Instructions to Labelers for CMS-367a, CMS-367b and CMS-367c

The following data fields are required for the relevant collections:

DATA FIELDS – CMS-367a

Labeler Code: First segment of the National Drug Code (NDC) that identifies the labeler. Numeric values; 5-digit field; right-justified; zero-padded.

Product Code: Second segment of the NDC. Alpha-numeric values; 4-digit field; right-justified; zero-padded.

Package Size: Third segment of the NDC. Alpha-numeric values; 2-digit field; right-justified; zero-padded.

Period Covered: Calendar quarter and year covered by the pricing data submission. Numeric 5-digit field; format: QYYYY.

Valid values for Q:

1 = January 1 - March 31
2 = April 1 - June 30
3 = July 1 - September 30
4 = October 1 - December 31

Valid values for YYYY: 4-digit calendar year equal to 1991 or later.

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.

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.

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.

Instructions to Labelers for CMS-367a, CMS-367b and CMS-367c

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.

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.

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.

Valid Values:

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)

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.

Instructions to Labelers for CMS-367a, CMS-367b and CMS-367c

DATA FIELDS – CMS-367b

Labeler Code: First segment of the National Drug Code (NDC) that identifies the labeler. Numeric values; 5-digit field; right-justified; zero-padded.

Product Code: Second segment of the NDC. Alpha-numeric values; 4-digit field; right-justified; zero-padded.

Package Size: Third segment of the NDC. Alpha-numeric values; 2-digit field; right-justified; zero-padded.

Month: Calendar month covered by the pricing data submission. Numeric values; 2-digit field; format: MM.

Valid values for MM:

01 = January
02 = February
03 = March
04 = April
05 = May
06 = June
07 = July
08 = August
09 = September
10 = October
11 = November
12 = December

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.

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 point ('.') and 6 decimal places; right-justified; zero-padded for AMP values with fewer than 12 digits.

Form CMS-367b 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.

Instructions to Labelers for CMS-367a, CMS-367b and CMS-367c

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 2 decimal places; right-justified; zero-padded.

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.

Valid Values:

Y = Yes
N = No
X = Not a 5i drug
Z = Not Applicable

Form CMS-367b 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.

Instructions to Labelers for CMS-367a, CMS-367b and CMS-367c

DATA FIELDS – CMS-367c

Labeler Code: First segment of the National Drug Code (NDC) that identifies the labeler. Numeric values; 5-digit field; right-justified; zero-padded.

Product Code: Second segment of the NDC. Alpha-numeric values; 4-digit field; right-justified; zero-padded.

Package Size: Third segment of the NDC. Alpha-numeric values; 2-digit field; right-justified; zero-padded.

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

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

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.

Form CMS-367c 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.

Instructions to Labelers for CMS-367a, CMS-367b and CMS-367c

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

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.

Termination Date: The date a drug is withdrawn from the market or the drug's last lot expiration date. Zero or blank-filled for drug without Termination Dates. Numeric values; 8-digit field; format: MMDDYYYY.

Form CMS-367c 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.

Instructions to Labelers for CMS-367a, CMS-367b and CMS-367c

Drug Type: Identifies a drug as prescription (Rx) or over-the-counter (OTC). Numeric values; 1-digit field.

Valid Values:
1 = Rx
2 = OTC

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.

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.

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.

Package Size Intro Date (PSID): The date the package size is first available on the market. 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.

5i Drug Indicator: Identifies whether a product is a 5i Drug. 1-character field.

Valid Values:

Y = Yes
N = No

Form CMS-367c 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.

Instructions to Labelers for CMS-367a, CMS-367b and CMS-367c

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

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.

Form CMS-367c 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.

Instructions to Labelers for CMS-367a, CMS-367b and CMS-367c

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.

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.

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.)

Form CMS-367c 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.

