

513.100 MFN Model payments and MFN participants.

(a) General. Subject to the exceptions specified in paragraph (d) of this section, the MFN Model payments specified under this part apply only to claims for an MFN Model drug furnished to an MFN beneficiary by an MFN participant.

(b) MFN participants. Subject to the exclusions specified in paragraph (c) of this section, the MFN Model requires participation by each Medicare participating provider and supplier that submits a claim (except for claims specified in paragraph (d) of this section) for a separately payable drug that is an MFN Model drug furnished to an MFN beneficiary.

(c) Excluded providers and suppliers. The following are excluded from participation in the MFN Model:

(1) Children's hospitals (defined under section 1886(d)(1)(B)(iii) of the Act).

(2) PPS-exempt cancer hospitals (defined under section 1886(d)(1)(B)(v) of the Act).

(3) Critical access hospitals (CAHs) (defined under section 1820 of the Act).

(4) Indian Health Service (IHS) facilities (as described in section 1880 of the Act)), except when MFN Model drugs are furnished and such service is described in section 1880(e)(2)(B) of the Act.

(5) Federally Qualified Health Centers (FQHCs) (defined under section 1861(aa)(4) of the Act).

(6) Rural Health Clinics (RHCs) (defined under section 1861(aa)(2) of the Act).

(7) Hospitals that are not subsection (d) hospitals (as defined in section 1886(d)(1)(B) of the Act) and are paid on the basis of reasonable costs subject to a ceiling under section 1886(b) of the Act.

(8) Extended neoplastic disease care hospitals (defined in section 1886(d)(1)(B)(vi) of the Act).

(9) For the first quarter and second quarter of performance year 1, acute care hospitals that participate in any model authorized under section 1115A of Act for which payment for outpatient hospital services furnished to Medicare FFS beneficiaries, including MFN Model drugs, is made under such model on a fully capitated or global budget basis under a waiver of section 1833(t) of the Act.

(10) Beginning with the third quarter of performance year 1, acute care hospitals that participate in any model authorized under section 1115A of Act for which payment for

outpatient hospital services furnished to Medicare FFS beneficiaries, including MFN Model drugs, is made under such model on a fully capitated or global budget basis under a waiver of section 1833(t) of the Act, where the parameters of such model adjust for the difference in payment for MFN Model drugs between the MFN Model and non-MFN Model drug payments such that savings under the MFN Model are incorporated into the other CMS Innovation Center model's parameters (for example, the annual global budget) for the duration of the MFN Model.

(d) Exceptions. The MFN Model payments specified under this part do not apply to any of the following:

(1) Claims for MFN Model drugs furnished in the inpatient hospital setting under those circumstances where Part A would not pay for hospital services.

(2) Claims for MFN Model drugs administered during an inpatient hospital stay or included on an inpatient hospital claim.

(3) Claims administered by the DME MACs as described in § 421.404(c)(2) of this chapter.

(4) Claims paid under the End-Stage Renal Disease Prospective Payment System, including claims paid using the transitional drug add-on payment adjustment.

(e) MFN participant requirements during the MFN Model. During the model performance period described in § 513.1(c), MFN participants must do all of the following:

(1) Adhere to the beneficiary protections requirements under § 513.410.

(2) Adhere to the MFN Model-specific billing instructions requirements established by CMS and the MAC responsible for processing the MFN participant's claims, including without limitation those described in § 513.200.

(3) Participate in MFN Model monitoring and evaluation activities in accordance with § 403.1110(b) of this chapter, including collecting and reporting information as the Secretary determines is necessary to monitor and evaluate the MFN Model, including without limitation "protected health information" as that term is defined at 45 CFR 160.103.

(f) MFN participant requirements after the MFN Model. For 2 years after termination of the MFN Model, MFN participants must participate in MFN Model monitoring activities as described in § 513.420.