

§ 158.605 Responses to allegations of noncompliance.

In determining whether to impose a civil monetary penalty, HHS may review and consider documentation provided in any complaint or other information, as well as any additional information provided by the responsible entity to demonstrate that it has complied with Affordable Care Act requirements. The following are examples of documentation that a potential responsible entity may submit for HHS's consideration in determining whether a civil monetary penalty should be assessed and the amount of any civil monetary penalty:

- (a) Any evidence that refutes an alleged noncompliance.
- (b) Evidence that the entity did not know, and exercising due diligence could not have known, of the violation.
- (c) Evidence documenting the development and implementation of internal policies and procedures by an issuer to ensure compliance with the Affordable Care Act requirements regarding MLR. Those policies and procedures may include or consist of a voluntary compliance program. Any such program should do the following:
 - (1) Effectively articulate and demonstrate the fundamental mission of compliance and the issuer's commitment to the compliance process.
 - (2) Include the name of the individual in the organization responsible for compliance.
 - (3) Include an effective monitoring system to identify practices that do not comply with Affordable Care Act requirements regarding MLRs and to provide reasonable assurance that fraud, abuse, and systemic errors are detected in a timely manner.
 - (4) Address procedures to improve internal policies when noncompliant practices are identified.
- (d) Evidence documenting the entity's record of previous compliance with Affordable Care Act requirements regarding MLRs.