

# 513.500 Waivers of Medicare program requirements for purposes of testing the MFN Model.

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CMS waives the Medicare program requirements in the following provisions that are necessary solely for purposes of testing the MFN Model:

(a) Sections 1833(t)(6) and 1833(t)(14) of the Act and §§ 419.62 and 419.64 of this chapter related to Medicare payment amounts for drugs and biologicals under the hospital outpatient prospective payment system (OPPS) as necessary to permit testing of an alternative payment amount for MFN Model drugs.

(b) Section 1833(i)(2)(D) of the Act related to Medicare payment to ASCs for drugs and biologicals as necessary to permit testing of an alternative payment amount for MFN Model drugs.

(c) Sections 1847A(b) and 1847A(c) of the Act and §§ 414.904 and 414.802 of this chapter related to use of the ASP-based, WAC-based, or other applicable payment methodology and calculation of manufacturers' ASP as necessary to permit testing of an alternative payment for MFN Model drugs and to exclude certain units of MFN Model drugs from manufacturers' ASPs.

(d) Section 1833(a)(1) of the Act related to Medicare payment portion of the allowed payment amount for an included MFN Model drug that is determined under § 513.220 as necessary to permit testing of an innovative payment approach for the alternative add-on payment amount.

(e) Section 1833(a)(1)(S) of the Act related to Medicare payment for drugs and biologicals is 80 percent of the lesser of the actual charge or the payment amount established in section 1842(o) of the Act as necessary to permit testing of an innovative payment approach for the total allowable MFN Model payment as determined under subpart C.

(f) Section 1833(a)(1)(G) of the Act related to the amounts paid with respect to facility services furnished in connection with certain surgical procedures and with respect to services furnished to an individual in an ASC must be 80 percent of the lesser of the actual charge for the services or the amount determined by the Secretary under such revised payment system as necessary to permit testing of an innovative payment approach for the total allowable MFN Model payment as determined under subpart C.

(g) Section 1833(t) of the Act related to how beneficiary copayment is calculated under the OPPS as necessary to permit testing of an innovative payment approach for the total allowable MFN Model payment as determined under subpart C of this part.

(h) Section 1833(t)(9)(B) of the Act related to the requirement that Medicare account for adjustments to ensure that the amount of expenditures under the OPPS for the year does not increase or decrease from the estimated amount of expenditures under the OPPS that would have been made if the adjustments had not been made.