DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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**CENTER FOR MEDICARE**

TO: All Part D Sponsors

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SUBJECT: Improving Drug Utilization Review Controls in Part D

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The purpose of this memorandum is to solicit comments from Part D sponsors and other interested stakeholders on how the Medicare Part D program can more successfully exert control over payment for inappropriate overutilization of drugs. In particular, we would like sponsors to comment on what it would take in terms of resources and timelines to implement a beneficiary-centric approach to managing overutilization that we outline, below.

By 'overutilization' we mean the filling of multiple prescriptions written by different prescribers at different pharmacies for the same or therapeutically equivalent drugs in excess of all medically-accepted norms of dosing. The Part D MEDIC has reported evidence of patterns of such excessive utilization in the Part D data. The MEDIC specifically reports detecting such patterns in three drug classes: opioids, antiretrovirals, and atypical antipsychotics. The CMS Center for Program Integrity, oversight agencies and law enforcement officials consider these patterns to be highly indicative of drug seeking behavior due to drug abuse or diversion.

Since the beginning of the Medicare Part D program, CMS regulations have instructed Part D sponsors to implement cost-effective drug utilization management processes to monitor and control for both under- and over-utilization [§423.153(b)]. However, our understanding is that controls currently in place to address overutilization are largely limited to claim-level edits that do not seem to effectively address the type of overutilization described above. We understand that:

- Concurrent drug utilization management edits in place today to control for overutilization are generally limited to "refill-too-soon", "maximum-therapeutic-dose-exceeded", and "therapeutic duplication" edits.
- Refill-too-soon edit logic is generally limited to review of claims for the same prescription number (one prescriber and one pharmacy).

- Maximum-therapeutic-dose-exceeded edit logic is generally limited to review of claims for the same drug product for a given time period (multiple prescribers or pharmacies, but same drug identifier).
- Therapeutic duplication edits should flag multiple concurrent prescriptions for drugs within a therapeutic class (multiple prescribers or pharmacies, and different drugs within a class). However, we understand that these edits are frequently disregarded for drug classes in which treatment guidelines reflect the use of multiple drugs, such as with antiretroviral 'cocktails'.

We believe that some sponsors do a better job than others in administering these existing edits and that current performance could be improved. However, given the limited perspective of existing edits, we also believe that new, beneficiary-level (in contrast to claim-level) controls should also be developed to take a broader perspective on utilization. That is, we envision an enhanced retrospective drug utilization review process in which sponsors (and/or their drug claim adjudicators) would consider the drug classes of opioids, antiretrovirals, and atypical antipsychotics, and:

- Establish clinical upper thresholds for appropriate dosing consistent with clinical guidelines through sponsor Pharmacy and Therapeutics (P&T) committees. By clinical upper thresholds we mean levels of drugs or combinations of drugs within the therapeutic class that if actually administered would be a threat to patient health and safety;
- Create and monitor beneficiary-level utilization reports that could identify unusual patterns of drug use at or near the established clinical thresholds over longer timeframes and across drug products;
- Assign clinical staff, such as case managers, to review these reports and the beneficiaries' medication histories, and determine whether interventions with beneficiaries, prescribers or pharmacies are warranted to ascertain medical necessity of high dosages;
- Determine medical necessity of apparently excessive patterns of prescribing;
- Deny payment for any claims at point of sale that represent amounts in excess of the sponsor's clinical threshold (or other beneficiary-specific threshold) that cannot be justified after clinical medical necessity review;
- Address any exception requests through the exceptions and appeal processes.

We would expect that sponsors would utilize the appropriate clinical expertise in developing what we are calling the clinical upper thresholds. For example, we would expect that infectious disease specialists in the treatment of AIDs would participate in the development of thresholds around utilization of antiretrovirals. We would also expect that claim denial would only be applied on a case-by-case basis following medical necessity reviews, attempts to intervene with duplicative prescribers, and/or a determination of fraud. CMS would carefully monitor complaints, appeals, and claim audit results to ensure that such thresholds were not implemented in such a way as to impede access to drugs in the absence of a beneficiary-specific case management approach.

We note that the process outlined above builds on the long-standing report generation recommendations included in Chapter 9 of the Prescription Drug Manual. We request stakeholders to submit comments on what would be required in terms of resources and timeline

to implement such processes. We would also welcome suggestions on alternative approaches to addressing excessive utilization and any other information about this issue that CMS should evaluate in considering future guidance on this matter. We are specifically interested in exploring approaches that sponsors can implement within the existing Part D statutory authority and without passing the responsibility for controls off onto other parties, such as network pharmacies or CMS.

Please submit comments and any questions to PartDformularies@cms.hhs.gov by October 31, 2011. Please include "DUR" in the subject line of your email to our designated mailbox.