2016 (old version)	2019 (new version)	Type of Change	Reason for Change
File Format Title: CMS Record Specification DDR Drug Product Data File Format For Text File Submissions to CMS	File Format Title: DDR Product 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 Code Field	Package Size Field	Rev	To align field name with other Medicaid Drug Rebate Program documentation.
Package Size Field - Remarks - "NDC #3"	Package Size Field - Remarks - "NDC 3"	Rev	To align verbiage with the other 367 forms
FDA Thera Eq. Code Field	Therapeutic Equivalence Code (TEC) Field	Rev	To align field name with other Medicaid Drug Rebate Program documentation.
Drug Type Indicator Field	Drug Type Field	Rev	To align field name with other Medicaid Drug Rebate Program documentation.
Units Per Pkg Size Field	Units Per Pacakge Size (UPPS) Field	Rev	To align field name with other Medicaid Drug Rebate Program documentation.
DRA Baseline AMP Field	N/A	Deletion	The DRA Baseline AMP field is no longer collected from manufacturers; therefore, we are removing it from the 367c form
Package Size Intro Date Field	Package Size Intro Date (PSID) Field	Rev	To align field name with other Medicaid Drug Rebate Program documentation.
Purchased Product Date Field	Purchased Product Date (PPD) Field	Rev	To align field name with other Medicaid Drug Rebate Program documentation.
ACA Baseline AMP Field	N/A	Deletion	The ACA Baseline AMP field is no longer collected from manufacturers; therefore, we are removing it from the 367c form
COD Status Field	Covered Outpatient Drug (COD) Status Field	Rev	To align field name with other Medicaid Drug Rebate Program documentation.

Type of Change: Rev = Revision, Del = Deletion, Add = Addition, and Red = Redesgnation.

2016 (old version)	2019 (new version)	Type of Change	Reason for Change
FDA Appl No./OTC Mono No. Field	FDA Application Number/OTC Monograph Number Field	Rev	To align field name with other Medicaid Drug Rebate Program documentation.
Field Positions are 1-183	Field positions decreased from 1-183 to 1-159	Rev	Field positions were adjusted due to the deletion of the DRA Baseline AMP and ACA Baseline AMP fields

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2016 (old version)	2019 (new version)	Type of Change	Reason for Change
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 53.5 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.	Form CMS-367c (Exp.) is used by manufacturers to report a new drug to CMS either electronically or via file transfer, or when the manufacturer has to report a change to the product data of an existing drug electronically or via file transfer. When needed, the use of Form CMS-367c 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. 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 43.5 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.	Rev	Per new PRA Disclosure Statement requirements

Type of Change: Rev = Revision, Del = Deletion, Add = Addition, and Red = Redesgnation.

2016 (old version)	2019 (new version)	Type of Change	Reason for Change
Data Definitions Title - Drug Product Data Fields - CMS 367c	Drug Product (CMS 367c Form) Data Elements Definitions	Rev	To align verbiage with the other 367 forms
N/A	Record ID: Contant of "P". The P Record ID indicates that the information reported for this NDC represents product data.	New	A data definition for the Record ID field was previously missing for the 367c 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 other Medicaid Drug Rebate Program documentation.
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 other Medicaid Drug Rebate Program documentation.
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 other Medicaid Drug Rebate Program documentation.
Drug Category: Alpha numeric values, 1-characeter Valid Values: S = Single source I = Innovator multiple source N = Non-innovator multiple source	Drug Category: Indicates whether the drug is single source (S), innovator multiple source (I), or non-innovator multiple source (N). 1-character field. Valid values: S = Single source I = Innovator multiple source N = Non-innovator multiple source	Rev	To align verbiage with other Medicaid Drug Rebate Program documentation.

