the unusual circumstances involved with their request. However, we decline to accept the commenter's recommendation to provide an estimated completion date for all requests placed in the complex processing queue. Such a policy is not required by the FOIA and, while we estimate the completion date based on our reasonable judgment as to how long it will likely take to complete the request, given the uncertainty inherent in establishing any estimate, the estimated completion date would be subject to change at any time.

One commenter recommended giving priority to records and data requests that give detailed and accurate information about where to find the records in question. The commenter believes that requesters who make such requests should be rewarded with cheaper fees and faster processing time. Requesters who give detailed and accurate information receive a number of benefits under the FOIA and this regulation already. First, if a request provides detailed and accurate information about where to find the records, there is a strong likelihood that the request will be considered perfected and quickly routed for search. Second, there is a strong likelihood that it will be unnecessary to toll the processing time to clarify the scope of the request if the requested records are well-described and we are given accurate information about where to find the records in question. Third, if the request provides accurate information about where to find the records in question, the search can be conducted more quickly which could reduce search fees, if those are associated with the request, and it could speed up the processing time. Finally, we have adopted multitrack processing and place requests on the simple or complex track based on the estimated amount of work or time needed to process the request. Providing information that helps us locate documents responsive to a request makes it more likely that the request will be placed on the simple track and processed more quickly. Given these advantages, we do not believe it is necessary to provide any additional benefits to requesters who provide detailed and accurate information about where to find the records in question.

One commenter suggested that the rule be modified to inform requesters that they are entitled to judicial review if the agency does not meet statutorily imposed deadlines. The commenter further stated that HHS should reference 5 U.S.C. 552(a)(6)(C) in the rule and clarify how a requester may exhaust his or her administrative remedies. After carefully considering this comment, we decline to adopt the commenter's suggested change. The FOIA statute itself already makes clear

that a failure to comply with the time limits for either an initial request or an administrative appeal may be treated as a “constructive exhaustion” of administrative remedies. Once there has been a “constructive exhaustion”, a requester may immediately thereafter seek judicial review if he or she wishes to do so. It is unnecessary for this rule to simply restate information that is already in the FOIA statute concerning the exhaustion of administrative remedies.

One commenter suggested defining the term “voluminous” in § 5.25(f). In revising the rule, we have removed the term “voluminous” from the referenced section. The term “voluminous” was contained in a recitation of the statutory definition of unusual circumstances. Since the FOIA statute already contains this information, it was unnecessary to include in the rule. However, even if the term “voluminous” remained in the rule, we do not believe it is appropriate to define it here. The term “voluminous” can be understood by the plain meaning in the statute, legislative intent, and any case law interpreting that term.

One commenter suggested we consider adding subsections that fully explain referrals, consultations, and coordination with other federal agencies or entities. We have accepted the commenter’s suggestion. Section 5.25 provides a full explanation of the Department’s procedures for rerouting of misdirected requests, referrals, consultations, and coordination.

How does HHS determine estimated completion dates for FOIA requests? (§ 5.26)

One commenter expressed a concern about § 5.26(a). In the view of the commenter, the language of this provision suggested that estimated completion dates are only provided when a requester asks for them. The commenter recommended that we provide estimated completion dates whenever a request is first placed in the complex processing queue, whenever we determine that

an estimated completion date must change for a request, or when a requester asks for an update on expected completion date, and that the language in this section be updated to reflect that. In response to this comment, we have amended the language in this section to clarify that we will provide estimated completion dates when we notify requesters of any unusual circumstances involved with their request and when a requester has asked for an estimated completion date. However, we decline to accept the commenter's recommendation of providing an estimated completion date for any request placed in the complex processing queue or whenever an estimated completion date must change for a request. As previously stated, while we estimate the completion date based on our reasonable judgment as to how long it will likely take to complete the request, given the uncertainty inherent in establishing any estimate, the estimated completion date would be subject to change at any time.

How do I request expedited processing? (§ 5.27)

Multiple commenters submitted comments concerning the criteria for granting expedited processing of FOIA request described in § 5.27(c). One commenter expressed concern that we did not include the need to meet a litigation deadline in an administrative appeal or in a court action as a case deemed appropriate for granting expedited processing. In the opinion of the commenter, a failure to include this policy into the rule would contradict the statute and constitute an invalid departure from established agency precedent. The commenter expressed three specific concerns with the rule as it relates to the omission of any express provision to grant expedited processing in cases where the information is needed to meet a deadline in litigation. First, the commenter believes the proposed rule is in conflict with the FOIA statute. The FOIA statute provides for expedited processing "in other situations". The commenter is of the opinion that this meant Congress intended for agencies to make expedited processing available for a broader range

of FOIA requests than just those defined as serving a “compelling need.” Second, the commenter is under the impression that HHS has a longstanding policy of allowing expedited processing in cases where the information is needed to meet a deadline in litigation. In support of this, the commenter cited a stipulated court order in *Home Health Line, Inc. v. Health Care Financing Admin.*, 90-cv-1006-LFO (D.D.C.1990), and a notice published by the Centers for Medicare & Medicaid Services (CMS) (formerly the Health Care Financing Administration (HCFA)), as a stipulation of dismissal and settlement of the case, outlining its policy for expedited processing. The notice was published at 55 FR 51342 (Dec. 13, 1990). The cited notice includes language stating that “HCFA follows its first-in/first-out practice for processing requests except where the requester demonstrates exceptional need or urgency.” 55 FR 51342. The notice further states that there are three categories of requester needs which HCFA has determined frequently [demonstrate exceptional need of urgency].” *Id.* One of the three categories of requester needs described in the notice is “where the requester needs the specific records in question to meet a deadline in litigation, either in a court or before an administrative tribunal.” *Id.* The commenter asserted that the agency cannot change its policy on expedited processing without violating the court order and the conditions of settlement in the *Home Health Line, Inc.* case. Finally, the commenter cited the Administrative Procedure Act to state that agencies must both acknowledge and explain the reasons for a departure from established policies or precedent. In the opinion of the commenter, there is no good reason for the agency to depart from a policy of granting expedited processing to meet a litigation deadline in an administrative appeal or court. The commenter has particular concern because, according to the commenter, under HHS regulations governing appeals to the PRRB, FOIA is the only means available to hospitals and other providers to obtain relevant and material evidence concerning the accuracy of Medicare payment determinations by HHS.

We reject this comment and will discuss each point in the order it was raised by the commenter. First, the commenter is incorrect when stating that the rule is in conflict with the FOIA statute because the rule does not provide for the expedited processing of requests “in other cases determined by the agency.” 5 U.S.C. Sec. 552(a)(6)(E)(i)(II). The plain language of the FOIA statute makes clear that the decision to provide for expedited processing “in other cases” is left to the discretion of the agency and the agency is free not to deem any other case appropriate. Second, we acknowledge that CMS had a policy of ordinarily granting expedited processing on a variety of circumstances, both administrative in nature and in response to specific needs stated by a requester, and that this policy was published in the *Federal Register* for the public’s benefit. However, at the time, HHS had not promulgated any rule with respect to expedited processing. This rule now promulgates rules for the entire Department providing for expedited processing of requests for records and supersedes the guidance CMS published at 55 FR 51342. Finally, while the adopted regulations do not represent a change in policy for the whole Department, we acknowledge that the only circumstance in CMS’s policy which we have chosen to retain in this rule is when a failure to obtain requested records on an expedited basis could reasonably be expected to pose an imminent threat to the life or physical safety of an individual. We believe that this change to CMS’s policy is necessary to establish fairness in the FOIA process. When granting expedited processing, we must consider the interest of all requesters in having their requests treated equally. We must also bear in mind that whenever we grant expedited processing to one requester, other requesters waiting patiently in line will have to wait longer for a response. As a result, the Department must only grant expedited processing in truly exceptional circumstances. The basic purpose of FOIA is to ensure that there is an informed citizenry, which is vital to the functioning of a democratic society, necessary to check against corruption, and needed to hold government officials accountable to the public. All members of the public are

beneficiaries of the FOIA, and while this includes parties to a litigation, historically, a requester's rights are not affected by his or her litigation need for government records. *See NLRB v. Robbins Tire & Rubber Co.*, 437 U.S. 214, 242 n.23 (1978). We additionally note that the number of FOIA requests which the Department must process has increased exponentially since 1990, which is yet another reason why we have decided to only grant expedited processing in very limited circumstances. For these reasons, we disagree with the commenter's contention that CMS does not have a good reason to depart from its current expedited processing policy.

A second commenter recommended that HHS provide for expedited processing of state survey documents such as investigator notes, witness statements, witness lists, and documents reviewed during the course of the investigation. The commenter believes that HHS should commit to responding to these types of requests so that nursing home residents can receive these documents before their claims are time barred by a statute of limitations. We must, unfortunately, decline to accept this recommendation. While specific requesters may have a strong personal need to receive responsive records as quickly as possible, the agency must consider the interests of all requesters waiting patiently in line and make sure that everyone is treated equally. As a result, we only grant expedited processing in truly exceptional circumstances. Moreover, the FOIA is fundamentally meant to inform the public about agency action and not to benefit private litigants. *NLRB v. Sears Roebuck & Co.*, 421 U.S. 132, 143 n.10 (1975). For those reasons, we decline to accept this recommendation.

One commenter recommended that a requester's history of making requests for expedited processing should be considered when determining whether to grant expedited processing. In the opinion of the commenter, organizations that always request expedited processing for all requests

should receive greater scrutiny in their requests for expedited processing than organizations that do not request expedited processing when their requests are obviously not urgent. In response to this comment, we decline to accept the commenter's recommendation. Each request for expedited processing is evaluated on its own merits. We do not provide special treatment to some requesters over others based on their history of making requests.

When granting expedited processing, one commenter thought that we should consider the fact that a requester has a history of making requests for records that eventually became frequently requested records. In response to this comment, we decline to accept the commenter's recommendation. Each request for expedited processing is evaluated on its own merits. We do not provide special treatment to some requesters over others based on a history of requesting records that become frequently requested records.

One commenter recommended granting expedited processing in situations where the requested records implicate an ongoing public health issue. We grant expedited processing in two cases: (1) where a failure to obtain requested records on an expedited basis could reasonably be expected to pose an imminent threat to the life or physical safety of an individual, and (2) where there is an urgent need to inform the public about an actual or alleged Federal Government activity. We only grant expedited processing in limited circumstances because we must consider the interests of all requesters waiting patiently in line and make sure that everyone is treated equally. For this reason, we must decline to adopt this comment.

