

42 C.F.R. § 10.21

Claims.

- (a) *Initiating an action.* Any covered entity or manufacturer may initiate an action for monetary damages or equitable relief against a manufacturer or covered entity, as the case may be, by filing a written petition for relief with HRSA and mailing a copy of the petition with any attachments to the General Counsel or other senior official of the opposing party at its principal place of business by certified mail, return receipt requested, within three days of filing the claim. The petition should satisfy the pleading requirements of Rules 8, 10, and 11 of the Federal Rules of Civil Procedure, including setting forth the factual basis for invoking the 340B ADR Panel's jurisdiction. A claim must include all of the requirements in paragraph (d) of this section. Additional information to substantiate a claim may be submitted.
- (b) *340B ADR Panel's jurisdiction.* The 340B ADR Panel shall have jurisdiction to entertain any petition where the damages sought exceed \$25,000 or where the equitable relief sought will likely have a value of more than \$25,000 during the twelve-month period after the 340B ADR Panel's final agency decision, provided the petition asserts claims of the type set forth below.

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