DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR MEDICARE

DATE: March 5, 2012

TO: Pharmaceutical Manufacturers

FROM: Cheri Rice /s/
Director, Medicare Plan Payment Group

SUBJECT: Medicare Coverage Gap Discount Program—Dispute Resolution

Background

As part of the Medicare Coverage Gap Discount Program (CGDP), manufacturers are required to provide applicable beneficiaries with applicable discounts on the negotiated price of applicable drugs. Applicable beneficiaries are Part D enrollees that do not receive income related subsidies under section 1860D-14(a) of the Social Security Act (the Act), have reached or exceeded the initial coverage limit (ICL) under section 1860D-2(b)(3) of the Act, and have not incurred costs for covered Part D drugs in the year equal to the annual out-of-pocket threshold specified in 1860D-2(b)(4)(B) of the Act.

The Centers for Medicare & Medicaid Services (CMS) generates invoices to manufacturers for applicable discounts based on prescription drug event (PDE) data submitted by the Part D sponsors. Manufacturers have the right to dispute invoiced discount payments based on the "Medicare Part D Discount Information on the Manufacturer Data Report." Within 60 days of receipt of the information, manufacturers must electronically submit all disputes using the "Manufacturer Dispute Submission File" format provided by the Third Party Administrator (TPA).

The PDEs accepted from Part D plan sponsors are saved after a rigorous set of data edits are applied. These include 15 different edits focused exclusively on the CGDP. For example, Edit 867 will reject a PDE submission if the Food and Drug Administration (FDA) data available at the time does not designate the drug as having a New Drug Application (NDA) or a Biologic License Application (BLA). Without these designations the drug is ineligible for the coverage gap discount. Detailed information on PDE submissions, including the editing process, can be obtained on the TPA's website. We specifically recommend reviewing the "2011 PDE Participant Guide."[1]

In addition to the substantive editing process, PDEs with coverage gap amounts are subject to further data analysis by CMS before they are used to generate invoices to the manufacturers for the CGDP. Accordingly, we expect relatively few PDE errors that would require a dispute to correct and will generally deny these types of disputes unless the evidence presented demonstrates a failure in the editing and review process. Moreover, CMS will deny disputes if the discount payment is accurately calculated, even if the dispensing event may not have been clinically appropriate. In other words, the dispute process

[1] Available online at http://www.mcoservice.com/internet/Cssc.nsf/files/PDEParticipantGuide%20cameraready%20081811.pdf/$FIle/PDEParticipantGuide%20cameraready%20081811.pdf

is not intended to be a retrospective utilization management review where the clinical decision making of the prescriber, provider, or Part D plan is called into question.

The remainder of this guidance further clarifies CMS expectations regarding dispute submissions based upon a detailed analysis of the data collected as part of the dispute resolution process for PDEs submitted for the 2011 coverage year. A table summarizing the dispute submission requirements by dispute reason code is provided in the Appendix.

Basis for Disputes

This guidance specifies the standard that manufacturers must satisfy in order for the TPA to review and validate a disputed discount payment. First and foremost, disputes should be based only on Medicare Part D policy. We have received inappropriate disputes that have been based on interpretations of prescription drug policies from other government programs (e.g., Medicaid) that are not germane to Medicare Part D. We strongly recommend that manufacturers become familiar with the chapters of the "Part D Prescription Drug Benefit Manual" available online at http://www.cms.gov/PrescriptionDrugCovContra/.

Manufacturers must explain why they believe that the invoiced gap discount amount is likely in error. In making the decision to file a dispute, manufacturers should consider that CMS already performs editing on PDE records and conducts outlier analysis that checks for duplicates, applicable National Drug Codes (NDCs), and incorrect gap discount calculations, prior to invoicing. The TPA takes into consideration previous CMS analysis and validations performed before or during the resolution of the dispute when making a dispute determination. The following sections (organized by dispute reason code) clarify what we expect manufacturers to demonstrate in order to justify a review and determination by the TPA.