Finally, one commenter suggested that records released in response to a request that receives expedited processing or a fee waiver should be made proactively available one year after it is

released to the requester even if the information has not been requested three or more times. We have decided not to accept this comment. Even if a record has not been released and requested three or more times, we will make available additional records if we believe they are of interest to the public and are appropriate for public disclosure. However, not every record released in response to a request that receives expedited processing or a fee waiver may fall into that category.

How does HHS respond to my request? (§ 5.28)

Several commenters recommended modifying the rule to incorporate changes made to the FOIA as a result of the FOIA Improvement Act. As a result of the FOIA Improvement Act, we have modified the language of § 5.28(a) to indicate that we will provide requesters with a notification of their right to seek assistance from the appropriate FOIA Public Liaison in all disclosure determination letters, and we have modified § 5.28(b) to indicate that we will provide requesters with a notification of their right to seek dispute resolution services from the appropriate FOIA Public Liaison and the Office of Government Information Services in all disclosure determination letters that include an adverse determination.

How may I request assistance with the FOIA process? (§ 5.29)

One commenter wanted to know who at the various offices is available for helping to ensure that the FOIA is processed properly. The commenter can seek assistance from the FOIA Requester Service Center that is processing the request. Each FOIA Requester Service Center also has a FOIA Public Liaison who can assist in reducing delays, clarifying the scope of a request, increasing transparency, providing status updates, and assisting in dispute resolution. The contact information for each FOIA Requester Service Center and the name of each FOIA Public Liaison is available

through the web link included in this section. In addition, requesters can seek assistance from the Office of Government Information Services (OGIS) including mediation services.

Several commenters suggested modifying the rule to incorporate the requirements of the FOIA resulting from the FOIA Improvement Act. Section 3 of the FOIA Improvement Act requires each agency to include procedures for engaging in dispute resolution with the FOIA Public Liaison and the Office of Government Information Services (OGIS). These procedures are included in this section of the rule. In addition, throughout the rule, we have included provisions that provide for the assistance of the appropriate FOIA Public Liaison and the Office of Government Information Services (OGIS) or give notification of their services.

What are the reasons records may be withheld? (§ 5.31)

One commenter stated that a section describing the exemptions to the FOIA was unnecessary, and at most should simply restate the exemptions set forth in 5 U.S.C. 552(b). The commenter further stated that the scope of the exemptions is determined by the courts and not agency regulations.

After considering this comment and other comments concerning this section, we have removed language describing the scope of each exemption and simply restated the exemptions as set forth in the FOIA statute.

One commenter suggested revising the opening paragraph of § 5.31 to reflect the presumption of openness codified in the FOIA Improvement Act. Another commenter suggested adding similar language to the end of the section. We have made the recommended change and have included a reference to the foreseeable harm standard in this section. We have chosen to place this reference in the opening paragraph of the section.

One commenter noted that all FOIA exemptions are discretionary, not mandatory. Therefore, all language describing an Exemption should state that an Exemption “authorizes” the withholding of information instead of “requires”. We have accepted this comment and made the recommended change. We note, however, that the ability to make a discretionary release will vary according to the exemption involved and whether the information is required to be protected by some other legal authority. Some of the FOIA's exemptions, such as Exemption 2 and Exemption 5, protect a type of information that is not generally subject to a disclosure prohibition. By contrast, the exemptions covering national security, commercial and financial information, personal privacy, and matters within the scope of nondisclosure statutes protect records that are also encompassed within other legal authorities that restrict their disclosure to the public. *See Attorney General Holder's FOIA Guidelines*, 74 FR 51879, (October 8, 2009) (describing exemptions where discretionary disclosure can most readily be made and those for which discretionary disclosure is not available). Thus, agencies are constrained in their ability to make discretionary disclosures of records covered by Exemptions 1, 3, 4, 6, and & certain subparts of Exemption 7.

Several commenters expressed concern regarding the descriptions of the scope of Exemptions 4, 5, and 6. These comments have been rendered moot, however, since the language in this section now simply restates the Exemptions as they are set forth in the FOIA statute.

One commenter provided feedback on § 5.31(d)(4)(ii) concerning the amount of time we provide submitters to respond to a predisclosure notification. The provision states that submitters have ten working days to object to disclosure and that HHS FOIA Offices may extend this period as appropriate and necessary. The commenter thought that we should take into consideration the

time limits within which agencies must respond to FOIA requests. Furthermore, the commenter recommended that the regulation state that the agency will expeditiously provide predisclosure notification and should make clear that the amount of time provided to a submitter to respond to a predisclosure notification should not exceed the remaining amount of time in which the agency is required by law to process the request. After considering this comment, we have decided not to accept it. We attempt to process all FOIA requests as expeditiously as possible. However, it sometimes is not possible to know whether a predisclosure notification is necessary to process a request or where a predisclosure notification needs to be sent until a search for records has been conducted and a review of the records has begun. It is unclear how adding a requirement that we expeditiously provide predisclosure notification would speed up that process. We also do not think it is reasonable to restrict a submitter's opportunity to object to disclosure based on the amount of time in which we are required by law to process the request. All submitters should be given ten working days (or where appropriate and necessary, ten or more working days) to object to the disclosure of information they provided to the government regardless of how long it takes for HHS to conduct the search or determine that a predisclosure notification is required.

One commenter provided input regarding § 5.41(d)(4)(iii). More specifically, the commenter expressed concern with the rule's language regarding the requirements of a notice of intent to disclose. The language, as written, suggested that we would release information over the objection of a submitter within five days of the date of the notice of intent to disclose. The commenter suggested that this could potentially allow for a release of information less than five days after the notice of intent to release, which would be unreasonable. The commenter also noted that the timeframe for the release of records after a notice of intent to disclose was based on the date of the notice whereas with § 5.41(d)(4)(ii), the date to provide objections to a

predisclosure notification was based on the date of receipt of the notification. Moreover, as written, FOIA Offices were given the authority to extend the timeframe for responding to a predisclosure notification letter but not for releasing records after providing a notice of intent to release. In accordance with Executive Order 12600 and in response to this comment, we have modified the requirements regarding the notice of intent to disclose to require that the notice include a specified disclosure date and that the date be at least five working days after the date of the notice. This will provide a reasonable number of days before a release and it gives flexibility to FOIA Offices to provide more than five working days when necessary. In order to be consistent, we also have revised the predisclosure notification procedures to base the amount of time to object on the date of the notice rather than the date of receipt. This is administratively easier to track and, as communication has become more electronic, the date of the notice and the date of receipt are often the same. Finally, all provisions regarding confidential commercial information are now located in their own subpart, Subpart D.

Multiple commenters suggested modifying the description of Exemption 5 to include the restriction on applying the deliberative process privilege to records that were created 25 years or more before the date on which the records were requested. This limitation to the deliberative process privilege was added by the FOIA Improvement Act and it is now reflected in this rule.

Records not subject to the requirements of the FOIA – law enforcement exclusions (§ 5.32)

One commenter stated that they found it unusual and highly irregular for HHS to include a description of the law enforcement record exclusions. In response to this comment, we have removed the descriptions of the exclusions and have simply included a citation to the section of the FOIA statute that references exclusions.

General information on fees for all FOIA requests (formerly § 5.41)

One commenter recommended that requesters be given at least 20 working days to make an advance payment (§ 5.41(b)) or respond to an agency communication in the course of negotiating fees (§ 5.41(e)) and, if the agency takes more than twenty working days from the date of the request to initiate these actions with the requester, the requester should receive the same amount of time to respond to the agency. In response to this comment, we have increased the number of days to make an advance payment and respond to an agency communication from at least 10 working days to at least 20 working days. We believe that this provides requesters with a reasonable amount of time to respond to us before we assume that they are no longer interested in pursuing their request.

What fee policies apply to HHS records? (formerly § 5.42)

One commenter suggested editing the provision on minimum fees to state that “[w]e do not send an invoice to requesters if *assessable* processing fees are less than \$25.” We have accepted the commenter’s suggestion and made the change.

What is the FOIA fee schedule for obtaining records? (formerly § 5.43)

Two commenters recommended removing language related to the fees we charge for the use of a computer to conduct a search in § 5.43(a)(2). One commenter thought that the language was archaic and should be removed. The second commenter considered the cost of a computer to be a sunk cost to the Department and stated that the computer would have been running anyway if it hadn’t been used to conduct the search. We decline to accept the commenters’ recommendations. When establishing the fee schedule, we follow the Uniform Freedom of Information Fee Schedule

and Guidelines published by the Office of Management and Budget (OMB), which establishes uniform standards for fee matters. Conformity with the OMB Guidelines is required by the FOIA. *See* 5 U.S.C. 552(a)(4)(A)(i). The OMB Fee Guidelines state that with regard to computer searches for records “[a]gencies should charge at the actual direct cost of providing the service. This will include the cost of operating the [computer] for that portion of operating time that is directly attributable to searching for records responsive to a FOIA request and operator/programmer salary apportionable to the search.” In order to conform with the OMB Fee Guidelines, we have included the same provision in our rule.

How does HHS calculate FOIA fees for different categories of requesters? (formerly § 5.44)

The commenter thought that some of the language in § 5.44(c) was potentially redundant and ambiguous. The commenter did not consider it necessary to state both that if you do not fall into the categories in paragraphs (a) and (b) of this section (a commercial requester or an educational or noncommercial scientific institution requester, or a member of the news media), you are an “other requester”. The commenter believed that this language suggested a conjunctive relationship when none was intended to exist. The commenter suggested using “i.e.” instead of “and are” to clarify things. In response to this comment, we have edited § 5.44(c) to make the language identifying an “other requester” clearer.

Multiple commenters recommended amending this section in order to reference new provisions to the FOIA created by the FOIA Improvement Act that place further limitations on assessing search fees (or, for a requester with preferred status, duplication fees) if response time is delayed. At the recommendation of the commenters and in accordance with the FOIA Improvement Act, the recommended change has been made to this section.