Instructions to Labelers for CMS-367a, CMS-367b and CMS-367c

Labelers will have two data reporting options within DDR: first, they may key their data online on an NDC-by-NDC basis; second, they may transfer a saved file to DDR. Labelers that key their data online will have an interactive "pop-up" help function when the DDR has detected a potential data error. Labelers that opt to transfer their data via a file to DDR can check the system periodically for a report that outlines any errors detected, as well as alerts for potential errors or data issues. These File Transfer Edit Reports include the following error/ alert messages, along with instructions to the labeler to correct each data issue:

	New Message	Type	Reason For Occurrence
E1	Product record contains a missing or invalid labeler code	Error	Labeler code (NDC1) on the product record is blank or does not exist in the database.
E2	Pricing record contains a missing or invalid labeler code	Error	Labeler code (NDC1) on the price record is blank or does not exist in the database.
E3	Missing or incorrect product code	Error	Product code (NDC2) is blank or incorrect format or value.
E4	Missing or incorrect package size	Error	Package size code (NDC3) is blank or incorrect format or value.
E5	Deleted product - rejected by CMS	Error	Product or package size has been deleted by CMS.
E6	Drug Category is blank or is not S, I or N	Error	Drug Category field may not be blank and must be S, I or N.
E7	Missing or invalid TEC	Error	TEC is blank or is invalid code.
E8	Missing Drug Type or drug type is not 1 or 2	Error	Drug Type cannot be blank and must be 1 or 2.
E9	OBRA '90 Base AMP required	Error	Base AMP cannot be blank or contains zero when the drug category is S or I and the market date is earlier than 10/01/1993.
E10	Base AMP change is rejected	Error	Pricing changes after 12 quarters are not allowed.
E11	Base AMP is less than 6 decimal places and/or is not numeric	Error	Base AMP must be both numeric and 6 decimal places.
E12	Reserved	Error	Reserved
E13	Term Date is invalid and/or earlier than the Market Date	Error	Termination Date must be a valid date and later than the Market Date, and should be zero or blank-filled if not present.
E14	Missing or invalid Unit Type	Error	Unit Type is blank or not a valid value.
E15	UPPS is less than 3 decimal places and/or is not numeric and/or is missing or invalid	Error	Units Per Package Size must be both numeric and 3 decimal places and cannot be blank.
E16	Future FDA Approval Date not allowed	Error	FDA Approval Date must be equal to current quarter or earlier.
E17	Missing or invalid Market Date	Error	Market Date cannot be blank and must be a valid date.
E18	Market Date not allowed	Error	Market Date cannot be greater than current quarter plus one.
E19	Invalid FDA Approval Date	Error	FDA Approval Date must be a valid date.

	New Message	Type	Reason For Occurrence
E20	Market Date is less than FDA Approval Date	Error	Market Date must be equal to or greater than the FDA Approval Date.
E21	Missing FDA Drug Name	Error	FDA Drug Name cannot be blank.
E22	Missing or invalid DESI	Error	DESI cannot be blank and must equal 2, 3, 4, 5 or 6.
E23	Product code does not exist	Error	Product code (NDC2) not found - pricing rejected.
E24	Missing year and/or quarter	Error	Quarter and/or year is blank (QYYYY).
E25	Quarter must be 1, 2, 3, or 4	Error	Quarter is not equal to 1, 2, 3 or 4.
E26	Invalid year	Error	Year reported is not numeric or is greater than current year.
E27	Year earlier than start of rebate program	Error	Year on the price record cannot be earlier than 1991.
E28	Future quarterly pricing not allowed	Error	Pricing quarter cannot be greater than current quarter.
E29	Best Price must contain 6 decimal places	Error	Best Price is less than 6 decimal places.
E30	Best Price must be present, numeric and greater than zero for category S or I drugs	Error	Best Price is blank, non-numeric, or zero.
E31	AMP must contain 6 decimal places	Error	AMP is less than 6 decimal places.
E32	AMP must be present, numeric, and greater than zero	Error	AMP is blank, non-numeric, or zero.
E33	Package size code does not exist	Error	Package size code (NDC3) not found - pricing rejected.
E34	Pricing change rejected	Error	Pricing changes not allowed after 12 quarters.
E35	AMP change not approved by CMS	Error	Only Best Price change approved by CMS.
E36	Best Price change not approved by CMS	Error	Only AMP change approved by CMS.
E37	Monthly pricing data rejected	Error	Monthly pricing changes not allowed after report period ends.
E38	UPPS cannot contain decimals when Unit Type is EA	Error	UPPS cannot contain decimals when Unit Type is EA.
E39	Pricing data submitted for a period more than 4 quarters after Termination Date	Error	Labeler submitted pricing data greater than 4 quarters after Termination Date. Review for accuracy.
E40	Missing month and/or year	Error	Month and/or year is blank (MMYYYY).
E41	Month must be a two-digit numeric value	Error	Month must be equal to 01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 11, or 12.
E42	Year earlier than start of monthly data collection	Error	Year on the price record cannot be earlier than 2007.
E43	Future monthly pricing not allowed	Error	Pricing month cannot be greater than current month.
E44	Package size is terminated	Error	Pricing record cannot be used to change AMP and/or Best Price because package size was terminated for the quarter specified. Only active

