

**Justification for Nonmaterial/Nonsubstantive Change
Notice of Denial of Medicare Prescription Drug Coverage
CMS-10611, OCN 0938-1308**

Due to our belief that the best use of the agency's limited translation resources is to wait until OMB approves a PRA package before expending monies to have it translated, the Spanish version of the subject notice was excluded from the package that was approved on November 22, 2022.

Subsequent to OMB's approval, this Nonmaterial/Nonsubstantive Change request includes the Spanish translation of the Medicare Outpatient Observation Notice. Otherwise, there are no program changes or burden adjustments.