2019 (old version)	2020 (new version)	Type of Change	Reason for Change	Burden Change
File Format Header: DDR PRODUCT DATA FILE FORMAT FOR TEXT FILE SUBMISSIONS TO CMS	**File Format Header:** MEDICAID DRUG REBATE PROGRAM MDP PRODUCT DATA FILE SUBMISSION TO CMS Form CMS-367c FILE FORMAT Effective: July 1, 2021	Rev	To align Header with other Medicaid Drug Rebate Program documentation.	N/A
N/A	**New File Format Column:** Ordinal Position Coresponding Rows Numbered 1-21	Add	To update File Format to include .CSV Ordinal Numbering Column	N/A
File Format - Column Name Update: Field	**File Format - Column Name Update:** Field Name (.TXT) Header Row (.CSV	Rev	To include .CSV Header Row in additon to the .TXT Field Name	N/A
File Format - Remarks Fields: See Data Element Definitions	**File Format - Remarks Fields:** See Data Definitions	Rev	To remove the word "Element" throughout all the Remarks as it is not relevant	N/A
File Format - Position Fields: 1 - 159	**File Format - Position Fields:** 1 - 162	Rev	Field positions were adjusted due to the deletion of the DRA Baseline AMP and ACA Baseline AMP fields	N/A
File Format Field: Therapeutic Equivalence Code (TEC)	**File Format Field:** Therapeutic Equivalence Code	Rev	To remove (TEC)	N/A
File Format Field: OBRA'90 Baseline AMP Size: 12 Position: 44 - 55 Remarks: 99999.999999	**File Format Field:** OBRA'90 Baseline AMP Size: 15 Position: 44 - 58 Remarks: 99999999.999999	Rev	Updated field size from 12 to 15 digits	N/A
File Format Field: Units Per Package Size (UPPS) Position: 56 - 66	**File Format Field:** Units Per Package Size Position: 59 - 69	Rev	To remove (UPPS), and to update field positions due to OBRA '90 Baseline AMP increased field size	N/A
File Format Field: FDA Product Name Position: 67 - 129	**File Format Field:** FDA Product Name Position: 70 - 132	Rev	To update field positions due to OBRA '90 Baseline AMP increased field size.	N/A
File Format Field: Package Size Intro Date (PSID) Poisition: 130 - 137	**File Format Field:** Package Size Intro Date Position: 133 - 140	Rev	To remove (PSID), and to update field positions due to OBRA '90 Baseline AMP increased field size	N/A
File Format Field: Purchased Product Date (PPD) Poisition: 138 - 145	**File Format Field:** Purchased Product Date Position: 141 - 148	Rev	To remove (PPD), and to update field positions due to OBRA '90 Baseline AMP increased field size	N/A
File Format Field: 5i Drug Indicator Poisition: 146 - 146	**File Format Field:** 5i Drug Indicator Poistion: 149 - 149	Rev	To update field positions due to OBRA '90 Baseline AMP increased field size.	N/A