How may I request a fee waiver? (formerly § 5.45)

One commenter expressed concern with the description of the factors described in § 5.45(b) used to determine whether a requester is eligible for a fee waiver or a reduction in fees. The commenter specifically pointed out an issue with § 5.45(b)(5) which stated that, to be eligible for a fee waiver, a requester must explain how the requester “intend[s] to disseminate the requested information to a broad spectrum of the public.” The commenter noted that in *Cause of Action v. FTC*, the D.C. Circuit specifically held that “proof of the ability to disseminate the released information to a broad cross-section of the public is not required.” 799 F.3d 1108, 1116 (D.C. Cir. 2015). Rather, “the relevant inquiry...is whether the requester will disseminate the disclosed records to a reasonably broad audience of persons interested in the subject.” *Id.* In addition to noticing an issue with § 5.45(b)(5), the commenter also thought § 5.45(b)(5) and § 5.45(b)(4) were duplicative. Likewise, the commenter thought that § 5.45(b)(3) should be deleted because it duplicated §§ 5.45(b)(1), (2), (4) & (6). The commenter expressed concern that if these duplicative provisions remained in the rule, requesters would have to repeat the same information numerous times in order to be eligible for a fee waiver. In response to this comment, we have modified this section to include a streamlined list of the fee waiver factors based on *Cause of Action v. FTC*. We believe that this streamlined list satisfies the commenter’s concerns of correctly stating the standard for being able to disseminate information and reducing redundancy.

How do I file an appeal? (formerly § 5.52)

As a result of an amendment to the FOIA by the FOIA Improvement Act, two commenters recommended increasing the number of days to appeal an adverse determination to no less than 90 days after the date of an adverse determination. We have accepted this comment and increased

the number of days to appeal to 90 days after the date of an adverse determination. Note that the contents of this provision have moved to § 5.61 (When may I appeal HHS's FOIA determination?).

One commenter suggested that we use the postmark date rather than the date the appeal is received by the agency when determining whether an appeal has been submitted in a timely manner. The same commenter suggested that the appeal timeframe commence once the disclosure determination is received by the requester instead of the date of the adverse determination letter. After considering this comment, we have decided to partially accept it. The rule has been modified to indicate that we will base the timeliness of an appeal on the postmark date or, in the case of an electronic submission, the transmittal date. The rule has been further modified, however, to stipulate that if a postmark date is illegible, we will revert to using the date of receipt to determine the timeliness of the appeal submission. We also specify that an electronic submission transmitted after normal business hours will be considered transmitted on the next day for the purposes of determining the timeliness of an appeal submission. Finally, we reject the commenter's suggestion that the appeal timeframe commence once notice of the adverse determination is received by the requester. The FOIA statute itself bases the minimum timeframe that agencies must provide for a requester to appeal a request on a specific number of days "after the date of such adverse determination", not on the date such determination is received by the requester. Moreover, we believe that a 90 day appeal timeframe, as currently structured, provides requesters with a reasonable amount of time to submit a timely request. Note that the provision discussed by this comment has moved to § 5.61 (When may I appeal HHS's FOIA determination?).

One commenter observed that § 5.52(b) stated that an appeal could be submitted electronically; however, in the opinion of the commenter, the rule failed to identify a means of submitting administrative appeals electronically. In response to this comment, we have clarified that instructions on how to submit a FOIA appeal electronically can be found by using the web links provided in the section.

What avenues are available to me if I disagree with HHS’s appeal decision? (formerly § 5.54)

One commenter expressed concern with the language in paragraph (a) of § 5.54, which states that a requester must submit an administrative appeal in order to seek judicial review. In expressing this concern, the commenter suggested that this language was dubious and referenced examples cited in the Department of Justice Guide to the Freedom of Information Act where multiple courts had held that “exhaustion of administrative remedies is not required prior to seeking court review of an agency’s denial of requested expedited access.” U.S. DEP’T OF JUSTICE, *Litigation Considerations* 44 & n. 144, GUIDE TO THE FREEDOM OF INFORMATION ACT (last updated Nov. 26, 2013), *available at* <https://www.justice.gov/sites/default/files/oip/legacy/2014/07/23/litigation-considerations.pdf#p29>. In response to this comment, we have amended the language to state that “[b]efore seeking review by a court of an adverse determination, you generally must first submit a timely administrative appeal.” The modified language informs requesters of the need to generally submit an administrative appeal prior to seeking judicial review without suggesting that this is required in all cases.

Miscellaneous

One commenter suggested that we provide our understanding of what the term “due diligence” means. Based on the context of the comment, it appears that the commenter was referring to the use of the term in the FOIA statute at 5 U.S.C. 552(a)(6)(C)(i), which states that “[i]f the Government can show exceptional circumstances exist and that the agency is exercising due diligence in responding to the request, the court may retain jurisdiction and allow the agency additional time to complete its review of the records.” We believe that the concept of exceptional circumstances is adequately explained in the FOIA statute and it is unnecessary to include a provision about that subject in this rule. With regard to the term “due diligence”, we believe that the term can best be understood by the plain meaning in the statute, legislative intent, and any case law interpreting that term. We, therefore, decline to provide any further interpretation of this term.

One commenter noted that in certain cases we spelled out numbers and in other cases we used figures. *Compare, e.g.,* § 5.31(d)(4)(iii)(“5 working days”), and § 5.23(b)(“10 working days”), *with* § 5.31(d)(5)(iv)(“five working days”), *and* § 5.25(f)(“ten working days”). In response to this comment, we have replaced the referenced spelled out numbers with figures.

Finally, in response to public comments and feedback from within the Department, we have made the following changes: moved and clarified the provision on oral requests from § 5.2(a) to § 5.22(e); clarified the definition of non-commercial scientific institution (§ 5.3); clarified the definition of fee waiver (§ 5.3); removed references to the Program Support Center (PSC) (§§ 5.3, 5.62(b)(2)(formerly § 5.52(b)(2))) (the PSC FOIA Office has been dissolved and its responsibilities have transferred to the Office of the Secretary (OS) FOIA Office); renamed “reading room” “FOIA Library” (§ 5.3, § 5.22(i)); clarified the definition of “record” (§ 5.3); clarified the definition of

“submitter” (§ 5.3); clarified that an individual seeking records under the Privacy Act has access rights under the FOIA (§ 5.5); clarified the information needed to make a first-party request (§ 5.22(f)) and a third-party request (§ 5.22(g)); added additional information describing when a requester should provide a HIPAA Authorization Form (§ 5.22(h)(formerly § 5.22(c))); merged the contents of § 5.24 (Does HHS accept electronic FOIA requests?) with § 5.23 (Where do I send my FOIA request?); removed unnecessary language from § 5.25(a); revised language in §§ 5.24(b) and (c) (formerly §§ 5.25 (b) and (c)) to distinguish the procedures used to assist a requester in perfecting their request from those used to clarify a reasonably described request through tolling; removed unnecessary language from §§ 5.27(a) and 5.28(a); clarified the language in § 5.28(d); moved confidential commercial information procedures to its own subpart (§§ 5.41-5.42); removed former § 5.31(d)(4)(iv) because it was redundant to § 5.31(d)(4)(v) (now located at § 5.42(a)(4)); removed unnecessary language from former § 5.31(d)(4)(iii) (now located at § 5.42(a)(3)); merged former § 5.42 (What fee policies apply to HHS records?) with former § 5.41 (General information on fees for all FOIA requests.) (now located at § 5.51); clarified the notice provisions of § 5.51(a) (formerly § 5.41(a)) to conform with the OMB Fee Guidelines; removed § 5.51(i) (formerly § 5.42(c)) as a result of the clarification of § 5.51(a) (formerly § 5.41(a)); replaced a reference to a website where FOIA fee rates would be posted with a description of the calculation used to determine hourly rates for manual searching, computer operator/programmer time, and time spent reviewing records (§ 5.52 What is the FOIA fee schedule for obtaining records?)(formerly § 5.43); and clarified § 5.52(c)(2) (formerly § 5.43(c)(2)).

Regulatory Analysis

Executive Order 12866

The rule has been drafted and reviewed in accordance with Executive Order 12866, 58 FR 51735 (Sept. 30, 1993), section 1(b), Principles of Regulation, and Executive Order 13563, 76

FR 3821 (January 18, 2011), Improving Regulation and Regulatory Review. The rule is not a “significant regulatory action” under section 3(f) of Executive Order 12866. Accordingly, the rulemaking has not been reviewed by the Office of Management and Budget.

Regulatory Flexibility Act

The Department certifies under 5 U.S.C. 605(b) that the rule will not have a significant economic impact on a substantial number of small entities because the proposed revisions do not impose any burdens upon FOIA requesters, including those that might be small entities.

Therefore, a regulatory flexibility analysis is not required by the Regulatory Flexibility Act.

Unfunded Mandates Reform Act of 1995

The rule will not result in the expenditure by State, local, or tribal governments in the aggregate, or by the private sector, of \$100 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions are deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Executive Order 12612

This rule has been reviewed under Executive Order 12612, Federalism, and it has been determined that it does not have sufficient implications for federalism to warrant preparation of a Federalism Assessment.

Paperwork Reduction Act

The rule contains no new information collection requirements subject to review by the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of subjects in 45 CFR Part 5

Freedom of information.

In consideration of the foregoing, HHS revises part 5 of title 45, Code of Federal Regulations, to read as follows:

PART 5 – FREEDOM OF INFORMATION REGULATIONS

Subpart A—General Information About Freedom of Information Act Requests

Sec.

- 5.1 Purpose.
- 5.2 Presumption of openness and proactive disclosures.
- 5.3 Definitions.
- 5.4 Regulatory scope.
- 5.5 Interrelationship between the FOIA and the Privacy Act of 1974.

Subpart B—How to Request Records under FOIA

- 5.21 Who can file a FOIA request?
- 5.22 What do I include in my FOIA request?
- 5.23 Where do I send my FOIA request?
- 5.24 How does HHS process my FOIA request?
- 5.25 How does HHS handle requests that involve more than one OpDiv, StaffDiv, or Federal agency?
- 5.26 How does HHS determine estimated completion dates for FOIA requests?
- 5.27 How do I request expedited processing?
- 5.28 How does HHS respond to my request?
- 5.29 How may I request assistance with the FOIA process?

Subpart C—Exemptions to Disclosure

- 5.31 What are the reasons records may be withheld?
- 5.32 Records not subject to the requirements of the FOIA – law enforcement exclusions.

Subpart D—Confidential Commercial Information

- 5.41 How does a submitter identify records containing confidential commercial information?
- 5.42 How does HHS process FOIA requests for confidential commercial information?

