

513.1 Basis, scope, and duration.

(a) Basis. This part implements the test of the Most Favored Nation (MFN) Model under section 1115A of the Act. Except as specifically noted in this part, the regulations under this part do not affect payment, coverage, program integrity, or any other requirements that otherwise apply to providers of services and suppliers under this chapter.

(b) Scope. This part sets forth the following:

(1) The types of providers and suppliers required to participate in the MFN Model and applicable requirements.

(2) The beneficiaries included in the MFN Model.

(3) The drugs included in the MFN Model.

(4) The methodologies for establishing Medicare payment amounts for and making payments for MFN Model drugs, including an alternative add-on payment.

(5) Beneficiary protections.

(6) Beneficiary cost-sharing.

(c) Duration. The MFN Model has a performance period of 7 performance years. The first performance year (performance year 1) begins on January 1, 2021, and the final performance year ends on December 31, 2027, unless sooner terminated in accordance with § 513.1000.