

2016 (old version)	2019 (new version)	Type of Change	Reason for Change	Burden Change
CMS RECORD SPECIFICATION DDR MONTHLY PRICING DATA FILE FORMAT FOR TEXT FILE SUBMISSIONS FOR TRANSFER TO CMS	DDR MONTHLY PRICING DATA FILE FORMAT FOR TEXT FILE SUBMISSIONS TO CMS	Rev	To increase consistency across Medicaid Drug Rebate Program documents	N/A
NDC #1	NDC 1	Rev	To increase consistency across Medicaid Drug Rebate Program documents	N/A
NDC #2	NDC 2	Rev	To increase consistency across Medicaid Drug Rebate Program documents	N/A
NDC #3	NDC 3	Rev	To increase consistency across Medicaid Drug Rebate Program documents	N/A
Average Mfr Price	Average Manufacturer Price (AMP)	Rev	To increase consistency across Medicaid Drug Rebate Program documents	N/A

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<p>CMS-367b (Exp. 03/31/2019), OMB No. 0938-0578 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 44.8 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>Form CMS-367b (Exp.) is used by manufacturers on a monthly 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-367b on a monthly 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 44.8 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	To conform to new disclosure statement rules	N/A

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MONTHLY PRICING DATA FIELDS CMS 367b	Monthly Pricing (CMS 367b Form) Data Element Definitions	Rev	Renamed for clarity	N/A
N/A	Record ID: Constant of "M". The M Record ID indicates that the information reported for this NDC represents monthly pricing data.	Add	To increase consistency across Medicaid Drug Rebate Program documents	N/A
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 increase consistency across Medicaid Drug Rebate Program documents	N/A
Product Code: Second segment of National Drug Code. Alpha-numeric values, 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 increase consistency across Medicaid Drug Rebate Program documents	N/A
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 increase consistency across Medicaid Drug Rebate Program documents	N/A
Month: Calendar month covered by data submission. Numeric 2-digit field, MM.	Month: Calendar month covered by the pricing data submission. Numeric values; 2-digit field; format: MM.	Rev	To increase consistency across Medicaid Drug Rebate Program documents	N/A
Year: Calendar year covered by data submission. Numeric 4-digit field, YYYY. Valid values for YYYY: 4-digit calendar year.	Year: Calendar year covered by the pricing data submission. Numeric values; 4-digit field; format: YYYY. Valid values for YYYY: 4-digit calendar year equal to 2007 or later.	Rev	To increase consistency across Medicaid Drug Rebate Program documents	N/A

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Average Manufacturer 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.	Average Manufacturer Price (AMP): The AMP per unit per product code for the month/year 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 pointplace (‘.’) and 6 decimal places; right-justified, zero-padded for AMP values with fewer than 12 digits.	Rev	To increase consistency across Medicaid Drug Rebate Program documents	N/A
Average Manufacturer Price (AMP) Units: The total sum of all units included in the calculation of the AMP per product code for the monthly reporting period covered. If a drug is distributed in multiple package sizes, there will be one AMP unit for the product, which is the same for all package sizes. Numeric values, 14-digit field: 11 whole numbers, the decimal place (‘.’) and two (2) decimal places; right-justified; zero-filled.	AMP Units: The total sum of all units included in the calculation of the AMP per product code for the monthly reporting period. If a drug is distributed in multiple package sizes, there will be one AMP unit value for the product, which is the same for all package sizes. Numeric values; 14-digit field: 11 whole numbers, the decimal point (‘.’) and 2decimal places; right-justified; zero-padded.	Rev	To increase consistency across Medicaid Drug Rebate Program documents	N/A

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<p>5i Threshold: A manufacturer enters "Y" in this field if the AMP of the 5i drug is calculated using the alternate 5i AMP methodology, or a manufacturer enters "N" in this field if the AMP of the 5i drug is calculated using the standard (non-5i) methodology. A manufacturer enters "X" in this field if the drug was not classified as a 5i drug for the monthly reporting period. For months prior to the month in which the 5i Threshold field was implemented, or for months in which the NDC or labeler was not active, a manufacturer enters "Z" in this field to indicate the field was not applicable. Alpha-numeric values, 1-digit field.</p>	<p>5i Threshold: A value indicating whether the reported AMP was calculated using the alternate 5i AMP methodology (i.e., a 5i Threshold value of "Y"), or using the standard (non-5i) methodology (i.e., a 5i Threshold value of "N"). A 5i Threshold value of "X" should be reported if the NDC was not classified as a 5i drug for the month/year combination being reported. For months prior to July 2014 (i.e., the month in which the 5i Threshold field was implemented), a 5i Threshold value of "Z" should be reported to indicate the field was not applicable. 1-character field.</p>	Rev	To increase consistency across Medicaid Drug Rebate Program documents	N/A

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