

513.450 Limitations on review.

There is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for any of the following:

- (a) The selection of models for testing or expansion under section 1115A of the Act.
- (b) The selection of organizations, sites, or participants, including MFN participants, to test the MFN Model, including a decision by CMS to remove an MFN participant from the MFN Model.
- (c) The elements, parameters, scope, and duration of such MFN Model for testing or dissemination, including without limitation all of the following:
 - (1) The selection of the model geographic area for the MFN Model by CMS.
 - (2) The selection of MFN Model drugs by CMS.
 - (3) The selection of included international data, including selection of countries, international drug pricing databases, and international drug pricing data.
- (d) Determinations regarding budget neutrality under section 1115A(b)(3) of the Act.
- (e) The termination or modification of the design and implementation of an MFN Model under section 1115A(b)(3)(B) of the Act.
- (f) Determinations about expansion of the duration and scope of the MFN Model under section 1115A(c) of the Act, including the determination that the MFN Model is not expected to meet criteria described in paragraphs (c)(1) or (2) of such section.