(b) **Gravity of the violation(s).** It should be considered a mitigating circumstance if the responsible entity has done any of the following:

1. **Made adjustments to its business practices to come into compliance with HIPAA requirements so that the following occur:**
   - Adjustments to business practices to come into compliance with HIPAA requirements.
   - All employers, employees, individuals and non-Federal governmental entities are identified that are or were issued any policy, certificate of insurance or plan document, or any form used in connection therewith that failed to comply.
   - All employers, employees, individuals, and non-Federal governmental plans are identified that were denied coverage or were denied a right provided under HIPAA requirements.
   - Each employer, employee, individual, or non-Federal governmental plan adversely affected by the violation has been, for example, offered coverage or provided a certificate of creditable coverage in a manner that complies with HIPAA requirements.
   - The adjustments are completed in a timely manner.
   - The adjustments are completed in a timely manner.

2. **Discovered areas of noncompliance without notice from CMS and voluntarily reported that noncompliance, provided that the responsible entity submits the following:**
   - Documentation verifying that the rights and protections of all individuals adversely affected by noncompliance have been restored.
   - Documentation verifying that the rights and protections of all individuals adversely affected by noncompliance have been restored.
   - A plan of correction to prevent future similar violations.
   - A plan of correction to prevent future similar violations.

3. **Demonstrated that the violation is an isolated occurrence.**

4. **Demonstrated that the financial and other impacts on affected individuals is negligible or nonexistent.**

5. **Demonstrated that the noncompliance is correctable and that a high percentage of the violations were corrected.**

For every violation subject to a civil money penalty, if there are substantial or several aggravating circumstances, CMS sets the aggregate amount of the penalty at an amount sufficiently close to or at the maximum permitted by §150.315 to reflect that fact. CMS considers the following circumstances to be aggravating circumstances:

(a) The frequency of violation indicates a pattern of widespread occurrence.

(b) The violation(s) resulted in significant financial and other impacts on the average affected individual.

(c) The entity does not provide documentation showing that substantially all of the violations were corrected.

CMS may take into account other circumstances of an aggravating or mitigating nature if, in the interests of justice, they require either a reduction or an increase of the penalty in order to assure the achievement of the purposes of this part, and if those circumstances relate to the entity’s previous record of compliance or the gravity of the violation.

Nothing in §§150.315 through 150.323 limits the authority of CMS to settle any issue or case described in the notice furnished in accordance with §150.307 or to compromise on any penalty provided for in §§150.315 through 150.323.

(a) **Circumstances under which a civil money penalty is not imposed.** CMS does not impose any civil money penalty on any failure for the period of time during which none of the responsible entities knew, or exercising reasonable diligence would have known, of the failure. CMS also does not impose a civil money penalty for the period of time after any of the responsible entities knew, or exercising reasonable diligence would have known of the failure, if the failure was due to reasonable circumstances.