Duplicate Invoice Item (D01)

CMS performs editing on PDE records, as they are submitted by Part D sponsors, that checks for duplicates submitted by the same contract/ Plan Benefit Package (PBP) and across different contract/PBPs. If the conditions for this edit are met (i.e. the Medicare Health Insurance Claim Number (HICN), Service Provider ID, Service Provider ID Qualifier, Prescription/Service Reference Number, Date of Service and Fill Number match), only the first instance of the PDE is saved and all other duplicates are rejected and not saved to the system. CMS also performs an analysis of saved PDE data to further identify potential duplicates submitted by the same contract/PBP and across different contract/PBPs. All potential duplicates identified under this process are presented to Part D sponsors in order to validate that multiple prescriptions were, in fact, dispensed. If the Part D sponsor agrees that the PDEs in question are duplicates, they must delete the duplicative PDE. Because of our rigorous editing and analysis protocols, it is unlikely that manufacturers will be able to identify a potential duplicate that has not already been identified, particularly given the subset of PDE data fields available on the Manufacturer Data Report. Therefore, if an invoiced PDE is disputed under D01, the dispute will be denied unless: (1) the PDE has been identified by CMS analysis of saved PDE data as a potential duplicate, AND (2) the Part D sponsor concurs that the PDE is a duplicate and has not yet deleted the duplicative PDE.

Manufacturers filing disputes under D01 must populate the Supporting Detail Reference Number field in the Manufacturer Dispute Submission File. For duplicate invoice item disputes, the manufacturer must clearly demonstrate that the invoiced item in question is a duplicate of another invoiced item. To date, we have received disputes in which the Supporting Detail Reference Number was identical to the Detail Reference Number of the PDE being disputed. When a PDE is invoiced in one quarter and is adjusted in a subsequent quarter in a way that impacts a field displayed on the Manufacturer Data Report, the Detail Reference Number remains the same between invoices. Therefore, manufacturers should use discretion

when disputing for D01 in this case, as we believe this scenario to represent an adjustment to a previously invoiced PDE rather than a true duplicate.

Closed Pharmacy (D02)

CMS performs editing on PDE records as they are submitted by Part D sponsors to confirm that a pharmacy was open on the Date of Service (DOS) provided on the submission. CMS PDE editing systems receive a data feed from the National Council for Prescription Drug Programs (NCPDP) that includes "Store Open" and "Store Close" dates. This information is used to build a history file that is updated monthly. As PDEs are submitted by Part D sponsors, the system uses the reported Service Provider ID to determine the "Store Open" and "Store Close" date known as of the day that the PDE was submitted. The system will reject PDEs with DOS that are greater than the store close date plus six months. Through extensive analysis of NCPDP data, we have observed instability in reported "Store Close" date where a pharmacy is reported as closed then later that information is corrected to show a continuous open period. Beyond six months, retroactive changes to store open and close dates decrease dramatically. Because of this, CMS allows a six month grace period following the DOS.

While we believe we reject most PDEs submitted with Service Provider IDs that were not operating as of the DOS, there is a small chance that some of these PDEs will be saved to our system. Therefore, it is reasonable for a manufacturer to dispute an invoiced PDE for this reason. Manufacturers must provide the Store Close Date in the Supporting Date 1 field of the Dispute File. When disputes are received for this reason, we will consult the NCPDP historical data to determine if the pharmacy was open on the DOS according to the information on record as of the time of the dispute review. We do not include a lag time in store close dates when making dispute determinations.

Not Part D Covered Drug (D03)

We have observed confusion among manufacturers regarding the intent of this dispute reason. The purpose of this code is for manufacturers to indicate that an NDC should not be covered under the Part D program under any circumstances. Manufacturers should not use the dispute reason code of "Not Part D Covered Drug" to file a dispute on the basis that the drug is potentially a non-applicable CGDP drug, but otherwise would be covered under Medicare Part D. Manufacturers that dispute a discount payment on the basis that the drug is a Part D covered drug but is not eligible to receive the discount, should use the reason code of D09 Marketing Category is Not NDA or BLA. We have also observed that this dispute reason code has also been used to file disputes on the basis of the last lot expiration date. For these disputes, manufacturers should use reason code D07 Last Lot Expiration Date.

Additionally, we note that drugs disputed for Medicare Part B versus Part D coverage are largely dependent on indication and/or patient setting. Manufacturers wishing to dispute for this reason should first confirm that the Service Provider ID field on the invoiced PDE in question does not represent a pharmacy. Absent any clinical review, if a drug that can be covered under Part B or Part D is dispensed through a pharmacy, we can only assume that the indication or patient setting supports being billed correctly under Part D. Therefore, disputed PDEs meeting these criteria will be denied.

Excessive Quantity (D04)

Manufacturers who file a dispute on the basis that the quantity is excessive should demonstrate that the quantity is inconsistent with the packaging of the product and that the quantity is considered excessive given the days' supply. Legitimate variations in patient characteristics often warrant appropriate dosing in excess of the Food and Drug Administration (FDA) approved labeling. When there is a maximum FDA labeled daily dose, CMS will generally not uphold disputes for quantities that represent doses less than

three times the maximum. Disputes should be based on quantities that likely represent errors that are not medically appropriate under any circumstances and may represent a threat to the health of a Medicare beneficiary.