2016 (old version)	2019 (new version)	Type of Change	Reason for Change
Unit Type: One of the 8 unit types by which the drug is dispensed. Alphanumeric values, 3-character field, left-justified. Valid values: AHF = Injectable Anti-Hemophilic Factor CAP = Capsule EA = EACH GM = Gram ML = Milliliter SUP = Suppository TAB = Tablet TDP = Transdermal Patch	Unit Type: One of the 8 unit types by which a drug may be dispensed. 3-character field; left-justified; blank-filled for Unit Type values with fewer than 3 characters. Valid values: AHF = Injectable Anti-Hemophilic Factor CAP = Capsule EA = EACH GM = Gram ML = Milliliter SUP = Suppository TAB = Tablet TDP = Transdermal Patch	Rev	To align verbiage with other Medicaid Drug Rebate Program documentation.
FDA Approval Date: NDA or monograph approval date. Numeric values, 8-digit field, format: MMDDYYYY.	FDA Approval Date: NDA (including Authorized Generic), ANDA, or BLA approval date. For covered outpatient drugs for which the FDA does not require approval, use 9/30/1990 or, if the drug was first marketed after 9/30/1990, the actual date first marketed. Numeric values; 8-digit field; format: MMDDYYYY.	Rev	To align verbiage with other Medicaid Drug Rebate Program documentation.

2016 (old version)	2019 (new version)	Type of Change	Reason for Change
FDA TEC: FDA-assigned Therapeutic Equivalence Codes. Alpha-numeric values, 2-character field. Valid Values: AA AB AN AO AP AT BC BD BE BN BP BR BS BT BX NR - Not Rated A1 thru A9 - AB value	Therapeutic Equivalence Code (TEC): FDA-assigned Therapeutic Equivalence Codes as found in the FDA's Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Alpha-numeric values; 2-digit field. Valid values: AA = Products in Conventional Dosage Forms Not Presenting Bioequivalence Problems AB = Products Meeting Necessary Bioequivalence Requirements assigned an FDA TEC of AB, or AB1 through AB9 AN = Solutions and Powders for Aerosolization AO = Injectable Oil Solutions AP = Injectable Aqueous Solutions and, in Certain Instances, Intravenous Non-Aqueous AT = Topical Products BC = Extended-Release Dosage Forms (Capsules, Injectables, and Tablets) BD = Active Ingredients and Dosage Form With Documented Bioequivalence Problems BE = Delayed-Release Oral Dosage Forms BN = Products in Aerosol-Nebulizer Drug Delivery Systems BP = Active Ingredients and Dosage Forms with Potential Bioequivalence Problems BR = Suppositories or Enemas That Deliver Drugs for Systemic Absorption BS = Products Having Drug Standard Deficiencies BT = Topical Products with Bioequivalence Issues BX = Drug Products for Which the Data Are Insufficient To Determine Therapeutic Equivalence NR = Not Rated	Rev	To align verbiage with other Medicaid Drug Rebate Program documentation.

2016 (old version)	2019 (new version)	Type of Change	Reason for Change
Market Date: For S and I drugs, the date the drug was first marketed by the original labeler (i.e., NDA holder). For N drugs, the date the drug was first marketed under the labeler's rebate agreement. 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, since dates earlier than the start of the Drug Rebate Program have no bearing on the program. Numeric values, 8-digit field, format: MMDDYYYY.	Market Date: For S, I and N drugs marketed under an FDA-approved application (e.g. ANDA, BLA, NDA, NDA Authorized Generic), the earliest date the drug was first marketed under the application number by any labeler. For drugs marketed without an FDA-approved application (e.g., OTC monograph, unapproved drug), the earliest date the drug was first marketed by any labeler. For all drugs (i.e., those marketed with or without an FDA-approved application) that were purchased or otherwise acquired from another labeler, the Market Date should be equal to the Market Date of the original product. 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, since dates earlier than the start of the Medicaid Drug Rebate Program have no bearing on the program. Numeric values; 8-digit field; format: MMDDYYYY.	Rev	To align verbiage with other Medicaid Drug Rebate Program documentation.

