DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR BENEFICIARY CHOICES

August 21, 2006

Memorandum To: All Part D Sponsors

Subject: HPMS Q & As -- Safety Syringes, Clarification on a Part D Coverage Exclusion, & Unused Prescriptions

From: Cynthia Tudor, Ph.D., Director, Medicare Drug Benefit Group

The following questions and answers will be posted to the Frequently Asked Question Database on the CMS website.

Safety Syringe Clarification

Q: Are Part D sponsors required to cover so called "safety syringes" for the administration of insulin?

A: In a July 5, 2006 Q&A, we considered "safe needle devices" as special packaging as required by our Long Term Care (LTC) Service and Performance criteria and suggested reimbursement through dispensing fees. While we continue to maintain that the syringes, associated with the administration of insulin dispensed in the long term care setting, must maintain a safety device, based upon comments from the public, we believe these are better described in accordance with 1860D-2(e) of the Act which defines "medical supplies associated with the injection of insulin" as covered Part D drugs. Therefore, we are correcting our previous Q&A to define insulin syringes equipped with a safe needle device, in their entirety (syringe and device) as Part D drugs and subsequently they should be managed like any other Part D drug the plan places on their formulary.

Our authority to require these insulin syringes on plan formularies stems not only from the need to satisfy the LTC Service and Performance criteria, but from our FY 2007 formulary guidance where we instructed plans to provide coverage of dosage forms of drugs that are widely utilized in the LTC setting. Since the Occupational Safety & Health Administration (OSHA) requirements direct employers who employees are exposed to self-injected needles, such as nursing homes, to provide "safe needle devices", we maintain that safety enabled syringes are widely used in the LTC setting. Subsequently, Part D sponsors must make safety enabled insulin syringes available on their formularies for all of their long term care and institutionalized beneficiaries.

Clarification on a Part D Coverage Exclusion

Q: Does the exclusion of cough and cold medications extend to all clinical indications of these drugs?

A: No. Section 1927(d)(2)(D) of the Social Security Act specifies the exclusion as "Agents when used for the symptomatic relief of cough and colds." By including the language "when used for the symptomat*ic* relief of," we believe that Congress recognized there are clinical circumstances where cough and cold medications are necessary to treat other illnesses or injuries (e.g., to reduce the risk of broken bones in a patient with severe osteoporosis, or to minimize or eliminate shortness of breath or induced respiratory spasm in a patient with severe asthma). Therefore, we believe we have the authority to limit this exclusion, under Part D, to clinical situations that specifically involve symptomatic relief of cough and cold (i.e., when the agent is used to decrease cough frequency and severity, and reduce rhinitis for a limited duration). Therefore prescription cough and cold medications are eligible to meet the definition of a Part D drug in clinically relevant situations other than those of symptomatic relief of cough and colds. Part D Sponsors must ensure coverage determinations are made in line with this exclusion. Application of drug utilization management tools would be appropriate to ensure that reimbursement is made only in appropriate clinically relevant circumstances.

Unused Prescription Drugs under Part D

Q: Under Part D, can a beneficiary donate unused prescription drugs to State agencies or charitable organizations?

A: Yes. If a beneficiary, typically residing in a nursing home, finds that they have an unused prescription medication, paid for by the Medicare prescription drug benefit, they can donate this medication, to the extent allowable under Federal and State law and regulation, to State agencies and charitable organizations. Once the beneficiary has taken possession of, and insurance has paid for, the medication, the beneficiary is the owner of such medication and can dispose of the medication as they deem necessary.

In certain circumstances, specially-packaged unused drugs could be returned to long-term care pharmacies (LTCP) and resold, provided such returns and resales are consistent with provisions of Federal and State law. However, LTCP administrative costs to inspect, document, reverse claims, reimburse any beneficiary cost-sharing, and re-inventory any such returned medications cannot be included in either the Part D ingredient cost or a corresponding dispensing fee. Consequently, these associated restocking fees cannot be billed as Part D drug costs. Further, while facilitating returns is discretionary, for those plans and pharmacies that process returns for resale, they must adjust the PDE and TrOOP accordingly.

Please contact Greg Dill at (312) 353-1754 if you have any questions about this guidance.