

42 C.F.R. § 10.11

Manufacturer civil monetary penalties.

(a) *General.* Any manufacturer with a pharmaceutical pricing agreement that knowingly and intentionally charges a covered entity more than the ceiling price, as defined in § 10.10, for a covered outpatient drug, may be subject to a civil monetary penalty not to exceed \$5,000 for each instance of overcharging, as defined in paragraph (b) of this section. This penalty will be imposed pursuant to the applicable procedures at 42 CFR part 1003. Any civil monetary penalty assessed will be in addition to repayment for an instance of overcharging as required by section 340B(d)(1)(B)(ii) of the PHSA.

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