

---

## 42 C.F.R. § 423.2340

---

### Compliance monitoring and civil money penalties.

---

- (a) *General rule.* CMS monitors compliance by a manufacturer with the terms of the Discount Program Agreement.
- (b) *Basis for imposing civil money penalties.* CMS imposes a civil money penalty (CMP) on a manufacturer that fails to provide applicable beneficiaries applicable discounts for applicable drugs of the manufacturer in accordance with the Discount Program Agreement.
- (c) *Determination of the civil money penalty amounts.* CMS imposes a CMP for each failure by a manufacturer to provide an applicable discount in accordance with the Discount Program Agreement equal to the sum of the following:

This document is only available to subscribers. Please log in or purchase access.

[Purchase Login](#)