

2016 (old version)	2019 (new version)	Type of Change	Reason for Change
File Format Title: CMS Record Specification DDR Quarterly Pricing Data File Format For Text File Submissions for Transfer to CMS	File Format Title: DDR Quarterly Pricing Data File Format for Text File Submissions to CMS	Rev	To align verbiage with the other 367 forms
Labeler Code Field - Remarks - "NDC #1"	Labeler Code Field - Remarks - "NDC 1"	Rev	To align verbiage with the other 367 forms
Product Code Field - Remarks - "NDC #2"	Product Code Field - Remarks - "NDC 2"	Rev	To align verbiage with the other 367 forms
Package Size Field - Remarks - "NDC #3"	PackageSize Field - Remarks - "NDC 3"	Rev	To align verbiage with the other 367 forms
Period Covered Field - Remarks ' "QYYYY (Qtr/Yr)"	Period Covered Field - Remarks - "QYYYY"	Rev	To align verbiage with the other 367 forms
Average Mfr Price Field	Average Manufacturer Price (AMP) Field	Rev	To align verbiage with the other 367 forms
Best Price Field	Best Price (BP) Field	Rev	To align verbiage with the other 367 forms
Nominal Price Field	Nominal Price (NP) Field	Rev	To align verbiage with the other 367 forms
Customary Prompt Pay Disc. Field	Customary Prompt Pay (CPP) Discount	Rev	To align verbiage with the other 367 forms
Initial Drug Available for LE Field	Initial Drug Available for Line Extension	Rev	To align verbiage with the other 367 forms

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<p>Disclosure Statement - According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0578. The time required to complete this information collection is estimated to average 34.8 hours per response, including the time to review instructions, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.</p>	<p>Disclosure Statement - Form CMS-367a is used by manufacturers on a quarterly basis, to transmit pricing data for each of their covered outpatient drugs to CMS either electronically or via file transfer. The use of Form CMS-367a on a quarterly basis by manufacturers is considered mandatory under the authority of Section 1927 of the Social Security Act and the National Drug Rebate Agreement. Under the Privacy Act of 1974 any personally identifying information obtained will be kept private to the extent of the law.</p> <p>According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0578. The time required to complete this information collection is estimated to average 34.8 hours per response, including the time to review instructions, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.</p>	Rev	Per new PRA Disclosure Statement requirements
Data Definitions Title - Quarterly Pricing Data Fields - CMS 367a	Data Definitions Title - Quarterly Pricing (CMS 367a Form) Data Element Definitions	Rev	To align verbiage with the other 367 forms

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N/A	Record ID: Constant of "Q". The Q Record ID indicates that the information reported for this NDC represents quarterly pricing data.	New	A data definition for the Record ID field was previously missing for the 367a form.
Labeler Code: First segment of National Drug Code that identifies the labeler. Numeric values only, 5-digit field, right-justified and zero-filled.	Labeler Code: First segment of the National Drug Code (NDC) that identifies the labeler. Numeric values; 5-digit field; right-justified; zero-padded.	Rev	To align verbiage with the other 367 forms
Product Code: Second segment of National Drug Code. Alpha-numeric value, 4-digit field, right justified, zero-filled.	Product Code: Second segment of the NDC. Alpha-numeric values; 4-digit field; right-justified; zero-padded.	Rev	To align verbiage with the other 367 forms
Package Size Code: Third segment of National Drug Code. Alpha-numeric values, 2-digit field, right justified, zero-filled.	Package Size: Third segment of the NDC. Alpha-numeric values; 2-digit field; right-justified; zero-padded.	Rev	To align verbiage with the other 367 forms
<p>Period Covered: Calendar quarter and year covered by data submission. Numeric 5-digit field, QYYYY.</p> <p>Valid values for Q:</p> <p>1 = January 1 - March 31 2 = April 1 - June 30 3 = July 1 - September 30 4 = October 1 - December 31</p> <p>Valid values for YYYY: 4-digit calendar year</p>	<p>Period Covered: Calendar quarter and year covered by the pricing data submission. Numeric 5-digit field; format: QYYYY.</p> <p>Valid values for Q:</p> <p>1 = January 1 - March 31 2 = April 1 - June 30 3 = July 1 - September 30 4 = October 1 - December 31</p> <p>Valid values for YYYY: 4-digit calendar year equal to 1991 or later.</p>	Rev	To align verbiage with other Medicaid Drug Rebate Program documentation.

