

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
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## **MEDICARE PLAN PAYMENT GROUP**

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**Date:** November 28, 2018

**To:** All Part D Plan Sponsors

**From:** Jennifer Harlow, Deputy Director  
Medicare Plan Payment Group

**Subject:** November 2018 Updates to the Drug Data Processing System (DDPS)

The Centers for Medicare & Medicaid Services (CMS) is announcing upcoming changes to the Drug Data Processing System (DDPS).

CMS will post an updated Prescription Drug Event (PDE) Error Code Listing spreadsheet to the Customer Service and Support Center (CSSC) Operations website at <http://www.csscoperations.com> (choose Prescription Drug Event Data => Edits). Please submit questions regarding these updates to [PDEJan2011@cms.hhs.gov](mailto:PDEJan2011@cms.hhs.gov).

### **Change to the monthly implementation timeline for the FDA NDC SPL Data Elements (NSDE) file**

Currently, as detailed in the May 14, 2012 HPMS memo titled "Implementation starting September 1, 2012 of PDE Editing using the FDA Online Label Repository", CMS uses the NSDE file posted on the FDA website on the 15th of each month to update our DDPS PDE editing files on the 1st of each following month. If the 15th falls on a non-business day, CMS uses the NSDE file posted on the next business day.

Beginning with the NSDE file being implemented on December 1<sup>st</sup> for PDE editing, CMS will decrease the lead time between obtaining the NSDE file from the FDA website to implementation for PDE editing. Going forward, CMS will obtain a new NSDE file each month on the 4<sup>th</sup> business day prior to the 1<sup>st</sup> day of the following month to be implemented for PDE editing on the 1<sup>st</sup>. This change will help to decrease lag times between data in effect on the NSDE file and implementation into the DDPS system.

### **PDE editing for biosimilar drugs**

In accordance with the Bipartisan Budget Act of 2018, biosimilar drugs will be considered applicable drugs that will be able to receive Coverage Gap Discounts beginning January 1, 2019. CMS has modified current PDE editing and processing to ensure that biosimilar drugs will be eligible to receive a Coverage Gap Discount on PDEs submitted with a date of service (DOS) on or after January 1, 2019.

Currently, CMS does not accept PDEs with a Coverage Gap Discount for biosimilar drugs. For PDEs with a DOS prior to January 1, 2019, CMS will continue to only accept PDEs with a Coverage Gap Discount for applicable, covered Part D drugs that are not biosimilars.

The Message to be Reported for Edit 867 on the on the PDE Error Code listing spreadsheet has been updated to denote the new change. The new edit message is, *"FDA does not designate this drug as NDA or BLA, or this drug is a biosimilar drug with DOS prior to 1/1/2019; therefore it is ineligible for the coverage gap discount"*.