

Justification for Non-Substantive Change
Medicaid Drug Rebate Program (MDRP) Forms – States
Quarterly State Invoice (CMS-R-144)
State Agency Contact Form (CMS-368)
OMB 0938-0582

We believe that the following changes are minor in scope and, as such, we consider them to be non-substantive.

1-Form CMS-R-144 is required from States quarterly to report utilization for any drugs paid for during that quarter. There have been no updates to the CMS-R-144, however there was a minor verbiage update to one corresponding CMR-R-144 Data Definition, in which we removed the reference to our previous MDR system. These changes do not have an impact on our currently approved burden estimates.

2-We also propose to remove a one-time requirement and burden of 1,344 hours (24 hr x 56 states) for each manufacturer to make system updates to accommodate the updated field sizes and .CSV file formats for CMS-R-144. The one-time task has been met so we are removing the associated requirement and burden as a non-substantive change.

3-Form CMS-368 is a report of contact for the State to name the individuals involved in the Medicaid Drug Rebate Program (MDRP), and is required only in those instances where a change to the originally submitted data is necessary. Form CMS-368 has been revised to include a signature/date line for the submitter to confirm that the information provided is accurate, and we also updated the entire CMS-368 to a fillable format. Neither update will have an impact on our currently approved burden estimates.