Subpart E—Fees

- 5.51 General information on fees for all FOIA requests.
- 5.52 What is the FOIA fee schedule for obtaining records?
- 5.53 How does HHS calculate FOIA fees for different categories of requesters?

5.54 How may I request a fee waiver?

Subpart F—Appeals

5.61 When may I appeal HHS’s FOIA determination?

5.62 How do I file an appeal?

5.63 How does HHS process appeals?

5.64 What avenues are available to me if I disagree with HHS’s appeal decision?

Subpart G—Records Retention

5.71 How does HHS retain FOIA records?

Authority: 5 U.S.C. 552, 18 U.S.C. 1905, 31 U.S.C. 9701, 42 U.S.C. 1306(c), E.O. 12600, E.O. 13392

Subpart A — General Information About Freedom of Information Act Requests

§ 5.1 Purpose.

This part implements the provisions of the Freedom of Information Act (FOIA), 5 U.S.C. 552, as amended, for Department of Health and Human Services (HHS) records that are subject to the FOIA. This part should be read in conjunction with the text of the FOIA and the Uniform Freedom of Information Fee Schedule and Guidelines published by the Office of Management and Budget. This part contains the rules that we follow to process FOIA requests, such as the amount of time we have to make a determination regarding the release of records, who can decide to release records and who can decide not to release them, the fees we may charge, if applicable, the reasons why some records are exempt from disclosure under the FOIA, and the administrative and legal remedies available should a requester disagree with our initial disclosure determination.

(a) The FOIA provides a right of access to agency records, except to the extent that any portions of the records are protected from public disclosure by an exemption or exclusion in the statute. The FOIA does not require us to perform research for you or to answer your questions. The FOIA does not require agencies to create new records or to perform analysis of

existing records; for example, by extrapolating information from existing agency records, reformatting publicly available information, preparing new electronic programs or databases, or creating data through calculations of ratios, proportions, percentages, trends, frequency distributions, correlations, or comparisons. However, at our discretion and if it would conserve government resources, we may decide to supply requested information by consolidating information from various records.

(b) This part does not apply to data generated by an agency grant recipient under the provisions of 45 CFR part 75 to the extent the requirements of 45 CFR 75.322(e) do not apply to the data. We will not process your request under the FOIA or these regulations if that data is already available to the public through an archive or other source. In that situation, we will refer you to that other source. The procedures for requesting research data made available under the provisions of 45 CFR 75.322(e) are referenced in § 5.23(a).

§ 5.2 Presumption of openness and proactive disclosures.

(a) We will administer the FOIA with a presumption of openness. In accordance with 5 U.S.C. 552(a)(8) we will disclose records or information exempt from disclosure under the FOIA whenever disclosure would not foreseeably harm an interest protected by a FOIA exemption and disclosure is not prohibited by law. We also will consider whether partial disclosure of information is possible whenever we determine that a full disclosure of a requested record is not possible. This includes taking reasonable steps to segregate and release nonexempt information.

(b) Records that the FOIA requires agencies to make available for public inspection in an electronic format may be accessed through each OpDiv's and Staff Div's website. Each OpDiv and StaffDiv is responsible for determining which of its records must be made publicly available (including frequently requested records), for identifying additional records of interest

to the public that are appropriate for public disclosure, and for posting and indexing such records. Each OpDiv and StaffDiv must ensure that its website of posted records and indices is reviewed and updated on an ongoing basis. Each OpDiv and StaffDiv has a FOIA Requester Service Center or FOIA Public Liaison who can assist individuals in locating records. A list of agency FOIA Public Liaisons is available at <http://www.foia.gov/report-makerequest.html>.

§ 5.3 Definitions.

The following definitions apply to this part:

Agency is defined at 5 U.S.C. 551(1). HHS is an agency. Private entities performing work under a contractual agreement with the government are not agencies for the purpose of this definition. However, information maintained on behalf of an agency under Government contract, for the purposes of records management, is considered an agency record.

Chief FOIA Officer means a senior official of HHS, at the Assistant Secretary or equivalent level, who has agency-wide responsibility for ensuring efficient and appropriate compliance with the FOIA, monitoring implementation of the FOIA throughout the agency, and making recommendations to the head of the agency to improve the agency's implementation of the FOIA. The Secretary of HHS has designated the Assistant Secretary, Office of the Assistant Secretary for Public Affairs (ASPA), as the Agency Chief FOIA Officer (ACFO); that official may be contacted at HHS.ACFO@hhs.gov.

Commercial use means a use or purpose that furthers a commercial, trade, or profit interest of the requester or the person or entity on whose behalf the request is made.

Department or HHS means the U.S. Department of Health and Human Services.

Deputy Agency Chief FOIA Officer (DACFO) means a designated official within the Office of the Assistant Secretary for Public Affairs, who has been authorized by the Chief FOIA Officer to act upon their behalf to implement compliance with the FOIA, as described above.

This official is also the approving review authority for FOIA administrative appeals.

Direct costs mean those expenses that an agency incurs in searching for and duplicating (and, in the case of commercial use requests, reviewing) records in order to respond to a FOIA request. For example, direct costs include the salary of the employee performing the work (i.e., the basic rate of pay for the employee, plus 16 percent of that rate to cover benefits) and the cost of operating computers and other electronic equipment, such as photocopiers and scanners. Direct costs do not include overhead expenses such as the costs of space, and of heating or lighting a facility.

Duplication means the process of making a copy of a record and sending it to the requester, to the extent necessary to respond to the request. Such copies include both paper copies and electronic records. Fees for duplication are further explained within § 5.52.

Educational institution means any school that operates a program of scholarly research. A requester in this fee category must show that the request is made in connection with his or her role at the educational institution. Agencies may seek assurance from the requester that the request is in furtherance of scholarly research.

Example 1. A request from a professor of geology at a university for records relating to soil erosion, written on letterhead of the Department of Geology, would be presumed to be from an educational institution.

Example 2. A request from the same professor of geology seeking drug information from the Food and Drug Administration in furtherance of a murder mystery he is writing would not be presumed to be an institutional request, regardless of whether it was written on institutional stationery.

Example 3. A student who makes a request in furtherance of their coursework or other school-sponsored activities and provides a copy of a course syllabus or other reasonable

documentation to indicate the research purpose for the request, would qualify as part of this fee category.

Expedited processing means the process set forth in the FOIA that allows requesters to request faster processing of their FOIA request, if they can demonstrate a specific compelling need.

Fee category means one of the four categories established by the FOIA to determine whether a requester will be charged fees for search, review, and duplication. The categories are: commercial use requests; non-commercial scientific or educational institutions requests; news media requests; and all other requests. Fee categories are further explained within § 5.53.

Fee waiver means the waiver or reduction of fees if a requester is able to demonstrate that certain standards set forth in the FOIA and this part are satisfied, including that disclosure of the records is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester.

First-party request means a request by an individual for records pertaining to that individual, or an authorized representative acting on such an individual's behalf.

FOIA Public Liaison means an agency official who reports to the agency Chief FOIA Officer and serves as a supervisory official to whom a requester can raise concerns about the service the requester has received from the FOIA Requester Service Center. This individual is responsible for assisting in reducing delays, increasing transparency and understanding of the status of requests, and assisting in the resolution of disputes.

FOIA request means a written request that reasonably describes the records sought.

Freedom of Information Act (FOIA) means the law codified at 5 U.S.C. 552 that provides the public with the right to request agency records from Federal executive branch

agencies. A link to the text of the FOIA is at

<https://www.justice.gov/oip/freedom-information-act-5-usc-552>.

FOIA library records are records that are required to be made available to the public without a specific request under 5 U.S.C. 552(a)(2). We make FOIA library records available to the public electronically through our web pages (<http://www.hhs.gov/foia/reading/index.html>) and at certain physical locations. A list of the physical locations is available at <http://www.hhs.gov/foia/contacts/index.html>. Other records may also be made available at our discretion through our web pages (<http://www.hhs.gov>).

Freedom of Information Act (FOIA) Officer means an HHS official who has been delegated the authority to release or withhold records; to assess, waive, or reduce fees in response to FOIA requests; and to determine whether to grant expedited processing. In that capacity, the Freedom of Information Act (FOIA) Officer has the authority to task agency organizational components to search for records in response to a FOIA request, and to provide records located in their offices. Apart from records subject to proactive disclosure pursuant to subsection (a)(2) of the FOIA, only FOIA Officers have the authority to release or withhold records or to waive fees in response to a FOIA request. Our FOIA operations are decentralized, and each FOIA Requester Service Center has a designated official with this authority; the contact information for each FOIA Requester Service Center is available at <http://www.hhs.gov/foia/contacts/index.html>.

(1) The *HHS Freedom of Information Act (FOIA) Officer in the Office of the Secretary* means the HHS official who in addition to overseeing the daily operations of the FOIA program in that office and having the authority of a *Freedom of Information Act (FOIA) Officer*, is also responsible for the Department-wide administration and coordination of the FOIA and its implementing regulations and policies as they pertain to the programs and activities of the

Department. This individual serves as the principal resource with respect to the articulation of procedures designed to implement and ensure compliance with the FOIA and its implementing regulations and policies as they pertain to the Department. This individual reports through the DACFO to the ACFO to support oversight and compliance with the OPEN Government Act.

(2) [Reserved]

Frequently requested records means records, regardless of form or format, that have been released to any person under the FOIA and that have been requested 3 or more times or because of the nature of their subject matter, the agency determines have become or are likely to become the subject of subsequent requests for substantially the same records.

Immediate Office of the Secretary (IOS) means offices within the Office of the Secretary, responsible for operations and work of the Secretary. It includes the Office of the Deputy Secretary, Office of the Chief of Staff, the Secretary's Counselors, the Executive Secretariat, the Office of Health Reform, and the Office of Intergovernmental and External Affairs.

Non-commercial scientific institution means an institution that is not operated to further a commercial, trade, or profit interest and that is operated solely for the purpose of conducting scientific research the results of which are not intended to promote any particular product or industry. A requester in this category must show that the request is authorized by and is made under the auspices of a qualifying institution and that the records are sought to further scientific research and are not for a commercial use.

Office of the Inspector General (OIG) means the Staff Division within the Office of the Secretary (OS), which is responsible for protecting the integrity of HHS programs and the health and welfare of the beneficiaries of those programs. OIG is responsible for processing FOIA requests for the records it maintains.

