DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Medicare
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Center for Medicare
Medicare Plan Payment Group

Date: September 6, 2013

To: All Part D Plan Sponsors

From: Cheri Rice, Director
Medicare Plan Payment Group

Subject: Final Guidance on the Reopening for Coverage Year 2008

The Centers for Medicare & Medicaid Services (CMS) intends to reopen Part D payment reconciliation for CY 2008 this fall (please see HPMS memoranda dated April 2, May 29 and June 25, 2012 discussing CY 2008 reopening). In order to be included in the 2008 reopening, all Prescription Drug Events (PDEs) for 2008 must be submitted no later than 11:59 PM ET on September 30, 2013. CMS will still accept CY2008 PDEs after the reconciliation cutoff deadline, but such submissions will not impact the reopening. Part D sponsors were able to resubmit their 2008 Direct and Indirect Remuneration data in July 2013. CMS is currently reviewing the DIR reports and this review is expected to be completed by the end of September. Medicare Advantage and Prescription Drug System (MARx) payment data through September 2013 payment will also be used in the reopening.

CMS would like to remind sponsors of the March 22, 2011, the Office of Inspector General (OIG) report, "Review of Erectile Dysfunction Drugs in the Medicare Part D Program." For calendar years 2007 and 2008, the OIG found that sponsors submitted, and CMS sometimes accepted, PDE data for Erectile Dysfunction (ED) drugs approved only for the treatment of sexual or erectile dysfunction. Pursuant to section 1860D-2(e)(2)(A) of the Social Security Act, which incorporates section 1927(d)(2) of the Act by reference, Part D drugs do not include agents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration. The OIG found eighteen unique NDCs for ED drugs that are excluded from the Part D program and were associated with PDEs for 2007 and 2008 (See Attachment A). ED drugs covered under a supplemental benefit were excluded from the review. Unless covered under a supplemental benefit, sponsors should submit deletion PDEs for any PDEs submitted with the NDCs found in Attachment A of this memorandum. If sponsors fail to delete these PDEs, CMS will remove the PDEs from the reopening.

CMS has performed analysis of accepted PDE data for beneficiaries that were retroactively disenrolled from Medicare Part D and that analysis revealed that some sponsors failed to delete PDEs associated with these beneficiaries. If a beneficiary is not enrolled in Part D, the PDEs with dates of service after the

disenrollment date must be deleted because the costs associated with these PDEs are not Part D costs. CMS expects sponsors to delete these PDEs by the reopening cutoff deadline. CMS will remove any PDEs from the reconciliation file that the sponsor fails to delete by the deadline. This issue is not limited to benefit year 2008. CMS expects sponsors to evaluate their PDE data for all benefit years and delete any PDEs with dates of service after the disenrollment date. In future reconciliations and reopenings, CMS will remove these PDEs if the sponsor fails to delete them.

Refer to the August 7, 2013 HPMS memorandum regarding Medicare Part D Recovery Audit Contractor (RAC) Excluded Provider Audits. The Medicare Part D RAC has completed its Excluded Provider review for the 2008 plan year. Sponsors affected by the 2008 audit review received a Notification of Improper Payment (NIP) and will be provided an appeals process. CMS strongly encourages Part D sponsors to take the appropriate actions to address the PDEs in time for the reopening cutoff deadline.

As stated in §423.346(a), CMS may reopen and revise an initial or reconsidered final payment determination. The May 8, 2008 HPMS memorandum titled, "The Part D Reopenings Process and the Part D Appeals Process", indicates that sponsors may submit reopening requests for CMS to review or CMS may reopen on its own volition. CMS will review all sponsors for reopening, regardless of whether or not a sponsor submits a reopening request. As stated at §423.346(d), a decision not to reopen under this section is final and is not subject to review.

CMS will not conduct a Part D reopening for any contract that has terminated and received a final settlement from CMS. This decision impacts the 2008 reopening and any future reopenings, regardless of benefit year. Regardless of this decision, all sponsors must ensure that the PDE is both an accurate record of how the benefit was administered through the point-of-sale transaction (plus any subsequent financial adjustments) and the final adjudication status of each Part D claim. This requirement has been stated in various pieces of guidance including the Requirements for Submitting Prescription Drug Event Data guidance, released on April 27, 2006 and the Announcement of Calendar Year 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. All sponsors must comply with this requirement regardless of whether or not CMS reopens the reconciliation.

CMS will release future guidance indicating when the 2008 reopening reports will be distributed, when payment adjustments related to the 2008 reopening will be scheduled, and the deadline for the 2008 reopening attestations. Questions concerning this memorandum or the 2008 reopening in general should be directed to CMS at PDEJan2011@cms.hhs.gov.

Attachment A:

National Drug Code (NDC)	Trade Name
00002-4462-10	Cialis tablets
00002-4462-34	Cialis tablets
00002-4463-30	Cialis tablets
00002-4464-30	Cialis tablets
00002-4465-34	Cialis tablets
00009-5181-01	Caverject impulse powder for injection
00009-5182-01	Caverject impulse alprostadil for injection
00009-7686-04	Caverject sterile powder for injection
00069-4200-30	Viagra tablets
00069-4210-30	Viagra tablets
00069-4210-66	Viagra tablets
00069-4220-30	Viagra tablets
00069-4220-66	Viagra tablets
00085-1901-01	Levitra tablets
00085-1934-01	Levitra tablets
00085-1945-01	Levitra tablets
62541-0120-06	Muse suppositories
62541-0140-06	Muse suppositories