

DEPARTMENT OF HEALTH & HUMAN  
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**CENTER FOR MEDICARE**

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**DATE:** March 4, 2022  
**TO:** All Part D Plan Sponsors  
**FROM:** Jennifer R. Shapiro, Director, Medicare Plan Payment Group  
**SUBJECT:** Spring 2022 Updates to the Drug Data Processing System

The Centers for Medicare & Medicaid Services (CMS) is announcing upcoming changes to the Drug Data Processing System (DDPS). Updated documents, including a Prescription Drug Event (PDE) Edit Code Listing spreadsheet, PDE Inbound File Layout, and PDE Outbound File Layout, are posted to the [Customer Service and Support Center \(“CSSC”\) Operations website](#). Please submit questions regarding these updates to [PDEJan2011@cms.hhs.gov](mailto:PDEJan2011@cms.hhs.gov).

**Oral Antiviral Drugs for Treatment of COVID-19 that May Receive U.S. Food and Drug Administration Emergency Use Authorization (EUA) and are Procured by the U.S. Government (USG)**

On January 20, 2022, CMS issued HPMS memorandum “Prescription Drug Event Guidance Related to Oral Antiviral Drugs for Treatment of COVID-19 that Receive U.S. Food and Drug Administration Emergency Use Authorization and are Procured by the U.S. Government” on the [CMS website](#). As indicated in this guidance, CMS is informing Part D sponsors of the following completed updates to DDPS:

1. DDPS is currently accepting PDEs for USG-procured EUA oral antiviral drugs that have an additional dispensing fee amount reported in field 41 - Vaccine Administration Fee.
2. CMS has updated the description in the Definition/Values column for field 41 on the PDE Inbound and Outbound File Layouts. The updated description will include “the amount of additional dispensing fee paid for Emergency Use Authorization oral antiviral drugs procured by the U.S. Government over and above what is reported in field 30, Dispensing Fee Paid.”
3. The name of field 41 will be changed from *Vaccine Administration Fee* to *Vaccine Administration Fee or Additional Dispensing Fee* during a future system update to DDPS. Plan sponsors are encouraged to notify CMS of any obstacles or time constraints anticipated with respect to this PDE field name change.
4. Effective March 7, 2022, CMS will implement a new bypass condition for edit code 671 (“For DOS prior to 1/1/2011, if Catastrophic Coverage Code = 'blank', GDCA must be zero.

For DOS 1/1/2011 and forward, if (True Out-of-Pocket Accumulator + Patient Pay + Other TrOOP + Reported Gap Discount + LICS) <= OOP Threshold, GDCA must be zero”).

Specifically, given that a PDE has an NDC for a USG-procured EUA oral antiviral drug, edit 671 will be bypassed when all of the following conditions exist:

- Ingredient Cost = 0 and
- All drug costs are covered under Covered D Plan Paid Amount (Ingredient Cost + Sales Tax + Dispensing Fee + Vaccine Administration Fee = Covered D Plan Paid Amount) and
- One of the following is true:
  - TrOOP Accumulator = Annual OOP Threshold or
  - PDE Beginning Benefit Phase = D, N, or G and TrOOP Accumulator is less than the OOP Threshold and Ending Benefit Phase = C

CMS has been made aware of system challenges that some plan sponsors are facing in regards to reporting tier, formulary, and brand/generic code values on PDEs as stipulated in the January 20<sup>th</sup> HPMS Memorandum. CMS has considered industry feedback and, provided the fields contain a valid value, will not reject PDEs based on these fields when reporting USG-procured oral antiviral drugs.

#### **Part D Senior Savings Model PDEs**

On September 30, 2021, CMS issued HPMS memorandum “Updates to the Drug Data Processing System” on the [CMS website](#), which described a new edit code 870 bypass condition for Part D Senior Savings Model PDEs that would have straddled from the coverage gap phase to the catastrophic phase, but for the fact that this model reduces the patient pay such that the beneficiary’s TrOOP does not meet the TrOOP threshold. Effective May 9, 2022, for PDEs with dates of service (DOS) in 2021, this bypass condition will be extended to PDEs in this scenario that begin in the deductible or the initial coverage phase. The updated bypass conditions are as follows (bolded text indicates the updates):

- Submitting PBP is a Part D Senior Savings Model Participant on the DOS and
- **DOS is between 01/01/2021 and 12/31/2021** and
- PDE is squarely in the gap **or begins in the deductible or initial coverage phase** and
- PLRO > 0 and
- REPORTED GAP DISCOUNT <= CMS CALCULATED GAP DISCOUNT
- GDCB > (TrOOP Threshold for the benefit year - TrOOP Accumulator) / (1 – covered plan cost-sharing percentage)

As indicated in the updated bypass condition logic above, effective May 9, 2022, this bypass condition will be *limited* to PDEs with a DOS in 2021. Explicitly, this means that, beginning on May 9, 2022, PDEs with a DOS in 2022 that are squarely in the gap will no longer meet the requirements for this bypass. This bypass condition is no longer necessary for 2022 gap PDEs because CMS is currently using the model-specific gap discount calculation for PDEs in this scenario that are appropriately populated with a Part D Model Indicator value of ‘07.’ Effective

May 9, 2022, this model-specific gap discount calculation will also be applied to 2022 PDEs that begin in the deductible or initial coverage phase and would have straddled into the catastrophic phase, but for the fact that this model reduces the patient pay such that the beneficiary's TrOOP does not meet the TrOOP threshold.

Thank you.