2016 (old version)	2019 (new version)	Type of Change	Reason for Change
Termination Date: The date a drug is withdrawn from the market or the drug's last lot expiration 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.) Zero or blank- fill if not present. Numeric values, 8-digit field, format: MMDDYYYY.	Termination Date: The date a drug is withdrawn from the market or the drug's last lot expiration 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.) Zero or blank- filled for drugs without Termination Dates. Numeric values; 8-digit field; format: MMDDYYYY.	Rev	To align verbiage with other Medicaid Drug Rebate Program documentation.
Drug Type Indicator: Identifies a drug as prescription (Rx) or over-the-counter (OTC). Valid Values: 1 = Rx 2 = OTC	Drug Type: Identifies a drug as prescription (Rx) or over-the-counter (OTC). Numeric values; 1-digit field. Valid Values: 1 = Rx 2 = OTC	Rev	To align verbiage with other Medicaid Drug Rebate Program documentation.

2016 (old version)	2019 (new version)	Type of Change	Reason for Change
OBRA'90 Baseline AMP: The AMP per unit for the period that establishes the OBRA'90 Baseline AMP for innovator drugs. There will be one weighted baseline AMP for the product, which will be 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 ('.') and 6 decimal places; right-justified, zero-filled.	OBRA'90 Baseline AMP: The AMP per unit for the period that establishes the OBRA'90 Baseline AMP for single source or innovator multiple source drugs. There will be one weighted Baseline AMP for the product, which applies to all package sizes. Compute to 7 decimal places and round to 6 decimal places. Zero or blank-filled if the NDC does not have an OBRA '90 Baseline AMP, and for all 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 OBRA '90 Baseline AMP values with fewer than 12 digits.	Rev	To align verbiage with other Medicaid Drug Rebate Program documentation.
Units Per Package Size: Total number of units in the smallest dispensable amount for the 11-digit NDC. Numeric values, 11-digit field: 7 whole numbers, the decimal ('.') and 3 decimal places; right-justified, zero-filled.	Units Per Package Size (UPPS): The total number of units in the smallest dispensable amount for the 11-digit NDC. Numeric values; 11-digit field: 7 whole numbers, the decimal point ('.') and 3 decimal places; right-justified; zero-padded for UPPS values with fewer than 11 digits.	Rev	To align verbiage with other Medicaid Drug Rebate Program documentation.
FDA Product Name: Drug name as it appears on FDA listing form. Alpha-numeric values, 63-character fields, left- justified, blank-fill unused positions.	FDA Product Name: Drug name as it appears on FDA SPL listing. Alpha-numeric values; 63-character field; left- justified; blank-filled for FDA Product Names fewer than 63 characters.	Rev	To align verbiage with other Medicaid Drug Rebate Program documentation.

2016 (old version)	2019 (new version)	Type of Change	Reason for Change
DRA Baseline AMP (optional): For active innovator drugs with a Market Date less than July 1, 2007, the OBRA '90 or OBRA '93 Baseline AMP revised in accordance with relevant regulations and program guidance. There will be one weighted DRA Baseline AMP for the product, which will be the same for all package sizes. Per CMS-2238 FC, labelers had 4 quarters (i.e., January 2, 2008 - October 30, 2008) to report this optional field. Numeric vales, 12-digit field; 5 whole numbers, the decimal ('.') and 6 decimal places, right justified, zero-filled. Compute to 7 decimal places and round to 6 decimal places.	N/A	Deletion	The DRA Baseline AMP field is no longer collected from manufacturers; therefore, we are removing it from the 367c form
Package Size Introduction Date: The date the package size is first available on the market. Numeric values, 8-digit field, format: MMDDYYYY	Package Size Intro. Date (PSID): The date the package size is first available on the market. Numeric values; 8-digit field; format: MMDDYYYY.	Rev	To align verbiage with other Medicaid Drug Rebate Program documentation.
Purchased Product Date: The date the company currently holding legal title to the NDC first markets the drug under this NDC (this date can result, for example, from the purchase of an NDC from one company by another company, the re-designation of an NDC from one of a company's labeler codes to another of that same company's labeler codes, cross-licensing arrangements, etc.). Zero or blank- fill if not applicable. Numeric values, 8-digit field, format: MMDDYYYY	Purchased Product Date (PPD): The date the company currently holding legal title to the NDC first markets the drug under this NDC (this date can result, for example, from the purchase of an NDC from one company by another company, the re-designation of an NDC from one of a company's labeler codes to another of that same company's labeler codes, cross-licensing arrangements, etc.). Zero or blank- filled for drugs without Purchased Product Dates. Numeric values; 8-digit field; format: MMDDYYYY.	Rev	To align verbiage with other Medicaid Drug Rebate Program documentation.