Days' Supply (D05)

The days' supply is considered invalid if it is inconsistent with the packaging of the product. Manufacturers are required to provide supporting documentation in the "Additional Information" field or as an attachment when filing a dispute on the basis of invalid days supply. A dispute based on invalid days' supply should demonstrate that the days' supply is inconsistent with the packaging of the product or that it represents a days' supply that is unlikely in the Medicare population. A dispute filed for invalid days' supply on the basis that the days' supply is not a medically appropriate variation in dosing will generally be denied. We reiterate here that a discount payment is in error only if it is not accurately calculated. Disputing the days' supply is not intended as a means to review or second guess the clinical decision making of the prescriber or the Part D plan.

High Price of the Drug (D06)

Under this dispute reason code, we have observed several additional issues being disputed. Concerns over the maximum discount per PDE and cumulative maximum discount for a single beneficiary should be filed under D99 at this time. In the future, we will be creating distinct codes for these two reasons to facilitate dispute classification and streamline the dispute review process.

Appropriate disputes filed under D06 reason code call into question the unit price of the disputed NDC. To evaluate these disputes, CMS analyzes the per unit price of the disputed PDEs relative to all other PDEs accepted for the same NDC. If the price falls within an acceptable range according to actual PDE data the dispute is denied.

We have observed a number of D06 disputes that are based upon non-Part D pricing metrics. Under section 1860D-2(d) of the Act, Medicare Part D negotiated prices are not determined by formula and may differ by plan, as each sponsor enters into private negotiations to determine the price. We remind manufacturers that CMS is prohibited by section 1860D-11(i) of the Social Security Act from interfering "with the negotiations between drug manufacturers and pharmacies and PDP sponsors" and CMS "may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs." Since Part D negotiated prices are not determined by statutory formula (e.g., the average sales price (ASP) plus 6% used for Medicare Part B drugs or the average manufacturer price (AMP) used in the Medicaid drug rebate program) and are not specifically tied to common list prices such as average wholesale price (AWP) or wholesale acquisition cost (WAC), we do not consider these price points when evaluating the per unit price of a drug. Disputes should not be submitted solely based upon a calculated deviation between the Part D negotiated price and prices from other government programs or list prices. Disputes citing only these sources as the basis for the dispute will generally be denied unless the PDE in question also exceeds a threshold in the actual Part D data.

Manufacturers may want to consider using the "Prescription Drug Plan Formulary, Pharmacy Network, and Pricing Information Files" to guide their decisions with respect to pricing outliers.[2] These public use files (PUF) contain average monthly costs for formulary Part D drugs. Outlier models could be developed using these data to determine prices that substantively deviate from the average.

[2] For more information on these PUFs see the link below
https://www.cms.gov/NonIdentifiableDataFiles/09_PrescriptionDrugPlanFormulary,PharmacyNetwork,andPricingInformationFiles.asp

Occasionally, we are able to determine that an unreasonably high per unit price is likely attributable to a misreported days supply on the PDE. While this does fit the spirit of the dispute reason code, we are unlikely to uphold these disputes, as correcting the days supply field on the PDE alone will not change the quantity dispensed, drug cost, or reported gap discount amount.

Last Lot Expiration Date (D07)

CMS expects manufacturers to maintain up-to-date listings with the FDA and the electronic database vendors for which they provide their NDCs for pharmacy claims processing. Accurate NDC listings enable CMS and Part D sponsors to identify applicable drugs in the Discount Program. In order to dispute a discount payment on the basis of last lot expiration date, the manufacturer must demonstrate that the date of service post-dates the last-lot expiration date for the NDC. Manufacturers are required to provide the NDC directory drop date (the date that the NDC no longer appears on the FDA Directory) in the "Supporting Date 1" field. The manufacturer must also provide the last lot expiration date in the "Supporting Date 2" field. While providing supporting documentation in the "Additional Information" field is optional when disputing on the basis of last lot expiration, we strongly encourage manufacturers to do so. The manufacturer should demonstrate that it provided appropriate advance notice to database vendors, or advance notice to the FDA of the marketing end date.