Office of the Secretary (OS) means the HHS's chief policy officer and general manager, who administers and oversees the organization, its programs and activities. The Deputy Secretary and a number of Assistant Secretaries and Staff Divisions support OS. The HHS FOIA Office within ASPA processes FOIA requests for records maintained by OS Staff Divisions other than the OIG. In certain circumstances and at the HHS FOIA Office's discretion, the HHS FOIA office may also process FOIA requests involving other HHS OpDivs, as further described in § 5.28(a).

Operating Division (OpDiv) means any of the following divisions within HHS which are subject to this regulation:

Office of the Secretary (OS)

Administration for Children and Families (ACF)

Administration for Community Living (ACL)

Agency for Healthcare Research and Quality (AHRQ)

Agency for Toxic Substances and Disease Registry

(ATSDR) Centers for Disease Control and Prevention

(CDC)

Centers for Medicare & Medicaid Services (CMS)

Food and Drug Administration (FDA)

Health Resources and Services Administration (HRSA)

Indian Health Service (IHS)

National Institutes of Health (NIH)

Substance Abuse and Mental Health Services Administration (SAMHSA).

Operating Division and Staff Division Freedom of Information Act (FOIA) Officers

means the officials who are responsible for overseeing the daily operations of their FOIA programs in their respective Operating Divisions or Staff Divisions, with the full authority as described in the definition of *Freedom of Information Act (FOIA) Officer*. These individuals serve as the principal resource and authority for FOIA operations and implementation within their respective Operating Divisions or Staff Divisions.

Other requester means any individual or organization whose request does not qualify as a commercial-use request, representative of the news media request (including a request made by a freelance journalist), or an educational or non-commercial scientific institution request.

Record means any information that would be an agency record when maintained by an agency in any format, including an electronic format; and any information that is maintained for an agency by an entity under Government contract, for the purposes of records management.

Redact means delete or mark over.

Representative of the news media means any person or entity that actively gathers information of potential interest to a segment of the public, uses its editorial skills to turn raw materials into a distinct work, and distributes that work to an audience. The term “news” means information that is about current events or that would be of current interest to the public. Examples of news media entities include television or radio stations that broadcast news to the public at large and publishers of periodicals, including print and online publications that disseminate news and make their products available through a variety of means to the general public. We do not consider requests for records that support the news-dissemination function of the requester to be a commercial use. We consider “freelance” journalists who demonstrate a solid basis for expecting publication through a news media entity as working for that entity. A publishing contract provides the clearest evidence that a journalist expects publication; however, we also consider a requester’s past publication record.

Review means examining records responsive to a request to determine whether any portions are exempt from disclosure. Review time includes processing a record for disclosure (i.e., doing all that is necessary to prepare the record for disclosure), including redacting the record and marking the appropriate FOIA exemptions.

Search means the process of identifying, locating, and retrieving records to find records responsive to a request, whether in hard copy or in electronic form or format.

Staff Division (StaffDiv) means an organization component that provides leadership, direction, and policy and management guidance to the Office of the Secretary and the Department. The following StaffDivs are subject to the regulations in this part:

Immediate Office of the Secretary (IOS)

Assistant Secretary for Administration (ASA)

Assistant Secretary for Financial Resources (ASFR)

Assistant Secretary for Health (OASH)

Assistant Secretary for Legislation (ASL)

Assistant Secretary for Planning and Evaluation (ASPE)

Assistant Secretary for Public Affairs (ASPA)

Assistant Secretary for Preparedness and Response (ASPR)

Departmental Appeals Board (DAB)

Office for Civil Rights (OCR)

Office of the General Counsel (OGC)

Office of Global Affairs (OGA)

Office of the Inspector General (OIG)

Office of Medicare Hearings and Appeals (OMHA)

Office of the National Coordinator for Health Information Technology (ONC)

Submitter means any person or entity, including a corporation, State, or foreign government, but not including another Federal Government entity, that provides commercial or financial information, either directly or indirectly to the Federal Government.

Tolling means temporarily stopping the running of a time limit. We may toll a request to seek clarification or to address fee issues, as further described in § 5.24.

§ 5.4 Regulatory scope.

The requirements in this part apply to all OpDivs and StaffDivs of HHS. Some OpDivs and StaffDivs may establish or continue to maintain additional rules because of unique program requirements, but such rules must be consistent with this part and the FOIA. If additional rules are issued, they must be published in the Federal Register and you may get copies online at <https://www.federalregister.gov/>, <http://www.regulations.gov/> or by contacting one of our FOIA Requester Service Centers.

§ 5.5 Interrelationship between the FOIA and the Privacy Act of 1974.

The FOIA allows any person (whether an individual or entity) to request access to records. The Privacy Act, at 5 U.S.C. 552a(d), provides an additional right of access, allowing individuals to request records about themselves, if the records are maintained in a system of records (defined in 5 U.S.C. 552a(a)(5)).

(a) Requesting records about you. If any part of your request includes records about yourself that are maintained within a system of records as defined by the Privacy Act at 5 U.S.C. 552a(a)(5), you should make your request in accordance with the Privacy Act and the Department's implementing regulations at 45 CFR part 5b. This includes requirements to verify your identity. We will process the request under the Privacy Act and, if it is not fully granted under the Privacy Act, we will process it under the FOIA. You may obtain, under the FOIA,

information that is exempt from access under the Privacy Act, if the information is not excluded or exempt under the FOIA. If you request records about yourself that are not maintained within a system of records, we will process your request under the FOIA only.

(b) Requesting records about another individual. If you request records about another individual, we will process your request under the FOIA. You may receive greater access by following the procedures described in § 5.22(g).

Subpart B – How to Request Records under FOIA

§ 5.21 Who can file a FOIA request?

Any individual, partnership, corporation, association, or public or private organization other than a Federal agency, regardless of nationality, may submit a FOIA request to us. This includes state and local governments.

§ 5.22 What do I include in my FOIA request?

In your FOIA request:

(a) Provide a written description of the records you seek in sufficient detail to enable our staff to locate them with a reasonable amount of effort. The more information you provide, the better possibility we have of finding the records you are seeking. Information that will help us find the records would include:

- (1) The agencies, offices, or individuals involved;
- (2) The approximate date(s) when the records were created;
- (3) The subject, title, or description of the records sought; and
- (4) Author, recipient, case number, file designation, or other reference number, if available.

(b) Include your name, full mailing address, and phone number and if available, your e-

mail address. This information allows us to reach you faster if we have any questions about your request. It is your responsibility to keep your current mailing address up to date with the office where you have filed the FOIA request.

(c) State your willingness to pay all fees, or the maximum amount of fees you are willing to pay, and/or include a request for a fee waiver/reduction.

(d) Mark both your letter and envelope, or the subject line of your e-mail, with the words "FOIA Request."

(e) If you are unable to submit a written request to us due to circumstances such as disability or literacy, you may make a request orally to a FOIA Officer. FOIA Officers will put in writing an oral request made directly to them.

(f) If you are making a first-party request, you must comply with the verification of identity procedures set forth in 45 CFR part 5b.

(g) Where your request for records pertains to another individual, you may receive greater access by submitting either a notarized authorization signed by that individual or a declaration made in compliance with the requirements set forth in 28 U.S.C. 1746 by that individual authorizing disclosure of the records to the requester, or by submitting proof that the individual is deceased (e.g., a copy of a death certificate or an obituary). At our discretion, we may require you to supply additional information if necessary to verify that a particular individual has consented to disclosure of records about them.

(h) If you are requesting the medical records of an individual other than yourself from a government program that pays or provides for health care (e.g. Medicare, Indian Health Service) and you are not that individual's legally authorized representative, you should submit a Health Insurance Portability and Accountability Act (HIPAA) compliant release authorization form signed by the subject of records or the individual's legally authorized representative. The

HIPAA Privacy Rule requires that an authorization form contain certain core elements and statements which are described in the Privacy Rule's requirements at 45 CFR 164.508. If you are submitting a request for Medicare records to CMS, CMS has a release authorization form at the following link: <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS10106.pdf>.

(i) Before filing your request, you may find it helpful to consult the HHS FOIA Requester Service Centers online at <http://www.hhs.gov/foia/contacts/index.html>, which provides additional guidance to assist in submitting a FOIA request to a specific OpDiv or StaffDiv or to regional offices or divisions within an OpDiv or StaffDiv. You may also wish to check in the agency's electronic FOIA libraries available online at <http://www.hhs.gov/foia/reading/index.html>, to see if the information you wish to obtain is already available.

§ 5.23 Where do I send my FOIA request?

We have several FOIA Requester Service Centers (FOIA offices) that process FOIA requests. You should send your FOIA request to the appropriate FOIA Requester Service Center that you believe would have the records you seek. An up-to-date listing is maintained online at <http://www.hhs.gov/foia/contacts/index.html>. You also may submit your request electronically by e-mailing it to the appropriate FOIA Requester Service Center or by submitting it to the Department's web portal located at <https://requests.publiclink.hhs.gov/palMain.aspx>.

(a) If you are requesting research data made available under the provisions of 45 CFR 75.322(e), requests for such data should be addressed to the OpDiv that made the award under which the data were first produced. That OpDiv will process your request in accordance with established procedures consistent with the FOIA and 45 CFR 75.322(e).

(b) We officially receive your request when it reaches the FOIA Requester Service Center with responsibility for the OpDiv or StaffDiv where requested records are likely to be located, but no later than 10 working days after the request first arrives at any of our FOIA Requester Service Centers.

(c) If you have questions concerning the processing of your FOIA request, you may contact the FOIA Requester Service Center processing your request. If that initial contact does not resolve your concerns, you may wish to contact the designated FOIA Public Liaison for the OpDiv or StaffDiv processing your request. You can find a list of our FOIA Requester Service Centers and Public Liaisons at <http://www.hhs.gov/foia/contacts/index.html>.

§ 5.24 How does HHS process my FOIA request?

(a) Acknowledgement. We acknowledge all FOIA requests in writing within 10 working days after receipt by the appropriate office. The acknowledgement letter or e-mail informs you of your request tracking number, provides contact information, and informs you of any complexity we are aware of in processing that may lengthen the time required to reach a final decision on the release of the records. In addition, the acknowledgement letter or e-mail or a subsequent communication may also seek additional information to clarify your request.

