60.6 – Revision of Utilization Management Criteria Requirements

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Part D sponsors must not change existing utilization management criteria (i.e., prior authorization, step therapy, or quantity limits) to make them more restrictive or limiting without direct CMS approval. During the contract year, a Part D sponsor should not need significant revision of its approved criteria. For instance, submitted PA criteria should already have been evaluated for clinical accuracy, since in accordance with 42 CFR 423.120(b)(vi), the sponsor's Pharmacy and Therapeutics Committee has completed a thorough review of proposed PA criteria prior to submission of the formulary to CMS. Furthermore, during the annual enrollment period, beneficiaries may view plan prior authorization criteria as a component of making informed

decisions. To permit changes after the annual enrollment period could undermine beneficiaries' enrollment decisions and anticipated drug coverage. As a result, it is CMS' expectation that Part D sponsors will not update their utilization management criteria except under extraordinary circumstances, such as when new drug safety-related information becomes available during the contract year (e.g., FDA release of a new Black Box warning).

In the event that a Part D sponsor needs to make its utilization management criteria more restrictive, the sponsor will be required to submit the proposed changes to CMS in advance. CMS will address each request in order of receipt and will generally only permit criteria changes to incorporate new safety information. Conversely, Part D sponsors are not required to receive CMS approval in order to make their existing utilization management criteria less restrictive. For example, when sponsors are modifying their criteria to indicate coverage for new medically-accepted indications or removing certain diagnostic criteria, the sponsors are not required to notify CMS of such mid-year changes. However, even though there is no notice requirement, sponsors must still submit the appropriate updated utilization management criteria document reflecting the formulary enhancements during the next available HPMS formulary upload window.