We remind manufacturers that they are required to maintain updated electronic FDA listing of all NDCs, including the timely removal of NDCs no longer on the market from the FDA NDC Directory. Only manufacturers know the last-lot expiration dates for their NDCs and therefore, manufacturers are also responsible for ensuring that the electronic database vendors are prospectively notified when NDCs no longer represent products that are still available on the market.

Manufacturers will not be able to successfully dispute invoiced amounts based on inaccurate or out-of-date FDA NDC directory listings without documentation that the manufacturer notified the FDA of an error, or requested that an out-dated NDC be removed from the Directory, in order to show that it was not a result of manufacturer non-compliance with the Discount Program requirement. Manufacturers that fail to update their information in a timely fashion, and as a result, are billed for discounts based on incorrect information, must pay the amounts billed, and CMS will not consider such failure to be grounds for successful dispute of invoiced amounts. Manufacturers should refer to section 5 of the December 17, 2010, guidance for additional information on their responsibility to maintain up-to-date listings with both the FDA and the electronic database vendors (e.g., First DataBank and Medispan) used for pharmacy claims processing.

Early Fill (D08)

To date, the TPA has received very few disputes citing this reason as the basis for disputes. When reviewing these disputes, we seek Part D sponsor confirmation that both the first fill and the early fill were actually dispensed. There are many situations in which a beneficiary may receive an early fill of a prescription such as a vacation supply, replacement for lost or damaged medications, or another clinically appropriate temporary removal of pharmacy refill too soon edits. To reiterate, disputes will be denied if the discount payment is accurately calculated based upon accurate data for dispensing events that actually occurred.

Marketing Category is Not NDA or BLA (D09)

The CGDP makes manufacturer discounts available to applicable Medicare beneficiaries receiving applicable drugs while in the coverage gap. A dispute that is filed on the basis that the marketing category is neither a New Drug Application (NDA) nor a Biologic License Application (BLA) means that the manufacturer believes that the drug product is not an applicable drug due to the marketing category of the product on the date of service and that the product is therefore ineligible for the coverage gap discount.

On September 12, 2011, CMS issued guidance entitled "Update to Part D National Drug Code Edits" which describes the PDE editing logic that it uses to identify applicable drugs subject to the discount.[3] As of July 1, 2011, PDE edits for coverage gap discounts are based upon the marketing category specified in the new FDA NDC Directory, not the FDA Orange Book. The exception is for NDCs listed only on the old FDA NDC Directory, in which case, the PDE edits for the coverage gap discount are based on the marketing category specified in the FDA Orange Book. If the NDC is listed on both the new FDA NDC Directory and the old FDA NDC Directory, CMS will rely on the marketing category specified in the new NDC Directory, not the FDA Orange Book.

In June 2011, the FDA began posting the new FDA NDC Directory.[4] The new Directory identifies only those NDCs that have been electronically listed with the FDA and includes data fields such as marketing category, marketing start date, and marketing end date. While the FDA only updates the new Directory, the FDA also posted a final old NDC Directory on June 1, 2011, that includes both electronically listed and paper listed NDCs. The CMS system receives updates from the FDA eList on a monthly basis.

When performing edits to determine whether an NDC is an applicable drug, the CMS system first checks the eList for the NDC and uses the marketing category listed. If the drug is not on the eList, the editing logic then checks the old NDC directory for the application number to obtain the marketing category from the FDA Orange Book. Once the source of the marketing category information is determined, the CMS system identifies the marketing category and checks that the date of service for the PDE falls between the Marketing Category Start Date and the Marketing Category End Date.

When the TPA receives a dispute on the basis that the marketing category is neither NDA nor BLA, it confirms the marketing category at the time of submission and editing for the date of service in question. If the research into the dispute shows the marketing category to be NDA or BLA at the time of PDE submission for the DOS, then the dispute is denied.

CMS relies on the FDA listing data to identify applicable drugs in the CGDP. Manufacturers must ensure that all of their drug products are properly listed on the FDA NDC Directory. Manufacturers will not be able to successfully dispute invoiced amounts based on inaccurate or out-of-date FDA NDC directory listings without documentation that the manufacturer notified the FDA of an error. Manufacturers that fail to update their information in a timely fashion and, as a result, are billed for discounts based on incorrect information, must pay the amounts billed, and CMS will not consider such failures to be grounds for successful dispute of invoiced amounts.

[3] This memorandum is archived with all other Part D guidance memoranda in the Health Plan Management System (HPMS) and after a lag time on the CMS website at http://www.cms.gov/PrescriptionDrugCovContra/HPMSGH/list.asp#TopOfPage.

[4] The NDC Directory is available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm.

