Q: May Part D plans apply drug utilization management edits during a beneficiary's transition period?

A: Part D plans may only apply certain drug utilization management edits during a beneficiary's transition period. Drug utilization management edits that are appropriate during a beneficiary's transition period include the following:

- Edits to help determine Part B vs. Part D coverage
- Edits to prevent coverage of non-part D drugs (i.e. excluded drugs)
- Edits to promote safe utilization of a Part D drug (e.g. Quantity limits based upon Maximum recommended daily dose; Early refill edits)

Part D plans may implement additional step therapy or prior authorization edits during transition only if such edits are resolved at the point of sale. For example, if a prescriber writes a prescription for 5mg tablets at 2 tablets daily, Part D plans might have dose optimization edits in place to require the prescription to be changed to 10mg tablets, 1 tablet daily. However, during transition, Part D plans would need to allow pharmacies to override this edit if the prescriber will not authorize the change at point of sale. In other words, the beneficiary should leave the pharmacy with sufficient quantity of medication (either 5mg or 10mg tablets) to last the plan allowable days supply, unless the prescriber originally wrote for a lesser days supply. If the dose optimization edit (or any other step therapy/prior authorization edit) is overridden at point of sale for transition purposes only, but not permanently, the beneficiary must be so notified so that he or she can begin the exception process if necessary.

Irrespective of transition, all of these edits are subject to exceptions and appeals. For example, if a quantity limit edit (based upon maximum recommended daily dose) results in the dispensing of a quantity that is less than indicated on the prescription and is less than the plan allowable days supply (as determined by the prescribed daily dose), Part D sponsors must ensure that beneficiaries are made aware of this quantity limit and that an exception is required to obtain a greater quantity. Part D plans must expeditiously process such exception requests so that beneficiaries will not experience unintended interruptions in medically necessary Part D drug therapies and/or will not inappropriately pay additional cost-sharing associated with multiple fills of lesser quantities when the originally prescribed doses of Part D drugs are medically necessary.

Q: May Part D plans reject claims as "too soon" when an enrollee no longer has access to their previously filled prescription medication because they have been admitted to or discharged from a long term care (LTC) facility?

A: No. An early refill edit is a utilization management tool to promote compliance and to prevent waste. An early refill edit cannot be used to limit appropriate and necessary access to an enrollee's Part D benefit. For example, if a patient gets a prescription for 30 tablets for a 30 days supply (i.e. 1 tablet daily), but the

prescriber changes the dose to 2 tablets daily after only 10 days, it would be inappropriate for the Part D plan to deny as "too soon" a claim for a new prescription with the new dosage because the enrollee will not have enough medication to last until the originally scheduled refill date. Similarly, when an enrollee is admitted to or discharged from a LTC facility, he or she will not have access to the remainder of the previously dispensed prescription (through no fault of his or her own) and, therefore, the Part D plan must allow the enrollee to access a refill upon admission or discharge.

Q: Does the Part D definition of "medically accepted indication" (as defined in section 1927(k)(6) of the Social Security Act), which limits Part D coverage to only FDA labeled indications and off-label indications supported by citation in either AHFS, USP-DI, or DrugDex, also define the allowable drug doses that may be covered under Part D?

A: No. "Medically accepted indication" refers only to the diagnosis or condition for which a drug is being prescribed, not the dose being prescribed for such indication. Plans may have dose limitations based on FDA labeling, but an enrollee may request (and be granted) an exception to a dose limitation through the formulary exception process based on medical necessity criteria.