	New Message	Type	Reason For Occurrence
			package sizes can be used to change pricing.
E45	Monthly pricing data submitted for monthly periods beyond Termination Date	Error	Labeler submitted monthly pricing data greater than Termination Date. Review for accuracy.
E46	Reserved	Error	Reserved
E47	Reserved	Error	Reserved
E48	Reserved	Error	Reserved
E49	Pricing change submitted after expiration date	Error	Labeler submitted change after specified date.
E50	Product code access denied	Error	User does not have access to this product code.
E51	Labeler code access denied	Error	User does not have access to this labeler code.
E52	Customary Prompt Pay Discount is missing, not numeric, and/or is not equal to a value of zero or greater	Error	Customary Prompt Pay Discount must be present, numeric and equal to a value of zero or greater.
E53	Nominal Price is missing, not numeric and/or is not equal to a value of zero or greater	Error	Nominal Price must be present, numeric and equal to a value of zero or greater.
E54	Reserved	Error	Reserved
E55	Reserved	Error	Reserved
E56	DRA Base AMP submitted outside allowable timeframe	Error	The submission of DRA Base AMP is subject to requirements of CMS-2238-FC.
E57	Multiple package size error – labeler submitted different DRA Base AMPs across multiple package sizes of the same product	Error	DRA Base AMP was not weighted as required. Review/Correct.
E58	Market Date change requires additional pricing	Error	Market Date change to earlier date results in additional pricing due from labeler. If Market Date change is correct, labeler must process the change online in DDR.
E59	Market Date change invalidates labeler pricing	Error	Market Date change to later date causes submitted pricing for earlier quarters to become invalid. If Market Date change is correct, labeler must process the change online in DDR.
E60	Purchased Product Date field not properly reported	Error	Purchased Product Date must be supplied. If Market Date is within current reporting period, or if the product is being reported late and