Date of Service Prior to 1/1/2011 (D10)

To date, the TPA has not received any disputes on the basis that the date of service for the dispensing event was prior to 1/1/2011. CMS performs editing on PDE records that prevent PDEs with gap discount amounts from being accepted, and therefore invoiced, for DOS prior to 1/1/2011.

PDE Improperly Invoiced Beyond Manufacturer Agreement Invoice Period (D11)

To date, the TPA also has not received any disputes on the basis that the PDE was invoiced beyond the invoice period. Again, CMS performs editing on PDE records to prevent incorrect invoicing of gap discount amounts.

Invalid Prescription Service Reference Number (D12)

To date, the TPA has not received any disputes on the basis that the Prescription Service Reference Number is invalid. CMS performs editing on PDE records to prevent PDEs with invalid prescription service reference numbers from being accepted.

Other (D99)

Manufacturers have used the D99 dispute reason code to capture a variety of different concerns. The top three issues under dispute are the following:

1. **340B Pharmacy Disputes**-Part D sponsors must establish a pharmacy network sufficient to ensure access to covered Part D drugs for their enrollees (see Chapter 5 of the Prescription Drug Benefit Manual for more detail). As we have previously noted in Chapter 14 of the Prescription Drug Benefit Manual, Part D sponsors are allowed to count 340B pharmacies toward the Part D sponsor's retail pharmacy network requirements. Accordingly, disputes should not be filed merely because the prescription drug was dispensed from a 340B pharmacy. Moreover, the Social Security Act does not require a specific contractual relationship between the 340B pharmacy's acquisition cost and the price negotiated by the Part D sponsor. Thus, disputes should not be filed merely because of a difference between the Part D sponsor's negotiated price and the 340B pharmacy's acquisition cost.

2. **Maximum Gap Discount Disputes**-In the January 27, 2012, memorandum "Medicare Coverage Gap Discount Program—Maximum Applicable Discounts" we noted the confusion of some manufacturers with respect to Part D benefit designs that differ from the defined standard benefit. We have observed that several disputes have been received that reflect this lack of understanding. Therefore, we reiterate here that most Part D plans do not offer defined standard coverage. Part D sponsors frequently provide benefits that are actuarially equivalent to the defined standard coverage or enhanced with lower (or zero dollar) deductibles and fixed copays instead of 25% co-insurance before the initial coverage limit (ICL). In some cases, Part D sponsors have a lower than standard ICL. Consequently, beneficiaries will have incurred different levels of out-of-pocket spending when the reach the ICL depending upon their specific Part D plan benefit parameters. This means that beneficiaries could have more or less out-of-pocket spending remaining before they reach the annual out-of-pocket threshold. Disputes should not be filed merely because the invoice in question differs from the defined standard benefit design.[5]

[5] Information on how PDEs are mapped for alternate benefit designs is available in the PDE guide at: http://www.mcoservice.com/internet/Cssc.nsf/files/PDEParticipantGuide%20cameraready%20081811.pdf/$FIle/PDEParticipantGuide%20cameraready%20081811.pdf

3. **Employer Group Waiver Plans (EGWPs)**-Per section 1860D-22(b) of the Social Security Act, CMS has statutory authority to waive or modify requirements that hinder the design of, the offering of, or the enrollment in, employer/union sponsored standalone prescription drug plans (PDPs). Similar to other Part D plans, most employer group waiver plans (EGWPs) differ from the defined standard benefit. Often EGWPs offer lower deductibles or provide coverage for claims incurred in the Part D coverage gap. By contrast with other plan types, within the deductible and the initial coverage limit range, EGWPs may provide somewhat less coverage than defined standard benefit. Again, disputes should not be filed merely because the invoice in question differs from the defined standard benefit design. For more specific details concerning EGWPs see Chapter 12 of the Prescription Drug Benefit Manual.

If you have any further questions about the Part D coverage gap and how applicable discounts are determined under the Discount Program, please direct them to CGDPandmanufacturers@cms.hhs.gov.