Type of Change: Rev = Revision, Del = Deletion, Add = Addition, and Red = Redesgnation.

2016 (old version)	2019 (new version)	Type of Change	Reason for Change
5i Drug Indicator: Identifies whether a product is a 5i Drug. Alpha-numeric values; 1-digit field. Valid Values: Y = Yes N = No	5i Drug Indicator: Identifies whether a product is a 5i Drug. 1-characterdigit field. Valid Values: Y = Yes N = No	Rev	To align verbiage with other Medicaid Drug Rebate Program documentation.
5i Route of Administration: Identifies the method by which the 5i drug is administered to a patient. If a product is not a 5i drug, a value of “000” (Not Applicable) should be entered. Numeric values; 3-digit field. Valid Values: 000 = Not Applicable 001 = Implanted 002 = Infused 003 = Inhaled 004 = Injected 005 = Instilled	5i Route of Administration: Identifies the method by which the 5i drug is administered to a patient. If a product is not a 5i drug, a value of “000” (Not Applicable) should be reported. Numeric values; 3-digit field. Valid Values: 000 = Not Applicable 001 = Implanted 002 = Infused 003 = Inhaled 004 = Injected 005 = Instilled	Rev	To align verbiage with other Medicaid Drug Rebate Program documentation.

2016 (old version)	2019 (new version)	Type of Change	Reason for Change
ACA Baseline AMP (Optional): For active innovator drugs, the OBRA '90 OBRA '93 or DRA Baseline AMP revised in accordance with the statute and relevant program guidance. There will be one weighted ACA Baseline AMP for the product, which will be the same for all package sizes. Numeric values, 12-digit field; 5 whole numbers, the decimal ('.') and 6 decimal places; right-justified; zero-filled. Compute to 7 decimal places and round to 6 decimal places.	N/A	Deletion	The ACA Baseline AMP field is no longer collected from manufacturers; therefore, we are removing it from the 367c form

2016 (old version)	2019 (new version)	Type of Change	Reason for Change
Covered Outpatient Drug (COD) Status: A category that identifies whether or not a product meets the statutory definition of a covered outpatient drug in accordance with sections 1927(k)(2) to 1927(k)(4) of the Social Security Act. Numeric values, 2-character field. Valid Values: 01 = Abbreviated New Drug Application (ANDA) 02 = Biological License Application (BLA) 03 = New Drug Application (NDA) 04 = NDA Authorized Generic 05 = DESI 5* – LTE/IRS drug for all indications 06 = DESI 6* – LTE/IRS drug withdrawn from market 07 = Prescription Pre-Natal Vitamin or Fluoride 08 = Prescription Dietary Supplement/Vitamin/Mineral (Other than Prescription Pre-Natal Vitamin or Fluoride) 09 = OTC Monograph Tentative 10 = OTC Monograph Final 11 = Unapproved Drug – Drug Shortage 12 = Unapproved Drug – Per 1927(k)(2)(A)(ii) 13 = Unapproved Drug – Per 1927(k)(2)(A)(iii) *NDCs with a COD Status of DESI 5/6 are not eligible for coverage or rebates under the Medicaid Drug Rebate Program.	Covered Outpatient Drug (COD) Status: A category that identifies how a product meets the statutory definition of a covered outpatient drug in accordance with sections 1927(k)(2) to 1927(k)(4) of the Social Security Act. Numeric values; 2-digit field. Valid Values: 01 = Abbreviated New Drug Application (ANDA) 02 = Biological License Application (BLA) 03 = New Drug Application (NDA) 04 = NDA Authorized Generic 05 = DESI 5* – LTE/IRS drug for all indications 06 = DESI 6* – LTE/IRS drug withdrawn from market 07 = Prescription Pre-Natal Vitamin or Fluoride 08 = Prescription Dietary Supplement/Vitamin/Mineral (Other than Prescription Pre-Natal Vitamin or Fluoride) 09 = OTC Monograph Tentative 10 = OTC Monograph Final 11 = Unapproved Drug – Drug Shortage 12 = Unapproved Drug – Per 1927(k)(2)(A)(ii) 13 = Unapproved Drug – Per 1927(k)(2)(A)(iii) *NDCs with a COD Status of DESI 5/6 are not eligible for coverage or rebates under the Medicaid Drug Rebate Program.	Rev	To align verbiage with other Medicaid Drug Rebate Program documentation.

