Expansion of Part D Policy on Improving Utilization Review Controls

The section entitled, "Improving Drug Utilization Review Controls in Part D," of the Final CY 2013 Call Letter, set forth how Medicare Part D sponsors can comply with drug utilization management (DUM) requirements of 42 C.F.R §423.153 et seq. to prevent overutilization of prescribed covered Part D drugs. We have consolidated various documents related to this policy at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html.

In both the Final CY 2013 Call Letter and the HPMS memo of September 6, 2012, we indicated that our guidance applied only to overutilization of opioids. In the HPMS memo we also provided a possible targeting methodology that sponsors could use to identify potential instances of overutilization of opioids for case management.

In the September 2011 GAO report that identified instances of questionable access to prescription drugs, hydrocodone and oxycodone were noted as the most prevalent of the 14 classes of frequently abused drugs analyzed. While these drugs represented over 80 percent of the instances of potential doctor shopping that were identified, there were still 20 percent of instances that did not involve hydrocodone and oxycodone.

The comments we received on the draft version of this Call Letter both supported and opposed our expanding the Part D Policy on Improving Utilization Review Controls to other drugs or classes of drugs, such as anti-psychotic drugs, amphetamine derivatives, benzodiazepines and non-benzodiazepine sleep aids. In addition, the supportive comments were not in agreement on which drugs or classes of drugs would be appropriate or inappropriate to target. Therefore, we will not expand our guidance beyond the opioid class at this time, but note that a sponsor may voluntarily do so, which would include notifying CMS and the affected beneficiaries of any beneficiary-level claim edits that will be implemented.

Drug Class Quantity Limits

In the supplemental guidance to the "Improving Drug Utilization Review Controls in Part D" section of the CY 2013 Call Letter, we stated that we would develop a submission mechanism for plan-level point of sale (POS) edits based upon cumulative daily morphine equivalent dose (MED) across the opioid class. We did not receive any comments on the draft version of this Call Letter supportive of a cumulative MED level that could be implemented at POS that would not only be an effective safety measure, but also one that would not inappropriately restrict access to medically necessary drugs. Rather, comments received indicated that sponsors are generally not ready to implement plan-level cumulative MED point of sale edits across the opioid class. While this will not be a requirement for CY 2014, we will accept plan-level POS edits based upon cumulative MED across the opioid class for review from sponsors who will have the capability to implement them for CY 2014. Such information will not be provided as part of the HPMS formulary submission process; however, we will provide instruction on how to

submit them to CMS for review. CMS strongly encourages all sponsors to develop the ability to implement plan-level POS edits based upon cumulative MED across the opioid class as soon as possible.

We also note that sponsors who implement a plan-level POS edit based upon cumulative MED across the opioid class will be expected to submit QLs for all individual opioids as part of the HPMS formulary submission for our review. Utilizing the existing QL fields, QL amount and QL days, these Part D sponsors will submit the lesser of either the plan-approved QL for individual opioids or the QL that is equivalent to the cumulative MED level to be applied across the opioid class. This will provide for transparency in that both types of QLs would be displayed in Medicare Plan Finder. We recognize that claims for quantities below the QL could reject at point-of-sale (POS) depending upon previously dispensed quantities of other opioids due to the plan-level POS edit based upon cumulative MED. However, it is not feasible to collect additional quantity limit information based on all of the various possible combinations of opioids.

With respect to sponsors who do not plan to submit plan-level POS edits based upon cumulative MED across the opioid class, we would encourage these sponsors to submit QLs for opioids with their HPMS formulary submission. As we noted in the CY 2013 Call Letter, Part D sponsors may apply QLs to opioids even though there is no clearly defined maximum dose in the approved labeling.