Attachment

Summary of Dispute Submission Guidance by Reason Code

DISPUTE REASON CODE	DISPUTE REASON DESCRIPTION	DOCUMENTATION	COMMENTS
D01	**Duplicate Invoice Item**	**REQUIRED:** The SUPPORTING DETAIL REFERENCE NUMBER field must contain the Detail Reference Number (DRN) of the potential duplicate. **OPTIONAL:** Supporting evidence in the ADDITIONAL INFORMATION field.	Most PDEs disputed for this reason represent adjustments to previously invoiced items. Manufacturers should confirm that this is not the case by ensuring that the DRN from the disputed PDE and the DRN entered in the Supporting DRN field are different.
D02	**Closed Pharmacy**	**REQUIRED**: The SUPPORTING DATE 1 field should contain the NCPDP closed date. **OPTIONAL:** Supporting evidence in the ADDITIONAL INFORMATION field.	The date of service on the dispensing event should post-date the date entered as the NCPDP closed date.
D03	**Not PART D Covered Drug**	**REQUIRED**: The ADDITIONAL INFORMATION field should contain supporting evidence explaining the statutory exclusion that applies to the drug.	Manufacturers should confirm that the Service Provider ID in question does not represent a pharmacy for disputes on the basis that the drug is covered under Part B.

DISPUTE REASON CODE	DISPUTE REASON DESCRIPTION	DOCUMENTATION	COMMENTS
D04	**Excessive Quantity**	**REQUIRED**: The ADDITIONAL INFORMATION field should provide supporting evidence that: • The quantity is inconsistent with the packaging of the product; • The quantity is unlikely in the Medicare population; • The gap discount is based on an inaccurate calculation; and/or, • The gap discount was based upon inaccurate data that does not represent the dispensing event that occurred. Please provide the proprietary benchmark used to identify excessive quantity.	Disputes should be based on quantities that likely represent errors that are not medically appropriate under any circumstances.
D05	**Invalid Days' Supply**	**REQUIRED**: The ADDITIONAL INFORMATION field should contain supporting evidence that demonstrates that: • The days' supply is inconsistent with the packaging of the product; • The days' supply is unlikely in the Medicare population; • The gap discount is based on an inaccurate calculation; and/or, • The gap discount was based upon inaccurate data that does not represent the dispensing event that occurred.	A dispute based on invalid days' supply should demonstrate that the days' supply is inconsistent with the packaging of the product or that it represents a days' supply that is unlikely in the Medicare population.
D06	**High Price of the Drug**	**REQUIRED**: The ADDITIONAL INFORMATION field should contain supporting evidence	Manufacturers should not cite AMP, ASP, AWP, WAC or other non-Part D pricing benchmarks as a basis for the

DISPUTE REASON CODE	DISPUTE REASON DESCRIPTION	DOCUMENTATION	COMMENTS
		that demonstrates that: • The per unit price is excessive relative to the per unit price paid under the Part D program.	claim of high per unit price of a disputed PDE. Medicare Part D negotiated prices are not determined by formula and may differ by plan, as each sponsor enters into private negotiations to determine the price.
D07	**Last Lot Expiration Date**	**REQUIRED**: • The SUPPORTING DATE 1 field should contain the NDC Directory drop date. • The SUPPORTING DATE FIELD 2 should contain the last lot expiration date. **OPTIONAL:** Supporting evidence in the ADDITIONAL INFORMATION field.	The date of service of the dispensing event should post-date the last lot expiration date for the NDC.
D08	**Early Fill**	**REQUIRED:** The SUPPORTING DETAIL REFERENCE NUMBER field must contain the Detail Reference Number of the potential early fill. **OPTIONAL:** Supporting evidence in the ADDITIONAL INFORMATION field.	Manufacturers should consider valid reasons for early fills. Provided both fills can be confirmed as actually dispensed, the dispute will be denied.
D09	**Marketing Category is not NDA or BLA**	**REQUIRED**: The SUPPORTING DATE 1 field should contain the date of the FDA Directory update. **OPTIONAL:** Supporting evidence in the ADDITIONAL INFORMATION field.	Supporting evidence should demonstrate that: • The FDA was notified of a change or error in the FDA Directory; and/or • That updates to the FDA Directory were made prior to the DOS and processing date of the PDE.

DISPUTE REASON CODE	DISPUTE REASON DESCRIPTION	DOCUMENTATION	COMMENTS
D10	**Date of Service prior to 01/01/2011**	**OPTIONAL:** Supporting evidence in the ADDITIONAL INFORMATION field.	
D11	**PDE improperly invoiced beyond Manufacturer Agreement Invoice period**	**OPTIONAL:** Supporting evidence in the ADDITIONAL INFORMATION field.	
D12	**Invalid Prescription Service Reference Number**	**OPTIONAL:** Supporting evidence in the ADDITIONAL INFORMATION field.	
D99	**Other**	**REQUIRED**: The ADDITIONAL INFORMATION field should describe the basis of the dispute, including any supporting dates or detail reference numbers.	