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General Comment

We had sent these questions to CMS Part D Plan Reporting email, and were asked to send via the Federal Register:

We have a couple questions regarding the new Data Validation reporting section that has been added to the audit set, Part D Improving Drug Utilization Review Controls:

1.) The following statements can be found in the DV Standards, Sections 6aii and 6bii respectively:
o (6aii) The rejected opioid claim due to the soft formulary-level cumulative opioid MED POS edit is not associated with an early refill rejection transaction
o (6bii) The rejected opioid claim due to the hard formulary-level cumulative opioid MED POS edit is not associated with an early refill rejection transaction

Our question: These statements do not appear to be in the related CMS Technical Specifications for this reporting section. Given the difference, we want to make sure that plans should abide by the statements in the DV Standards and exclude soft and hard edit rejections due to early refills from DV reporting. Please advise.

2.) The following statement can be found in the DV Standards, Section 4ai:
o Organization provides documentation that its soft and/or hard formulary-level cumulative opioid MED POS edit was properly tested and validated prior to its implementation date.

Our question: We are seeking guidance from CMS as to what types of documentation you would recommend we secure from clients in order for us to comply with this review standard. Any examples or direction you could provide in this regard would be greatly appreciated.