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<p>Average Manufacturer's Price (AMP): The AMP per unit per product code for the period covered. If a drug is distributed in multiple package sizes, there will be one "weighted" AMP for the product, which is the same for all package sizes. Compute to 7 decimal places, and round to 6 decimal places. Numeric values, 12-digit field: 5 whole numbers, the decimal place ('.') and 6 decimal places; right-justified, zero-filled.</p>	<p>Average Manufacturer Price (AMP): The AMP per unit per product code for the period covered, based on sales. If a drug is distributed in multiple package sizes, there will be one "weighted" AMP for the product, which is the same for all package sizes. Compute to 7 decimal places, and round to 6 decimal places. Numeric values; 12-digit field: 5 whole numbers, the decimal point ('.') and 6 decimal places; right-justified; zero-padded for AMP values with fewer than 12 digits.</p>	Rev	To align verbiage with other Medicaid Drug Rebate Program documentation.
<p>Best Price: Per the statute and rebate agreement, the lowest price available per product code, regardless of package size. Compute to 7 decimal places and round to 6 decimal places. Zero-fill for Non-Innovator Multiple Source drugs. Numeric values, 12-digit field: 5 whole numbers, the decimal ('.') and 6 decimal places; right-justified, zero-filled.</p>	<p>Best Price (BP): Per the statute and rebate agreement, the lowest price available per product code, regardless of package size. Compute to 7 decimal places and round to 6 decimal places. Zero or blank-filled for Non-Innovator Multiple Source drugs. Numeric values; 12-digit field: 5 whole numbers, the decimal point ('.') and 6 decimal places; right-justified; zero-padded for BP values with fewer than 12 digits.</p>	Rev	To align verbiage with other Medicaid Drug Rebate Program documentation.

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<p>Nominal Price (NP): Sales that meet the statutory/regulatory definition of NP. Total dollar figure per 11-digit NDC, rounded to nearest dollar. 9-digit field; 9 whole numbers; right-justified, 0-filled. If no sales for a package size, fill with all zeroes.</p>	<p>Nominal Price (NP): Sales that meet the statutory/regulatory definition of NP. Labelers should determine an aggregate dollar amount (by adding up all package sizes), and report this aggregate NP dollar amount at the 9-digit NDC level. Total dollar figure, rounded to the nearest dollar. Zero or blank-filled if an NDC has no NP sales for the quarter/year being reported, and for every quarter/year in which an NDC is classified as a Non-Innovator Multiple Source drug. Numeric values; 9-digit field; 9 whole numbers; right-justified; zero-padded for NP values with fewer than 9 digits.</p>	Rev	To align verbiage with other Medicaid Drug Rebate Program documentation.
<p>Customary Prompt Pay Discount: Labelers may 1) allocate an individual CPP discount dollar amount per 11-digit NDC in each package size's record, or 2) report an aggregate discount dollar amount, by adding up all package sizes, and report this aggregate CPP discount dollar amount in one package size record and zero fill the remaining package sizes. 9-digit field; 9 whole numbers; right-justified, 0-filled.</p>	<p>Customary Prompt Pay (CPP) Discount: Labelers should determine an aggregate dollar amount (by adding up all package sizes), and report this aggregate CPP dollar amount at the 9-digit NDC level. Total dollar figure, rounded to nearest dollar. Zero or blank-filled if the NDC has no CPP discount for the quarter/year being reported. Numeric values; 9-digit field; 9 whole numbers; right-justified; zero-padded for CPP Discount values with fewer than 9 digits.</p>	Rev	To align verbiage with other Medicaid Drug Rebate Program documentation.

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<p>Initial Drug Available for LE: Identifies whether a line extension drug has an Initial Drug available for the quarter/year being reported.</p> <p>Valid Values:</p> <p>Y = Yes N = No X = X - Not an LE Drug Z = Not Applicable (for quarters prior to 2Q2016, or for quarters in which the NDC or labeler was not active)</p>	<p>Initial Drug Available for Line Extension: Identifies whether a line extension drug has an Initial Drug available for the quarter/year being reported. 1-character field.</p> <p>Valid Values:</p> <p>Y = Yes N = No X = X - Not an LE Drug Z = Not Applicable (for quarters prior to 2Q2016, or for quarters in which the NDC or labeler was not active)</p>	Rev	To align verbiage with other Medicaid Drug Rebate Program documentation.
<p>Initial Drug: Identifies the drug (from which a line extension drug is derived) with the highest additional rebate ratio (calculated as a percentage of AMP) for the quarter/year being reported. The Initial Drug's additional rebate ratio is then used in the alternative URA calculation for the line extension drug. The Initial Drug should fall under the same corporation as the corresponding line extension drug, and must be active within the MDR Program at the time it is reported as an Initial Drug. Numeric values only, 9-digit field, right-justified and zero-filled.</p>	<p>Initial Drug: Identifies the 9-digit NDC (from which a line extension drug is derived) with the highest additional rebate ratio (calculated as a percentage of AMP) for the quarter/year being reported. The Initial Drug's additional rebate ratio is then used in the alternative URA calculation for the line extension drug. The Initial Drug should fall under the same corporation as the corresponding line extension drug, and must be active within the MDR Program at the time it is reported as an Initial Drug. Zero-filled if the Initial Drug Available for LE field contains a value of N, X, or Z. Numeric values; 9-digit field; right-justified; zero-padded for Initial Drug values with fewer than 9 digits.</p>	Rev	To align verbiage with other Medicaid Drug Rebate Program documentation.

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Burden Change
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