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2019 (old version)	2020 (new version)	Type of Change	Reason for Change	Burden Change
File Format Field: 5i Route of Administration Poistion: 147 - 149	**File Format Field:** 5i Route of Administration Poistion: 150 - 152	Rev	To update field positions due to OBRA '90 Baseline AMP increased field size.	N/A
File Format Field: Covered Outpatient Drug (COD) Status Poistion: 150 - 151	**File Format Field:** Covered Outpatient Drug Status Poistion: 153 - 154	Rev	To remove (COD), and to update field positions due to OBRA '90 Baseline AMP increased field size	N/A
File Format Field: FDA Application Number / OTC Monograph Number Poistion: 152 - 158	**File Format Field:** FDA Application Number / OTC Monograph Number Poistion: 155 - 161	Rev	To update field positions due to OBRA '90 Baseline AMP increased field size.	N/A
File Format Field: Line Extension Drug Indicator Poistion: 159 - 159	**File Format Field:** Line Extension Drug Indicator Poistion: 162 - 162	Rev	To update field positions due to OBRA '90 Baseline AMP increased field size.	N/A
File Format Field: *Reactivation Date Size: *n/a Poistion: *n/a Remarks: *This field may only be submitted online via DDR. See Data Element Definitions	**File Format Field:** Reactivation Date Size: n/a Poistion: n/a Remarks: See Data Definitions	Rev	Removed extra verbiage/punctuation	N/A
Data Definitions Header: Drug Product (CMS 367c Form) Data Element Definitions	**Data Definitions Header:** MEDICAID DRUG REBATE PROGRAM MDP PRODUCT DATA FILE SUBMISSION TO CMS Form CMS-367c DATA DEFINITIONS Effective: July 1, 2021	Rev	To align Header with other Medicaid Drug Rebate Program documentation.	N/A
Data Definitions - Unit Type: Valid Values: AHF = Injectable Anti-Hemophilic Factor CAP = Capsule EA = EACH GM = Gram ML = Milliliter SUP = Suppository TAB = Tablet TDP = Transdermal Patch	**Data Definitions - Unit Type:** Valid Values: AHF = Injectable Anti-Hemophilic Factor CAP = Capsule EA = EACH GM = Gram ML = Milliliter SUP = Suppository TAB = Tablet TDP = Transdermal Patch mCi = Millicurie µCi = Microcurie	Rev	Added two additional Unit Types	N/A
Data Definitions - FDA Approval Date: ...For covered outpatient drugsfor which the FDA does not require approval,…	**Data Definitions - FDA Approval Date:** ...For covered outpatient drugs (CODs) for which the FDA does not require approval,…	Rev	To align verbiage with other Medicaid Drug Rebate Program documentation.	N/A

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Data Definitions - Market Date: ...If a Market Date falls on a date that is earlier than 9/30/1990, CMS will change it to 9/30/1990 in both the Medicaid Drug Rebate (MDR) system and the Drug Data Reporting for Medicaid (DDR) system,…	**Data Definitions - Market Date:** ...If a Market Date falls on a date that is earlier than 9/30/1990, CMS will change it to 9/30/1990 in the Medicaid Drug Programs (MDP) system,…	Rev	Updated verbiage to reference MDP not DDR	N/A
Data Definitions - Termination Date: ...(Note: Initial termination date submissions may be provided via file transfer; however, subsequent changes to this field may only be submitted online via DDR.)	**Data Definitions - Termination Date:** ...(Note: Initial termination date submissions may be provided via file transfer; however, subsequent changes to this field may only be submitted online via MDP.)	Rev	Updated verbiage to reference MDP not DDR	N/A
Data Definitions - Obra'90 Baseline AMP: ...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	**Data Definitions - Obra'90 Baseline AMP:** ...Numeric values; 15-digit field: 8 whole numbers, the decimal point ('.') and 6 decimal places; right justified; zero-padded for AMP values with fewer than 15 digits	Rev	Updated verbiage to account for increased field size from 12 - 15 digits	N/A
Data Definitions - Line Extension Drug Indicator: ...Labelers seeking an ADF exclusion at the time a drug is initially reported in DDR should submit an initial value of "R" in this field for CMS review and approval.	**Data Definitions - Line Extension Drug Indicator:** ...Labelers seeking an ADF exclusion at the time a drug is initially reported in MDP should submit an initial value of "R" in this field for CMS review and approval.	Rev	Updated verbiage to reference MDP not DDR	N/A
Data Definitions - Reactivation Date: ...(Note: This field may only be submitted online via DDR and is NOT part of the actual File Format.)	**Data Definitions - Reactivation Date:** ...(Note: This field may only be submitted online via MDP and is NOT part of the actual File Format.)	Rev	Updated verbiage to reference MDP not DDR	N/A

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