

513.230 Financial hardship exemptions, request process, and reconciliation payment.

(a) General. For purposes of the MFN Model, a financial hardship exemption for a performance year may be granted to an MFN participant by CMS, in its sole discretion and not subject to appeal, when the provisions in this section are met.

(b) Request for financial hardship exemption. To be eligible for a financial hardship exemption, the MFN participant must submit a request for financial hardship exemption in the form and manner and with the content specified by CMS, including without limitation the requirements of this paragraph (b).

(1) Timing and form of request. The MFN participant must submit its request for a financial hardship exemption to CMS in accordance the submission process posted on the MFN Model website and such request must be submitted within 60 calendar days following the end of the performance year for which the MFN participant seeks a financial hardship exemption.

(2) Request content. The MFN participant's request a financial hardship exemption must include, at a minimum, all of the following:

(i) Evidence of methods used to obtain each MFN Model drug that was furnished by the MFN participant during the performance year to any patient.

(ii) Average net acquisition cost for each MFN Model drug (inclusive of all on- and off-invoice discounts or adjustments, and any other price concessions related to the purchase of the MFN Model drug) that was furnished by the MFN participant during the performance year to MFN beneficiaries.

(iii) Average net acquisition cost for each MFN Model drug (inclusive of all on- and off-invoice discounts and adjustments, and any other price concessions related to the purchase of the MFN Model drug) that was furnished by the MFN participant during the performance year to patients who were not MFN beneficiaries.

(iv) Statement of any remuneration received by the MFN participant from manufacturers of MFN Model drugs, wholesalers, and distributors that is not reflected in the MFN participant's average net acquisition costs with a justification of why such remuneration should not be treated as a price concession related to the purchase of an MFN Model drug.

(v) Administrative information, including: MFN participant's name, TIN or CCN (as applicable), contact name, phone number, and email address.

(vi) The MFN participant's attestation that:

(A) The MFN participant experienced a reduction in Medicare Part B FFS payments for separately payable drugs on a per beneficiary basis during the performance year as compared to the prior year (that is, the four calendar quarters immediately preceding the performance year) due to its inability to obtain one or more of the MFN Model drugs at or below the MFN Model Payments for such drugs during the performance year;

(B) The MFN participant has not received and will not receive any remuneration from manufacturers of MFN Model drugs, wholesalers, and distributors related to the purchase of an MFN Model drug that was furnished by the MFN participant during the performance year that is not reflected in the MFN participant's submission; and

(C) The MFN participant submission is true, accurate and complete.

(c) Standard of review. (1) Incomplete requests for a financial hardship exemption, as determined by CMS, are not reviewed.

(2) CMS grants a financial hardship exemption to an MFN participant for a performance year, if the agency in its sole discretion determines the following requirements have been met:

(i) The MFN participant submits a timely, complete request for financial hardship exemption in accordance with the requirements of this section which in the sole discretion of CMS demonstrates all of the following:

(A) The MFN participant exhausted all reasonable methods to obtain MFN Model drugs at or below the MFN Model Payment for such drugs during the performance year.

(B) The MFN participant's average net acquisition cost for each MFN Model drug (including invoices and off-invoice discounts or adjustments) that was furnished by the MFN participant during the performance year to patients who were not MFN beneficiaries was not less than the MFN participant's average net acquisition costs for such MFN Model drug (including invoices and off-invoice discounts or adjustments) that was furnished by the MFN participant during the performance year to MFN beneficiaries.

(C) Any remuneration the MFN participant received from manufacturers of MFN Model drugs, wholesalers, and distributors that was not reflected in the MFN participant's average net acquisition costs was not a price concession related to the purchase of an MFN Model drug.

(ii) The MFN participant's excess reduction amount per beneficiary (as determined in paragraph (d)(6) of this section), is greater than zero.

(d) Excess reduction amount per beneficiary. CMS calculates the MFN participant's excess reduction amount per beneficiary using available final action claims data where Medicare

was the primary payer that is estimated to be more than 90 percent complete in accordance with the following steps:

(1) CMS calculates, separately for dates of service within the performance year and prior year, the MFN participant's total allowed charges for separately payable Medicare Part B drugs, and the total number of beneficiaries that had at least one claim for a service furnished by the MFN participant with a Medicare Part A or Medicare Part B allowed charge greater than \$0.

(2) CMS divides the MFN participant's total allowed charges for separately payable Medicare Part B drugs for dates of service within the performance year by the total number of beneficiaries that had at least one claim for a service furnished by the MFN participant with a Medicare Part A or Medicare Part B allowed charge greater than \$0 with a service date within the performance year, to calculate the MFN participant's average per beneficiary total allowed charges for separately payable Medicare Part B drugs for the performance year.

(3) CMS divides the MFN participant's total allowed charges for separately payable Medicare Part B drugs for dates of service within the prior year by the total number of beneficiaries that had at least one claim for a service furnished by the MFN participant with a Medicare Part A or Medicare Part B allowed charge greater than \$0 with a service date within the prior year, to calculate the MFN participant's average per beneficiary total allowed charges for separately payable Medicare Part B drugs for the prior year.

(4) CMS subtracts the MFN participant's average per beneficiary total allowed charges for separately payable Medicare Part B drugs for the performance year (as calculated in paragraph (d)(2) of this section) from the MFN participant's average per beneficiary total allowed charges for separately payable Medicare Part B drugs for the prior year (as calculated in paragraph (d)(3) of this section).

(5) CMS calculates 25 percent of the MFN participant's total allowed charges for all Medicare Part A and Part B claims with dates of service within the prior year and divides that amount by the total number of beneficiaries that had at least one claim for a service furnished by the MFN participant with a Medicare Part A or Medicare Part B allowed charge greater than \$0 with a service date within the prior year, to calculate 25 percent of the MFN participant's average per beneficiary total allowed charges for all Medicare Part A and Part B claims with dates of service within the prior year.

(6) CMS subtracts 25 percent of the MFN participant's average per beneficiary total allowed charges for all Medicare Part A and Part B claims with dates of service within the prior year (as calculated in paragraph (d)(5) of this section) from the difference calculated in paragraph (d)(4) of this section, to calculate the MFN participant's excess reduction amount per beneficiary.

(e) Reconciliation payment. (1) If CMS in its sole discretion grants a financial hardship exemption to an MFN participant for a performance year, CMS provides such MFN

participant a reconciliation payment for the performance year that equals the amount calculated by multiplying the excess reduction amount per beneficiary specified in paragraph (d)(6) of this section by the total number of beneficiaries that had at least one claim for a service furnished by the MFN participant with a Medicare Part A or Medicare Part B allowed charge greater than \$0 with a service date within the performance year.

(2) The amount of a reconciliation payment provided in accordance with this section is -

(i) Not subject to appeal;

(ii) Not subject to beneficiary cost-sharing, including any deductible or coinsurance; and

(iii) Made by CMS (or a CMS contractor) as soon as practical.