	New Message	Type	Reason For Occurrence
			there is no Purchased Product Date, then the Purchased Product Date should be blank or zero-filled.
E61	Purchased Product Date entry must be performed manually online via DDR	Error	Purchased Product Date entered is later than the Market Date or previously entered Purchased Product Date; therefore, prior period pricing may exist. This action will cause the removal/deletion of previously calculated URA values for the submitted pricing. Change/entry of Purchased Product Date must be performed manually in DDR.
E62	Changing a Purchased Product Date to an earlier date results in additional pricing due from labeler	Error	Purchased Product Date entered is earlier than the previous Purchased Product Date; therefore, additional pricing is due from the labeler. If the new Purchased Product Date is correct, labeler must process the change online in DDR.
E63	Purchased Product Date is less than the Market Date	Error	Purchased Product Date must be equal to or greater than the Market Date.
E64	Purchased Product Date not allowed	Error	Purchased Product Date cannot be greater than current quarter plus one.
E65	Package Size Intro Date not allowed	Error	Package Size Intro Date cannot be greater than current quarter plus one.
E66	Package Size Intro Date is less than Market Date or Purchased Product Date (if PPD present)	Error	Package Size Intro Date must be equal to or greater than the Market Date or the Purchased Product Date (if PPD present).
E67	Missing or Invalid Package Size Intro Date	Error	Package Size Intro Date cannot be blank and must be a valid date.
E68	Invalid Package Size Intro Date	Error	At least one Package Size Introduction Date must be equal to Market Date or Purchased Product Date.
E69	Changing a Package Size Introduction Date to an earlier date results in additional pricing due from labeler	Error	Package Size Introduction Date entered is earlier than the previous Package Size Introduction Date; therefore, additional pricing is due from the labeler. If the new Package Size Introduction Date is correct, labeler must process the change online in DDR.
E70	Package Size Introduction Date entry must be performed manually online via DDR	Error	Package Size Introduction Date entered is later than the previously entered Package Size Introduction Date; therefore, prior period pricing may exist. This action will cause the removal/deletion of previously submitted AMP values. Change/entry of Package Size Introduction Date must be performed manually in DDR.
E71	Termination Date change invalidates existing labeler data	Error	Termination Date change to an earlier date causes submitted pricing for earlier months and/or quarters to become invalid. If Termination Date is

	New Message	Type	Reason For Occurrence
			correct, labeler must process the change online in DDR.
E72	Multiple package size error – labeler submitted different Market Dates across multiple package sizes of the same product	Error	Market Date was not the same across all package sizes for the same product. Review/Correct.
E73	Multiple package size error – labeler submitted different FDA Approval Dates across multiple package sizes of the same product	Error	FDA Approval Date was not the same across all package sizes for the same product. Review/Correct.
E74	Multiple package size error – labeler submitted different Purchased Product Dates across multiple package sizes of the same product	Error	Purchased Product Date was not the same across all package sizes for the same product. Review/Correct.
E75	Pricing quarter prior to Market Date and/or Purchased Product Date	Error	Pricing quarter must be after the Market Date or Purchased Product Date if one is present unless pricing quarter is being submitted to establish the product's OBRA '93 Baseline AMP.
E76	AMP Units must contain 2 decimal places	Error	AMP Units value is less than 2 decimal places.
E77	AMP Units must be present, numeric and greater than or equal to zero	Error	AMP Units value is blank, non-numeric or less than zero.
E78	Monthly pricing change rejected	Error	Monthly pricing changes not allowed after 36 months.
E79	Multiple package sizes – AMP Units problem	Error	AMP Units must be the same value across all package sizes.
A1	Pricing submission equals current price	Alert	Submitted pricing data equaled the pricing data already in the database.
A2	Drug Category change not allowed	Alert	Drug Category has a different value than the current value. Cannot change from S/I to N or vice versa without CMS approval.
A3	Warning: Unit Type changed	Alert	Unit Type change often requires changes to UPPS and price. Review and adjust as needed
A4	Base AMP must be zero-filled if Market Date is greater than 9/30/1993 or for N drugs	Alert	Database uses AMP submitted for Base AMP quarter. Base AMP not required for N drugs.
A5	Market Date changes are not allowed	Alert	Market Date cannot be changed after 12 quarters without prior CMS approval.