2016 (old version)	2019 (new version)	Type of Change	Reason for Change
FDA Application Number/OTC Monograph Number: For drugs with a COD status of ANDA, BLA, NDA, or NDA Authorized Generic, this is the seven-digit application number (that is assigned by the FDA for approval to market a generic drug or new drug in the United States). Numeric field; 7 characters, fill with leading zeros as needed. For drugs with a COD status of OTC Monograph Tentative or Final, this is the FDA's regulatory citation for the OTC. 7 alpha-numeric characters. For drugs with a COD Status of OTC Monograph Final, the first four characters are a constant of "PART"; the last three characters are the numeric values for the appropriate regulatory citation for the product (e.g., "225"). For drugs with a COD Status of OTC Monograph Tentative, the first four characters are a constant of "PART"; the last three characters are the numeric values for the appropriate regulatory citation for the product, or 3 zeros if a Monograph Number is not available. For drugs with a COD Status other than ANDA, BLA, NDA, NDA Authorized Generic, OTC Monograph Final, or OTC Monograph Tentative, the FDA Application No./OTC Monograph No. field should be zero-filled.	FDA Application Number/OTC Monograph Number: For drugs with a COD status of ANDA, BLA, NDA, or NDA Authorized Generic, this is the application number (assigned by the FDA for approval to market a drug or biological in the United States) under which the NDC is currently marketed. Numeric values; 7-digit field; padded with leading zeros as needed. For drugs with a COD status of OTC Monograph Tentative or Final, this is the FDA's regulatory citation for the OTC. Alpha-numeric values; 7-digit field. For drugs with a COD Status of OTC Monograph Final, the first four characters are a constant of "PART"; the last three characters are the numeric values for the appropriate regulatory citation for the product (e.g., "225"). For drugs with a COD Status of OTC Monograph Tentative, the first four characters are a constant of "PART"; the last three characters are the numeric values for the appropriate regulatory citation for the product, or three zeros if a Monograph Number is not available. For drugs with a COD Status other than ANDA, BLA, NDA, NDA Authorized Generic, OTC Monograph Final, or OTC Monograph Tentative, the FDA Application No./OTC Monograph No. field should be zero-filled.	Rev	To align verbiage with other Medicaid Drug Rebate Program documentation.

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2016 (old version)	2019 (new version)	Type of Change	Reason for Change
Line Extension Drug Indicator: Identifies whether a product is a line extension drug as defined in Section 1927 (c)(2)(C) of the Social Security Act. Valid Values: Y = Yes N = No	Line Extension Drug Indicator: Identifies whether a product is a line extension drug as defined in Section 1927 (c)(2)(C) of the Social Security Act, including whether the drug is excluded from the statutory definition of a line extension on the basis of being an abuse-deterrent formulation (ADF). 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. 1-character field. Valid Values: Y = Yes N = No (i.e., neither LE nor ADF) R = Request for ADF Exclusion E = Excluded (Due to ADF)* *NOTE: This value may only be assigned by CMS and cannot be reported by a labeler.	Rev	To align verbiage with other Medicaid Drug Rebate Program documentation.
Reactivation Date: The date on which a terminated product is re-introduced to the market. (Note: This field may only be submitted online via DDR and is NOT part of the actual File Transfer Layout.)	Reactivation Date: The date on which a terminated product is re-introduced to the market. (Note: This field may only be submitted online via DDR and is NOT part of the actual File Format.)	Rev	To align verbiage with other Medicaid Drug Rebate Program documentation.

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Type of Change: Rev = Revision, Del = Deletion, Add = Addition, and Red = Redesgnation.