

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

TO: Part D Sponsors

FROM: Cynthia G. Tudor, Ph.D., Director, Medicare Drug Benefit and C & D Data Group
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SUBJECT: Part D Drug Shortages

DATE: April 27, 2012

The Centers for Medicare & Medicaid Services (CMS) has received questions about recent actions by the U.S. Food and Drug Administration (FDA) to increase the supply of critically needed drugs that have been in short supply. Specifically, we have been asked if the foreign versions of Part D drugs imported under the FDA's exercise of its enforcement discretion may be covered under Medicare Part D. In order to ensure access to these critically needed drugs in conjunction with the actions taken by the FDA, CMS will accept prescription drug events (PDE) submissions with national drug codes for these drugs but they cannot be discounted under the Medicare Coverage Gap Discount Program.

When making these determinations, CMS expects Part D sponsors to rely on the applicable drug shortage information made available by the FDA at <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm>. We emphasize that PDE allowances will be limited to the specific drug product(s), conditions, and the duration of the shortage as specified by the FDA.

If you have questions about the guidance in this memorandum, please contact Craig Miner at craig.miner@cms.hhs.gov or (410) 786-7937.