

§ 160.306 Complaints to the Secretary.

(a) *Right to file a complaint.* A person who believes a covered entity or business associate is not complying with the administrative simplification provisions may file a complaint with the Secretary.

(b) *Requirements for filing complaints.* Complaints under this section must meet the following requirements:

- (1) A complaint must be filed in writing, either on paper or electronically.
 - (2) A complaint must name the person that is the subject of the complaint and describe the acts or omissions believed to be in violation of the applicable administrative simplification provision(s).
 - (3) A complaint must be filed within 180 days of when the complainant knew or should have known that the act or omission complained of occurred, unless this time limit is waived by the Secretary for good cause shown.
 - (4) The Secretary may prescribe additional procedures for the filing of complaints, as well as the place and manner of filing, by notice in the Federal Register.
- (c) *Investigation.* (1) The Secretary will investigate any complaint filed under this section when a preliminary review of the facts indicates a possible violation due to willful neglect.
- (2) The Secretary may investigate any other complaint filed under this section.
 - (3) An investigation under this section may include a review of the pertinent policies, procedures, or practices of the covered entity or business associate and of the circumstances regarding any alleged violation.
 - (4) At the time of the initial written communication with the covered entity or business associate about the complaint, the Secretary will describe the acts and/or omissions that are the basis of the complaint.

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