

REVISION TO CMS-10141, OCN 0938-0964 - Justification of a Non-material Change

CMS-10396, the Medicare Part D Medication Therapy Management Program Standardized Format, was approved on January 20, 2012 by OMB under OCN 0938-1154. OCN 0938-1154 includes an information collection burden that was originally a component of OCN 0938-0964. Therefore, we are requesting a reduction to the collection burden included in OCN 0938-0964 as described below.

OCN 0938-0964 originated in 2005, and has been updated repeatedly since. The requirement that Part D Medication Therapy Management (MTM) programs must offer comprehensive medication reviews (CMRs) with written summaries was included in final rule CMS-4085-F, Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, and added to the Medicare Prescription Drug Benefit Program OMB Control Number 0938-0964 in 2010 (ICR reference number 201008-0938-020). The burden associated with this new requirement was the time and effort needed for Part D sponsors to conduct CMRs with their own written summaries, estimated to require 937,000 hours for 1,875,000 CMRs spread across 456 Part D sponsors, with a total annual cost of \$112.5 million (937,000 hours/year x \$120 cost/hour). We are requesting that this burden be removed from OCN 0938-0964.

The Affordable Care Act (ACA) under Section 10328 specified other changes to Part D Medication Therapy Management (MTM) programs, including a requirement that the Secretary develop a standardized format for the CMR action plan and summary. CMS' final rule, CMS-4144-F, "Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes," which was published in the Federal Register on April 15, 2011, revised §423.153(d)(1)(vii) to require CMR standardized action plans and summaries from Part D MTM programs to comply with requirements specified by CMS for the standardized format. CMS subsequently developed the Medicare Part D Medication Therapy Management Program Standardized Format, which was approved on January 20, 2012 by OMB under OCN 0938-1154.

The use of the CMS standardized format increases the burden associated with providing CMRs and written summaries. Because the CMS standardized format is a new form, we requested a new OCN be issued rather than revising the older Medicare Prescription Drug Benefit Program OCN 0938-0964. The new OCN 0938-1154 includes the burden estimated for the CMR summaries in OCN 0938-0964 plus additional burden related to the new standardized format, including training and programming requirements, additional time to complete the CMR, and printing and mailing costs, as fully described in the Supporting Statement for CMS-10396, OCN 0938-1154.

To summarize, the ICR for the standardized format, CMS-10396, includes and increases the CMR burden estimate that was originally included in OCN 0938-0964. The CMR burden should be removed from OCN 0938-0964 because we have included that burden in the estimates for the new standardized format, CMS-10396, OCN 0938-1154.

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