(b) Perfected requests. (1) A request is considered to be perfected (i.e., the 20 working day statutory response time begins to run) when—

(i) The request either has been received by the responsible FOIA office, or, in any event, not later than 10 working days after the request has been received by any HHS FOIA office;

(ii) The requested records are reasonably described; and

(iii) The request contains sufficient information to enable the FOIA office to contact you and transmit records to you.

(2) We provide at least 20 working days for you to respond to a request to perfect your

request, after notification. Requests must reasonably describe the records sought and contain sufficient information to enable the FOIA office to contact you and transmit records to you. If we determine that a request does not meet these requirements, we will attempt to contact you if possible. Should you not answer any correspondence, or should the correspondence be returned as undeliverable, we reserve the right to administratively close the FOIA request.

(c) Stops in processing time (tolling). We may stop the processing of your request one time if we require additional information regarding the specifics of the request. The processing time resumes upon our receipt of your response. We also may stop the processing of your request if we require clarification regarding fee assessments. If additional information or clarification is required, we will attempt to contact you using the contact information you have provided. The processing time will resume upon our receipt of your response. We will provide at least 20 working days after notification for you to respond to a request for additional information or clarification regarding the specifics of your request or fee assessment. Should you not answer any correspondence, or should the correspondence be returned as undeliverable, we may administratively close the FOIA request.

(d) Search cut-off date. As the end or cut-off date for a records search, we use the date on which we first begin our search for documents responsive to your request, unless you specify an earlier cut-off date, or a specific date range for the records search. We will use the date of the first search in those cases when you request records “through the present,” “through today,” or similar language. The FOIA allows you to request existing agency records. The FOIA cannot be used to request records which the agency may create in the future in the course of carrying out its mission.

(e) Processing queues. We place FOIA requests in simple or complex processing queues to be processed in the order received, on a first-in, first-out basis, absent approval for

expedited processing based upon a compelling need, as further explained and defined in § 5.27. We will place your request in the simple or complex processing queue based on the estimated amount of work or time needed to process the request. Among the factors we may consider are the number of records requested, the number of pages involved in processing the request, and the need for consultations or referrals. We will advise requesters of potential complicating factors in our acknowledgement letter or e-mail, or in subsequent communications regarding your request and, when appropriate, we will offer requesters an opportunity to narrow or modify their request so that it can be placed in the simple processing track.

(f) Unusual Circumstances. Whenever we cannot meet the statutory time limit for processing a request because of “unusual circumstances,” as defined in the FOIA, and we extend the time limit on that basis, we will notify you, before expiration of the 20-day period to respond and in writing of the unusual circumstances involved and of the date by which we estimate processing of the request will be completed. Where the extension exceeds 10 working days, we will provide you, as described by the FOIA, with an opportunity to modify the request or arrange an alternative time period for processing the original or modified request. We will make available a designated FOIA contact in the appropriate FOIA Requester Service Center or the appropriate FOIA Public Liaison for this purpose. In addition, we will inform you of the right to seek dispute resolution services from the Office of Government Information Services (OGIS).

(g) Aggregating requests. For the purposes of satisfying unusual circumstances, we may aggregate requests in cases where it reasonably appears that multiple requests, submitted either by a requester or by a group of requesters acting in concert, constitute a single request, involving clearly related matters, that would otherwise involve unusual circumstances. In the event that requests are aggregated, they will be treated as one request for the purposes of calculating both

response time and fees.

§ 5.25 How does HHS handle requests that involve more than one OpDiv, StaffDiv, or Federal agency?

(a) Re-routing of misdirected requests. When a FOIA Requester Service Center determines that a request was misdirected within HHS, the receiving FOIA Requester Service Center must route the request to the FOIA Requester Service Center of the proper OpDiv or StaffDiv within HHS.

(b) Consultation, referral, and coordination. When reviewing records located by an OpDiv or StaffDiv in response to a request, the OpDiv or StaffDiv will determine whether another agency of the Federal Government is better able to determine whether the record is exempt from disclosure under the FOIA. As to any such record, the OpDiv or StaffDiv must proceed in one of the following ways:

(1) *Consultation.* When records originated with an OpDiv or StaffDiv processing the request, but contain within them information of interest to another OpDiv, StaffDiv, agency or other Federal Government office, the OpDiv or StaffDiv processing the request should typically consult with that other entity prior to making a release determination.

(2) *Referral.* (i) When the OpDiv or StaffDiv processing the request believes that a different OpDiv, StaffDiv, or agency is best able to determine whether to disclose the record, the OpDiv or StaffDiv typically should refer the responsibility for responding to the request regarding that record to that other entity. Ordinarily, the entity that originated the record is presumed to be the best entity to make the disclosure determination. However, if the OpDiv or StaffDiv processing the request and the originating entity jointly agree that the OpDiv or StaffDiv processing the request is in the best position to respond regarding the record, then the record may be handled as a consultation.

(ii) Whenever an OpDiv or StaffDiv refers any part of the responsibility for responding to a request to another OpDiv, StaffDiv, or federal agency, it must document the referral, maintain a copy of the record that it refers, and notify the requester of the referral; informing the requester of the name(s) of the entity to which the record was referred, including that entity's FOIA contact information.

(3) *Coordination.* The standard referral procedure is not appropriate where disclosure of the identity of the OpDiv, StaffDiv, or federal agency to which the referral would be made could harm an interest protected by an applicable exemption, such as the exemptions that protect personal privacy or national security interests. In such instances, in order to avoid harm to an interest protected by an applicable exemption, the OpDiv or StaffDiv that received the request should coordinate with the originating entity to seek its views on the disclosability of the record. The release determination for the record that is the subject of the coordination should then be conveyed to the requester by the OpDiv or StaffDiv that originally received the request.

(c) Classified information. On receipt of any request involving classified information, the OpDiv or StaffDiv must determine whether the information is currently and properly classified in accordance with applicable classification rules. Whenever a request involves a record containing information that has been classified or may be appropriate for classification by another agency under any applicable executive order concerning the classification of records, the OpDiv or StaffDiv must refer the responsibility for responding to the request regarding that information to the agency that classified the information, or which should consider the information for classification. Whenever an OpDiv's or StaffDiv's record contains information that has been derivatively classified (for example, when it contains information classified by another agency), the OpDiv or StaffDiv must refer the responsibility

for responding to that portion of the request to the agency that classified the underlying information.

(d) Timing of responses to consultations and referrals. All consultations and referrals received by the Department will be handled according to the date that the FOIA request initially was received by the first OpDiv, StaffDiv, or federal agency.

(e) Agreements regarding consultations and referrals. OpDivs or StaffDivs may establish agreements with other OpDivs, StaffDivs, or federal agencies to eliminate the need for consultations or referrals with respect to particular types of records.

§ 5.26 How does HHS determine estimated completion dates for FOIA requests?

(a) When we provide an estimated completion date, in accordance with § 5.24(f) and upon request, for the processing of records that do not require consultation with another agency, we estimate the completion date on the basis of our reasonable judgment as to how long it will take to complete the request. Given the uncertainty inherent in establishing any estimate, the estimated completion date is subject to change at any time.

(b) When we provide an estimated completion date, in accordance with § 5.24(f) and upon request, for records that must be reviewed by another agency, our estimate may also be based on information from the other agency.

§ 5.27 How do I request expedited processing?

(a) To request expedited processing, you must submit a statement, certified to be true and correct, explaining the basis for your need for expedited processing. You must send the request to the appropriate FOIA Officer at the address listed at <http://www.hhs.gov/foia/contacts/index.html>. You may request expedited processing when you first request records or at any time during our processing of your request or appeal.

(b) We process requests on an expedited basis whenever we determine that one or more

of the following criteria exist:

(1) That a failure to obtain requested records on an expedited basis could reasonably be expected to pose an imminent threat to the life or physical safety of an individual; or

(2) There is an urgent need to inform the public about an actual or alleged Federal Government activity (this criterion applies only to those requests made by a person primarily engaged in disseminating information to the public).

(c) We will respond to your request for expedited processing within 10 calendar days of our receipt of your request to expedite. If we grant your request, the OpDiv or StaffDiv responsible for the review of the requested records will process your request as a priority, and it will be processed as soon as practicable. We will inform you if we deny your request for expedited processing and provide you with appeal rights. If you decide to appeal that denial, we will expedite our review of your appeal.

(d) If we must refer records to another agency, we will inform you and suggest that you seek expedited review from that agency.

§ 5.28 How does HHS respond to my request?

(a) The appropriate FOIA Officer will send you a response informing you of our release determination, including whether any responsive records were located, how much responsive material was located, whether the records are being released in full or withheld in full or in part, any fees you must pay for processing of the request, and your right to seek assistance from the appropriate FOIA Public Liaison.

(b) If we deny any part of your request, our response will explain the reasons for the denial, which FOIA exemptions apply to the withheld records, your right to appeal that determination, and your right to seek dispute resolution services from the appropriate FOIA Public Liaison or the Office of Government Information Services (OGIS). We will advise you

of the number of pages withheld or the estimated volume of withheld records, unless providing such information would harm an interest protected by an applicable FOIA exemption.

(c) Records may be withheld in full or in part if any of the nine FOIA exemptions apply. If we determine to withhold part of a record pursuant to an exemption, we will provide access to reasonably segregable non-exempt information contained in the record. On the released portion of the record, we indicate where the information has been redacted and the exemption(s) we applied, unless including that indication would harm an interest the exemption protects. In Subpart C of this part, we list the exemptions to disclosure that may apply to agency records.

(d) We also may deny your request for other reasons, including that a request does not reasonably describe the records sought; the information requested is not a record subject to the FOIA; the requested records do not exist, cannot be located, or have been destroyed; or that the requested records are not readily reproducible in the form or format requested.

(e) If a request involves a voluminous amount of material or searches in multiple locations, we may provide you with interim responses if feasible and reasonably possible, releasing the records on a rolling basis.

(f) Copies of records in the format you request will be provided if the records already exist in that format or if they are reasonably and readily reproducible in the format you request.

§ 5.29 How may I request assistance with the FOIA process?

(a) If you have questions concerning the processing of your FOIA request, you should first contact the FOIA Requester Service Center processing your request. Additionally, for assistance at any point in the FOIA process, you may contact the FOIA Public Liaison at the FOIA Requester Service Center processing your request. The FOIA Public Liaison is responsible for assisting you to reduce delays, increasing transparency and understanding of the status of requests, and assisting to resolve any FOIA disputes. Some FOIA Requester

Service Centers allow you to check the status of your request online. You can find a list of our FOIA Requester Service Centers and Public Liaisons at <http://www.hhs.gov/foia/contacts/index.html>.

