

§ 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).