DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR DRUG and HEALTH PLAN CHOICE

TO: All Part D Sponsors

FROM: Thomas Hutchinson, Director, Medicare Plan Payment Group
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SUBJECT: Update on National Drug Codes (NDCs)

DATE: December 9, 2008

The purpose of this memorandum is to inform you that we have undertaken a thorough analysis of our sources of information on NDCs and have developed new programming to provide better edits on NDCs that are submitted to CMS. Consistent with our previous guidance, CMS does not provide a Part D coverage list and making coverage determinations at the NDC level remains the responsibility of each Part D sponsor. However, as part of our continuing process of adjusting edits in our Drug Data Processing System (DDPS) in line with changes in the marketplace and our best judgment on which NDCs are most likely to represent Part D drugs based on currently available information, we are providing the following guidance on our latest edits.

Beginning February 1, 2009, the Centers for Medicare & Medicaid Services (CMS) will implement a new "NDC Redesign" functionality in DDPS. The major purpose of this new programming is to update edits in line with CMS' existing Part D coverage policy. To provide greater transparency, CMS has developed specific subcategories and reject codes that better group NDCs and explain their likely non-Part D drug status.

In addition to establishing more specific subcategories, the new programming affects the submission of approximately 4,000 NDCs that have previously been accepted and approximately 25 NDCs that have previously been rejected. These changes directly result from CMS' extensive analysis and review of NDCs listed in the First DataBank and Medi-Span® databases, as well as consultation with FDA staff. Additional information on the new subcategories follows below, and the complete list of new NDC subcategory codes and descriptions is provided in Attachment A. The list of affected NDCs can be located at http://www.csscoperations.com/ .

CMS expects Part D sponsors to determine if any of their enrollees will be affected by these changes and to notify any affected enrollees that their non-Part D prescription drug product cannot be paid for under the plan. Prompt notice will allow enrollees to obtain new prescriptions for alternative medications as soon as possible, when applicable.

Additional Information Relative to the Redesigned Prescription Drug Event (PDE) Reject Subcategories

- **Enhanced benefits:** Part D sponsors may only cover those excluded drugs that would otherwise meet the definition of a Part D drug but for its inclusion in one of the categories identified in Section 1927 (d)(2) of the Social Security Act. Therefore, drugs in the following new PDE reject subcategories may/may not be submitted as "E" drugs:

MAY	MAY NOT
201 Barbiturate	206 DESI 5, 6
202 Benzodiazepine	209 FDA Notice
204 Cough/Cold	203 Bulk
205 Cosmetic	207 Device
208 Erectile Dysfunction	211 Ingredient/Adjuvant
210 Fertility	212 Line Flush
218 Weight Agent	213 Medical Supply
217 Vitamin/Mineral	216 Part A/Part B
	215 OTC

- **Subcategories 203 (Bulk); 206 (DESI 5, 6); and 215 (OTC):** CMS generally will apply these edits based upon First DataBank and Medi-Span® indicators for these subcategories. Bulk products are not covered under Part D because they are not prescription drug products that are approved under sections 505, 505(j) or 507of the Federal Food Drug and Cosmetic Act. In addition, CMS will rely on information made publicly available by the Food and Drug Administration on the DESI status of marketed prescription drug products.

- **Subcategory 204 (Cough/Cold Agent):** CMS will apply this edit to all NDCs for cough and/or cold drug products containing one or more of the following ingredients:

    - Hydrocodone
    - Dextromethorphan
    - Codeine/Dihydrocodeine
    - Carbetapentane

  CMS also will apply the 204 (Cough/Cold Agent) reject edit to all unapproved cough and/or cold prescription drug products containing Guaifenesin or Carbinoxamine until such time as CMS identifies new subcategories for unapproved Guaifenesin or Carbinoxamine prescription drug products.

- **Subcategory 205 (Cosmetic):** CMS now will apply this edit to all NDCs for Hydroquinone hyperpigmentation prescription drug products except Monobenzone 20% because

Monobenzone 20% is the only product with vitiligo listed as a "medically accepted indication".

- **Subcategory 209 (FDA Notice):** CMS will apply this edit to prescription drug products that are included in drug categories for which the FDA has provided public notice that all unapproved products within the category are illegally marketed. Examples include unapproved quinine products, unapproved controlled-release nitrates, and unapproved IV colchicine products. Part D sponsors should refer to the FDA website for more information.

- **Subcategory 216 (Medicare Part A or B)**: CMS will apply this edit to NDCs for prescription drug products that are always Part B (e.g. Hemophilia clotting factors) and NDCs for prescription drug products have not been shown to be available except in settings that are covered under Medicare Part A or Part B.

If you have any questions concerning this memorandum, please contact Merri-Ellen James via email at merri-ellen.james@cms.hhs.gov or by phone at 410-786-4462.

ATTACHMENT A

SUBCATEGORY REJECT CODES AND DESCRIPTIONS

SUBCATEGORY CODE	SUBCATEGORY NAME	DESCRIPTION
201	Barbiturate	NDC is non-coverable under the Standard Part D Benefit
202	Benzodiazepine	NDC is non-coverable under the Standard Part D Benefit
203	Bulk	As identified by either Medi-Span® or First DataBank. NDC is non-coverable under the Part D Benefit
204	Cough/Cold Agent	NDC is non-coverable under the Standard Part D Benefit
205	Cosmetic	NDC is non-coverable under the Standard Part D Benefit
206	DESI 5, 6	As identified by First DataBank, Medi-Span® or the FDA. NDC is non-coverable under the Part D Benefit
207	Device	As identified by First DataBank, Medi-Span®, or the FDA. NDC is non-coverable under the Part D Benefit
208	Erectile Dysfunction	NDC is non-coverable under the Standard Part D Benefit
209	FDA Notice	as identified by the FDA. NDC is non-coverable under the Part D Benefit
210	Fertility Agent	NDC is non-coverable under the Standard Part D Benefit
211	Ingredient/Adjuvant	NDC is non-coverable under the Part D Benefit
212	Line Flush	NDC is non-coverable under the Part D Benefit
213	Medical Supply	NDC is non-coverable under the Part D Benefit
215	Over-the-Counter (OTC)	As identified by First Data Bank or Medi-Span®. NDC is non-coverable under the Part D Benefit
216	Part A/Part B	NDC is non-coverable under the Part D Benefit
217	Vitamin/Mineral	NDC is non-coverable under the Standard Part D Benefit
218	Weight Agent	NDC is non-coverable under the Standard Part D Benefit