(b) The Office of Government Information Services (OGIS), which is part of the National Archives and Records Administration, serves as the Federal FOIA ombudsman and assists requesters and agencies to prevent and resolve FOIA disputes through mediation. Mediation is a voluntary process. If we participate in the dispute resolution services provided by OGIS, we will actively engage as a partner to the process in an attempt to resolve the dispute and will follow the principles of confidentiality in accordance with the Administrative Dispute Resolution Act, 5 U.S.C. 571-8. You may contact OGIS at the following address: National Archives and Records Administration, Office of Government Information Services, 8601 Adelphi Road – OGIS, College Park, MD 20740-6001, or by e-mail at ogis@nara.gov, or by telephone at 202-741-5770 or 1-877-684-6448 (toll free).

Subpart C—Exemptions to Disclosure

§ 5.31 What are the reasons records may be withheld?

While we are committed to providing public access to as many of our records as possible, there are instances in which information falls within one or more of the FOIA's nine exemptions and disclosure would either foreseeably harm an interest protected by a FOIA exemption or disclosure is prohibited by law. We review all records and weigh and assess all legal and policy requirements prior to making a final disclosure determination. A description of the nine FOIA exemptions is provided in paragraphs (a) through (i) of this section.

(a) Exemption 1. Exemption 1 protects from disclosure information specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy and are in fact properly classified pursuant to such Executive

order.

(b) Exemption 2. Exemption 2 authorizes our agency to withhold records that are related solely to the internal personnel rules and practices of an agency.

(c) Exemption 3. Exemption 3 authorizes our agency to withhold records which are specifically exempted from disclosure by statute (other than 5 U.S.C. 552(b)) provided that such statute requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue; or establishes particular criteria for withholding or refers to particular types of matters to be withheld; and if enacted after the date of enactment of the OPEN FOIA Act of 2009, October 28, 2009, specifically cites to 5 U.S.C. 552(b)(3).

(d) Exemption 4. Exemption 4 authorizes our agency to withhold trade secrets and commercial or financial information obtained from a person and privileged or confidential.

(e) Exemption 5. Exemption 5 authorizes our agency to withhold inter-agency or intra agency memorandums or letters that would not be available by law to a party other than an agency in litigation with the agency, provided that the deliberative process privilege shall not apply to records created 25 years or more before the date on which the records were requested.

(f) Exemption 6. Exemption 6 authorizes our agency to protect information in personnel and medical files and similar files when the disclosure of such information would constitute a clearly unwarranted invasion of personal privacy.

(g) Exemption 7. Exemption 7 authorizes our agency to withhold records or information compiled for law enforcement purposes, but only to the extent that the production of such law enforcement records or information would cause the following harm(s):

- (1) Could reasonably be expected to interfere with enforcement proceedings;
- (2) Would deprive a person of a right to a fair trial or an impartial adjudication;
- (3) Could reasonably be expected to constitute an unwarranted invasion of personal

privacy;

(4) Could reasonably be expected to disclose the identity of a confidential source, including a state, local, or foreign agency or authority, or any private institution which furnished information on a confidential basis, and, in the case of a record or information compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting lawful national security intelligence investigation, information furnished by a confidential source;

(5) Would disclose techniques and procedures for law enforcement investigations or prosecutions, or would disclose guidelines for law enforcement investigations or prosecutions, if such disclosure could reasonably be expected to risk circumvention of the law; or

(6) Could reasonably be expected to endanger the life or physical safety of any individual.

(h) Exemption 8. Exemption 8 authorizes our agency to withhold records that are contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions.

(i) Exemption 9. Exemption 9 authorizes our agency to withhold geological and geophysical information and data, including maps, concerning wells.

§ 5.32 Records not subject to the requirements of the FOIA – law enforcement exclusions.

Under the FOIA, there is special protection for narrow categories of law enforcement and national security records. The provisions protecting those records are known as “exclusions” and are described in 5 U.S.C. 552(c). These exclusions expressly authorize Federal law enforcement agencies, under these exceptional circumstances, to treat the records as not subject to the requirements of the FOIA.

(a) Should an HHS OpDiv or StaffDiv maintain records which are subject to a FOIA exclusion, and consider employing an exclusion or have a question as to the implementation of an exclusion, the OpDiv or StaffDiv will consult with the Office of Information Policy, U.S. Department of Justice.

(b) Because records falling within an exclusion are not subject to the requirements of the FOIA, should any HHS OpDiv or StaffDiv maintain such excluded records, the OpDiv or StaffDiv will limit its response to those records that are subject to the FOIA.

Subpart D—Confidential Commercial Information

§ 5.41 How does a submitter identify records containing confidential commercial information?

A person who submits records to the government may designate part or all of the information in such records that they may consider to be exempt from disclosure under Exemption 4 of the FOIA. The person may make this designation either at the time the records are submitted to the government or within a reasonable time thereafter. The designation must be in writing. Any such designation will expire 10 years after the records were submitted to the government.

§ 5.42 How does HHS process FOIA requests for confidential commercial information?

(a) *Predisclosure notification.* The procedures in this section apply to records on which the submitter has designated information as provided in § 5.41. They also apply to records that were submitted to the government where we have substantial reason to believe that information in the records could reasonably be considered exempt under Exemption 4. Certain exceptions to these procedures are stated in paragraph (b) of this section.

(1) When we receive a request for such records, and we determine that we may be required to disclose them, we will make reasonable efforts to notify the submitter about these

facts. The notice will include a copy of the request, and it will inform the submitter about the procedures and time limits for submission and consideration of objections to disclosure. If we must notify a large number of submitters, we may do this by posting or publishing a notice in a place where the submitters are reasonably likely to become aware of it.

(2) The submitter has 10 working days from the date of the notice to object to disclosure of any part of the records and to state all bases for its objections. FOIA Offices in HHS and its organizational components may extend this period as appropriate and necessary.

(3) We review and consider all objections to release that we receive within the time limit. If a submitter fails to respond within the time period specified in the notice, we will consider the submitter to have no objection to disclosure of the information. If we decide to release the records, we inform the submitter in writing, along with our reasons for the decision to release. We include with the notice a description of the information to be disclosed or copies of the records as we intend to release them. We also provide the submitter with a specific date that we intend to disclose the records, which must be at least 5 working days after the date of the notice. We do not consider any information we receive after the date of a disclosure decision.

(4) If the requester files a lawsuit under the FOIA for access to records submitted to HHS, we promptly notify the submitter.

(5) We will notify the requester in these circumstances:

(i) When we notify a submitter that we may be required to disclose information under the FOIA, we will also notify the requester that notice and opportunity to comment are being provided to the submitter;

(ii) When the agency notifies a submitter of a final disclosure decision under the FOIA, and;

(iii) When a submitter files a lawsuit to prevent the disclosure of the information.

- (b) *Exceptions to predisclosure notification.* The notice requirements in paragraph (a) of this section do not apply in the following situations:
- (1) We determine that we should withhold the information under a FOIA exemption;
 - (2) The information has been lawfully published or made available to the public
 - (3) We are required by a statute (other than the FOIA), or by a regulation issued in accordance with the requirements of Executive Order 12600, to disclose the information; or
 - (4) The designation made by the submitter appears obviously frivolous. However, in such a case, the agency must provide the submitter with written notice of any final disclosure determination and intent to release, at least 5 working days prior to the specified disclosure date. We will notify the submitter as referenced in § 5.42(a)(3).

Subpart E—Fees

§ 5.51 General information on fees for all FOIA requests.

(a) We generally assume that when you request records you are willing to pay the fees we charge for services associated with your request. You may specify a limit on the amount you are willing to spend. We will notify you if it appears that the fees will exceed \$25.00 or your specified limit and ask whether you nevertheless want us to proceed with the search.

(b) If you have failed to pay FOIA fees in the past, we will require you to pay your past due bill and we may also require you to pay the anticipated fee before we begin processing your current request. If we estimate that your fees may be greater than \$250.00, we also may require advance payment or a deposit before we begin processing your request. If you fail to make an advance payment within 20 working days after the date of our fee letter, we will close the request.

(c) We may charge interest on unpaid bills beginning on the 31st calendar day following the day the FOIA fee invoice was sent. We may assess interest, administrative costs,

and penalties for overdue FOIA fee costs.

(d) If we determine that you (either acting alone or with a group of requesters) are breaking down a single request into a series of requests in order to avoid or reduce fees, we may aggregate all of these requests when calculating the fees. In aggregating requests, we may consider the subject matter of the requests and whether the requests were filed close in time to one another.

(e) If, in the course of negotiating fees, you do not respond to the agency within 20 working days of our last communication, your request will be closed.

(f) We may stop the processing of your request, if necessary, to clarify fee issues with you, and to confirm your willingness to pay applicable fees. Fee related issues may arise sequentially over the course of processing a request, and the FOIA allows agencies to stop the processing time as many times as necessary in order to clarify issues regarding fee assessment and willingness to pay fees.

(g) We may charge search fees even if the records are exempt from disclosure, or if we do not find any responsive records during our search.

(h) We do not send an invoice to requesters if assessable processing fees are less than \$25.00.

§ 5.52 What is the FOIA fee schedule for obtaining records?

In responding to FOIA requests for records, we charge the following fees, where applicable, unless we have given you a reduction or waiver of fees. The fees we charge for search and review are three-tiered, and the hourly charge is determined by the classification and grade level of the employee performing the search or review. When the search or review is performed by employees at grade GS-1 through GS-8 (or equivalent), an hourly rate will be charged based on the salary of a GS-5, step 7, employee; when done by a GS-9 through GS-14

(or equivalent), an hourly rate will be charged based on the salary of a GS-12, step 4, employee; and when done by a GS-15 or above (or equivalent), an hourly rate will be charged based on the salary of a GS-15, step 7, employee. In each case, the hourly rate will be computed by taking the current hourly rate listed for the specified grade and step in the General Schedule Locality Pay Table for the Locality of Washington-Baltimore-Northern Virginia, DC-MD-VA-WV-PA, adding 16% of that rate to cover benefits, and rounding to the nearest whole dollar.