	New Message	Type	Reason For Occurrence
A6	DESI change not allowed	Alert	DESI cannot be changed from a value of 2, 3, or 4 to a value of 5 or 6 or vice-versa.
A7	FDA Approval Date may not be after Market Date	Alert	Previous FDA Approval Date remains in database.
A8	Multiple package size OBRA ’90 Base AMP problem	Alert	OBRA ‘90 Base AMP was not weighted as required. CMS used highest submitted Base AMP which will result in highest possible AMP. Review/correct.
A9	Reserved	Alert	Reserved
A10	Multiple package size AMP problem	Alert	AMP was not weighted as required. CMS used highest submitted AMP which will result in highest possible AMP. Review/correct.
A11	Multiple package size FDA Approval Date problem	Alert	Initial FDA Approval Date does not change when new package size is added.
A12	Multiple package size Market Date problem	Alert	Initial Market Date does not change when new package size is added.
A13	Drug Category change made	Alert	Drug Category changed from S to I or vice-versa.
A14	Terminated package size - latest active Best Price used	Alert	When all package sizes are terminated, the best price from the last active quarter is used.
A15	Best Price greater than AMP	Alert	Best Price cannot be greater than AMP. CMS changed Best Price to equal AMP. Review/correct
A16	Multiple package size – Best Price problem	Alert	Best Price must be lowest price regardless of package size and the same value across all package sizes. CMS used lowest submitted Best Price which will result in highest possible URA. Review/correct.
A17	DRA Base AMP must be zero-filled if Market Date > 6/30/2007 or when drug category is “N”	Alert	DRA Base AMP is not required for NDCs with Market Dates > 6/30/2007 or for N drugs.
A18	Reserved	Alert	Reserved
A19	DRA Base AMP must be a valid numeric value with no blanks or special characters	Alert	DRA Base AMP, if supplied, must be numeric; 5 whole positive number and 6 decimals or must be zero-filled.
A20	Terminated package size – latest active AMP used	Alert	When all package sizes are terminated, the AMP from the last active quarter is used.
A21	Best Price not required for N drugs	Alert	Best Price not required for N drugs.
A22	Reserved	Alert	Reserved
A23	Reserved	Alert	Reserved

	New Message	Type	Reason For Occurrence
A24	Nominal Price invalid	Alert	For all active package sizes, Nominal Price must be a positive dollar value or zero.
A25	Multiple Package Size – AMP not submitted for all package sizes	Alert	AMP value for all package sizes not submitted. AMP for submitted package size will be stored for all active packages. Review/Correct.
A26	Product Record requires the submission of a quarterly pricing record (QYYYY) to establish the Baseline AMP	Alert	A new S or I product record with a Market Date earlier than the current quarter requires the submission of the quarterly AMP value needed to establish the product's OBRA '93 Baseline AMP.
A27	Nominal Price submitted for N drug – price will not appear in DDR	Alert	Nominal Price is not required for an N drug; therefore, the submitted price will not appear in DDR.
A28	Customary Prompt Pay Discount and/or Nominal Price submitted for terminated package size	Alert	When the last active package size of a product is terminated and it is within four quarters after the Termination Date, the Customary Prompt Pay Discount and/or Nominal Price field should be zero-filled for those four quarters.
A29	Valid Purchased Product Date value in database	Alert	Purchased Product Date exists in the database. Removal of PPD can be performed through the online system.
A30	Submitted Package Size Introduction Date is earlier than current reporting period	Alert	The Package Size Introduction Date submitted is earlier than the current reporting period; therefore, prior period monthly AMP values were automatically populated and prior quarterly NP and CPP values were zero-filled. These populated values all require certification – please review, correct where appropriate, and certify.
A31	Product Termination Date removed/changed to a later date	Alert	Removing or changing a product Termination Date to a later date results in additional pricing due from labeler. Review, enter missing pricing and certify any entered pricing.
A32	Reserved	Alert	Reserved
A33	Monthly AMP Units increased/decreased by 40% from last month.	Alert	Monthly AMP Units increased/decreased by 40% from last month, please review/correct.
A34	Reserved	Alert	Reserved
A35	AMP Units not required prior to October 2010	Alert	AMP Units are not required for periods prior to October 2010. Unit information not kept.
A36	AMP reported as 0.000001	Alert	AMP reported as 0.000001. Verify this is the actual AMP value for the NDC. If the AMP equals 0.000001 because the calculated AMP is negative or zero, report the most recent prior AMP.