(a) *Search fees*—(1) *Manual searches*. Fees will be assessed to search agency files and records in both hardcopy and electronic format. Such fees will be at the rate or rates for the classification of the employee(s) performing the search, as established in this section.

(2) *Computer searches*. We base the fees for computer searches on the actual cost to our agency of operating the computer and the salary of the operator.

(b) *Review fees*. (1) We charge review fees for time we spend examining documents that are responsive to a request to determine whether we must apply any FOIA exemptions to withhold information. Review time includes processing any record for disclosure (i.e., doing all that is necessary to prepare the record for disclosure), including redacting the record and marking the appropriate FOIA exemptions. We charge review fees even if we ultimately are unable to disclose a record.

(2) We do not charge review fees for time we spend resolving general legal or policy issues regarding the application of exemptions. However, we do charge review fees for time we spend obtaining and considering any formal objection to disclosure made by a confidential commercial information submitter.

(c) *Duplication fees*—(1) *Photocopying standard-sized pages*. The current charge for photocopying records is \$0.10 per page.

(2) *Reproduction of electronic records.* We will attempt to provide records in the format you sought, if the records are reasonably and readily reproducible in the requested format. We charge you for our direct costs for staff time and to organize, convert, and format data for release, per requester instructions, and for printouts or electronic media necessary to reproduce electronic records requested under the FOIA.

(3) *Copying other media.* We will charge you the direct cost of copying other media.

(d) *Mailing and special delivery fees.* We release records by United States Postal Service or, when appropriate, by electronic means, such as electronic mail or web portal. If a requester seeks special delivery, such as overnight shipping, we reserve the right to pass on the actual costs of special delivery to the requester. Requesters may provide their mailing account and billing information to the agency, so that they may pay directly for special delivery options.

(e) *Certification of records.* The FOIA does not require agencies to certify records as true copies. We may elect, as a matter of administrative discretion, to certify records upon request; however, such a request must be submitted in writing. Further, we will only certify as true copies records that have not left the agency's chain of custody. The charge for certification is \$25.00 per record certified.

(f) *Other statutes specifically providing for fees.* The fee schedule of this section does not apply to fees charged under any statute that specifically requires an OpDiv or StaffDiv to set and collect fees for particular types of records. In instances where records responsive to a request are subject to a statutorily-based fee schedule program, the OpDiv or StaffDiv must inform the requester of the contact information for that program.

§ 5.53 How does HHS calculate FOIA fees for different categories of requesters?

(a) If you are a commercial use requester, we charge you fees for searching, reviewing, and duplicating responsive records.

(b) If you are an educational or noncommercial scientific institution requester, or a member of the news media, you are entitled to search time, review time, and up to 100 pages of duplication (or the cost equivalent for other media) without charge. We charge duplication fees after the first 100 pages (or its cost equivalent).

(c) If you do not fall into either of the categories in paragraphs (a) and (b) of this section (i.e. you are an “other requester”), you are entitled to two hours of free search time, up to 100 pages of duplication (or the cost equivalent of other media) without charge, and you will not be charged for review time. We may charge for search time beyond the first two hours and for duplication beyond the first 100 pages (or its cost equivalent).

(d)(1) If we fail to comply with the FOIA’s time limits in which to respond to a request, we may not charge search fees, or, in the instances of the requester categories referenced in paragraph (b) of this section, may not charge duplication fees, except as described in (d)(2)-(4).

(2) If we have determined that unusual circumstances as defined by the FOIA apply and we provided timely written notice to the requester in accordance with the FOIA, a failure to comply with the time limit shall be excused for an additional 10 days.

(3) If we have determined that unusual circumstances, as defined by the FOIA, apply and more than 5,000 pages are necessary to respond to the request, we may charge search fees, or, in the instances of requests from requesters described in paragraph (b) of this section, may charge duplication fees if the following steps are taken: we must have provided timely written notice to the requester in accordance with the FOIA and must have discussed with the requester via written mail, e-mail, or telephone (or made not less than three good-faith attempts to do so) how the requester could effectively limit the scope of the request in accordance with 5. U.S.C. 552(a)(6)(B)(ii). If this exception is satisfied, we may charge all applicable fees incurred in the processing of the request.

(4) If a court has determined that exceptional circumstances exist, as defined by the FOIA, a failure to comply with the time limits shall be excused for the length of time provided by the court order.

§ 5.54 How may I request a fee waiver?

(a) Requesters may seek a waiver of fees by submitting a written application demonstrating how disclosure of the requested information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester.

(b) We must furnish records responsive to a request without charge or at a reduced rate when we determine, based on all available information, that the following three factors are satisfied:

(1) Disclosure of the requested information would shed light on the operations or activities of the government. The subject of the request must concern identifiable operations or activities of the Federal Government with a connection that is direct and clear, not remote or attenuated.

(2) Disclosure of the requested information would be likely to contribute significantly to public understanding of those operations or activities. This factor is satisfied when the following criteria are met:

(i) Disclosure of the requested records must be meaningfully informative about government operations or activities. The disclosure of information that already is in the public domain, in either the same or a substantially identical form, would not be meaningfully informative if nothing new would be added to the public's understanding.

(ii) The disclosure must contribute to the understanding of a reasonably broad audience of persons interested in the subject, as opposed to the individual understanding of

the requester. A requester's expertise in the subject area as well as the requester's ability and intention to effectively convey information to the public must be considered. We will presume that a representative of the news media will satisfy this consideration.

(3) The disclosure must not be primarily in the commercial interest of the requester. To determine whether disclosure of the requested information is primarily in the commercial interest of the requester, we will consider the following criteria:

(i) We will identify whether the requester has any commercial interest that would be furthered by the requested disclosure. A commercial interest includes any commercial, trade, or profit interest. Requesters will be given an opportunity to provide explanatory information regarding this consideration.

(ii) If there is an identified commercial interest, we will determine whether that is the primary interest furthered by the request. A waiver or reduction of fees is justified when the requirements of paragraphs (b)(1) and (2) of this section are satisfied and any commercial interest is not the primary interest furthered by the request. We ordinarily will presume that when a news media requester has satisfied factors (b)(1) and (2) of this section, the request is not primarily in the commercial interest of the requester. Disclosure to data brokers or others who merely compile and market government information for direct economic return will not be presumed to primarily serve the public interest.

(c) You should ask for waiver or reduction of fees when you first submit your request to HHS, and should address the criteria referenced in this section.

Subpart F—Appeals

§ 5.61 When may I appeal HHS's FOIA determination?

In order to fully exhaust all of your administrative remedies, you must file an appeal of an adverse agency determination in writing, and to be considered timely it must be postmarked, or

in the case of electronic submissions, transmitted within 90 calendar days from the date of such determination. Any electronic transmission made after normal business hours will be considered to have been transmitted on the next calendar day. If a postmark is not legible, the timeliness of a submission will be based on the date that we receive the appeal. Adverse determinations include:

- (a) Refusal to release a record, either in whole or in part;
- (b) Determination that a record does not exist or cannot be found;
- (c) Determination that a request does not reasonably describe the records sought;
- (d) Determination that the record you sought was not subject to the FOIA;
- (e) Denial of a request for expedited processing;
- (f) Denial of a fee waiver request; or
- (g) Fee category determination.

§ 5.62 How do I file an appeal?

- (a) You have the right to appeal an adverse agency determination of your FOIA request.
- (b) You may submit your appeal via mail or electronically.
 - (1) Please send your appeal to the review official at the address provided in your denial letter. If you are unsure who is the appropriate review official, please contact the FOIA Requester Service Center that processed your request to obtain that information.
 - (2) The addresses to mail FOIA appeals for CMS and OS are, respectively: Centers for Medicare & Medicaid Services, Attn: Principal Deputy Administrator, Room C5-16-03, 7500 Security Boulevard, Baltimore, MD 21244; and U.S. Department of Health and Human Services, Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, Room 729H, 200 Independence Avenue SW., Washington, DC 20201. Additionally, information, including how to submit a FOIA appeal electronically, can be found at the

following online locations for CMS and OS: <https://www.cms.gov/Regulations-and-Guidance/Legislation/FOIA/filehow.html> and <https://requests.publiclink.hhs.gov/palMain.aspx>.

(3) When submitting an appeal, you should mark both your letter and envelope with the words “FOIA Appeal” or include the words “FOIA Appeal” in the subject line of your e-mail. You should also include your FOIA request tracking number, a copy of your initial request, and a copy of our final determination letter.

(c) Your appeal should clearly identify the agency determination that is being appealed. It would be helpful if you provide specific reasons explaining why you believe the agency’s adverse determination should be reconsidered.

§ 5.63 How does HHS process appeals?

(a) We respond to your appeal within 20 working days after the appeal official designated in your appeal letter receives it. If, however, your appeal is based on a denial of a request for expedited processing, we will act on your appeal of that decision expeditiously. Before making a decision on an appeal of an adverse determination, the designated review official will consult with the Office of the General Counsel. Also, the concurrence of the Office of the Assistant Secretary for Public Affairs is required in all appeal decisions, including those on fees. When the review official responds to an appeal, that constitutes the Department's final action on the request.

(b) If we reverse or modify the initial decision, we will inform you in writing and, if applicable, reprocess your request. If we do not change our initial decision, we will respond in writing to you, explain the reasons for the decision, set out any FOIA exemptions that apply, and inform you of the provisions for judicial review. If a requester files a FOIA lawsuit in reference to an appeal, we will cease processing the appeal.

§ 5.64 What avenues are available to me if I disagree with HHS’s appeal decision?

(a) In our response letter, we notify you of your right to seek judicial review of an adverse determination as set forth in the FOIA at 5 U.S.C. 552(a)(4)(B). Before seeking review by a court of an adverse determination, you generally must first submit a timely administrative appeal.

(b) We also inform you that the Office of Government Information Services (OGIS) offers mediation services to resolve disputes between FOIA requesters and Federal agencies as a non-exclusive alternative to litigation. As referenced in § 5.29(b) you may contact OGIS via mail, e-mail, or telephone for assistance.

Subpart G—Records Retention

§ 5.71 How does HHS retain FOIA records?

We will preserve records created in administering the Department’s Freedom of Information program until disposition is authorized under an applicable General Records Schedule or other records schedule duly approved by the Archivist of the United States.

Dated: June 7, 2016.

Sylvia M. Burwell,
Secretary,
Department of Health and Human Services.

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