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

The following data fields are required for the relevant collections:

 QUARTERLY PRICING DATA FIELDS – CMS-367a

**Labeler Code**: First segment of National Drug Code that identifies the labeler. Numeric values only, 5-digit field, right-justified and zero-filled.

 **Product Code**: Second segment of National Drug Code. Alpha-numeric values, 4-digit field, right justified, zero-filled.

 **Package Size Code**: Third segment of National Drug Code. Alpha-numeric values, 2-digit field, right justified, zero-filled.

**Period Covered**: Calendar quarter and year covered by data submission. Numeric 5-digit field, 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.

**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.

**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.

**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.

**Customary Prompt Pay Discount (CPP)**: 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.

**Initial Drug Available for LE:** Identifies whether a line extension drug has an Initial Drug available for the quarter/year being reported.

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 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.

MONTHLY PRICING DATA FIELDS – CMS-367b

**Labeler Code**: First segment of National Drug Code that identifies the labeler. Numeric values only, 5-digit field, right-justified and zero-filled.

 **Product Code**: Second segment of National Drug Code. Alpha-numeric values, 4-digit field, right justified, zero-filled.

 **Package Size Code**: Third segment of National Drug Code. Alpha-numeric values, 2-digit field, right justified, zero-filled.

**Month**: Calendar month covered by data submission. Numeric 2-digit field, MM.

 Valid values for MM:

01 = January 07 = July

02 = February 08 = August

03 = March 09 = September

04 = April 10 = October

05 = May 11 = November

06 = June 12 = December

 **Year**: Calendar year covered by data submission. Numeric 4-digit field, YYYY. Valid values for YYYY: 4-digit calendar year.

**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) 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.

**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.

Valid Values:

Y = Yes

N = No

X = Not a 5i drugZ = Not Applicable

DRUG PRODUCT DATA FIELDS – CMS-367c

**Labeler Code**: First segment of National Drug Code that identifies the labeler. Numeric values only, 5-digit field, right-justified and zero-filled.

 **Product Code**: Second segment of National Drug Code. Alpha-numeric values, 4-digit field, right justified, zero-filled.

 **Package Size Code**: Third segment of National Drug Code. Alpha-numeric values, 2-digit field, right justified, zero-filled.

**Drug Category**: Alpha-numeric values, 1 character.

Valid values:

S = Single source

I = Innovator multiple source

 N = Non-innovator multiple source

**Unit Type**: One of the 8 unit types by which the drug is dispensed. Alpha-numeric values, 3-character field, left justified.

Valid values:

AHF = Injectable Anti-Hemophilic Factor

CAP = Capsule

SUP = Suppository

GM = Gram

ML = Milliliter

TAB = Tablet

TDP = Transdermal Patch

 EA = EACH

**FDA Approval Date**: NDA or monograph approval date. Numeric values, 8-digit field, format: MMDDYYYY.

**FDA TEC**: FDA-assigned Therapeutic Equivalence Codes. Alpha-numeric values, 2 character field.

Valid values:

AA BC BS

AB BD BT

AN BE BX

AO BN NR - Not rated

AP BP A1 thru A9 = AB value

AT BR

**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.

**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.

**Drug Type Indicator**: Identifies a drug as prescription (Rx) or over-the-counter (OTC).

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 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.

**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.

**FDA Product Name**: Drug name as it appears on FDA listing form. Alpha-numeric values, 63 characters, left justified, blank-fill unused positions.

**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 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.

**Package Size Introduction Date:** The date the package size is first available on the market. Numeric values, 8-digit field, format: MMDDYYYY

**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

**5i Drug Indicator:** Identifies whether a product is a 5i Drug. Alpha-numeric values; 1-digit field.

Valid Values:

Y = Yes

N = No

**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 |

**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.

**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.

### 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.

**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.)

**Line Extension Drug Indicator:** Identifies whether a product is a line extension drug as defined in Section 1927 (c)(2)(C)

Valid Values:

Y = Yes

N = No

**Edits & Alerts**

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 (certain fields must be keyed online). 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 Package Size Intro. Date | Error | Termination Date must be a valid date, must be greater than or equal to the Package Size Intro. 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. |
| 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 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 | Reserved | Error | Reserved |
| E53 | Reserved | Error | Reserved |
| 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 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 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. |
| E80 | The Submitted Best Price is Greater Than AMP | Error | Best Price cannot be greater than AMP. Please review and correct the submitted pricing. |
| E81 | Product Record is Missing Required 5i Drug Information | Error | The product record you submitted cannot be updated without including a valid value in the required 5i Drug Indicator and 5i Route of Administration fields. |
| E82 | Product requires 5i Drug Indicator and 5i Route of Administration field data | Error | Monthly pricing data cannot be submitted until the 5i Drug Indicator and 5i Route of Administration fields have been updated in the NDCs product file and then certified. |
| E83 | Product requires 5i Drug Indicator and 5i Route of Administration field data | Error | Quarterly pricing data cannot be submitted until the 5i Drug Indicator and 5i Route of Administration fields have been updated in the NDCs product file and then certified. |
| E84 | Change to 5i Drug Indicator field not allowed via file transfer | Error | Changes to 5i Drug Indicator are not permitted via file transfer. They must be performed online.  |
| E85 | Change to 5i Drug Indicator field not allowed | Error | Changes to 5i Drug Indicator are not permitted beyond four quarters after the effective date of the final rule. If you believe that the 5i Drug Indicator originally entered for this product is incorrect, please contact rxdrugpolicy@cms.hhs.gov. |
| E86 | Value missing or invalid value submitted | Error | 5i Drug Indicator value must be submitted in accordance with the record layout and data definitions as specified in the DDR User’s Guide and the DDR file transfer tab in DDR. |
| E88 | Value missing or invalid value submitted | Error | 5i Route of Administration field must be submitted in accordance with the record layout and data definitions as specified in the Labeler Data Guide and the DDR file transfer tab in DDR. |
| E89 | Value missing or invalid value submitted | Error | The 5i Monthly Threshold value must be submitted in accordance with the record layout and data definitions as specified in the DDR User’s Guide and the DDR File Transfer tab in DDR. |
| E90 | Incorrect value submitted for 5i Monthly Threshold field | Error | NDC was reported with a value of “N” in the 5i Drug Indicator field during this month/year; therefore, “X-Not a 5i Drug” is the only valid value in the 5i Monthly Threshold field for this time period. |
| E91 | Incorrect value submitted for 5i Monthly Threshold field | Error | NDC was reported with a value of “Y” in the 5i Drug Indicator field during this month/year; therefore, “Y-Yes” or “N-No” are the only valid values for the 5i Monthly Threshold field for this time period. |
| E92 | Incorrect value submitted for 5i Monthly Threshold field | Error | This reporting period was prior to the implementation of the 5i Monthly Threshold field; therefore, “Z—Not Applicable” is the only valid value. |
| E94 | ACA Base AMP is invalid | Error | ACA Base AMP must be a valid value (5 whole positive numbers and 6 decimal numbers) or zero-filled when the drug category is S or I and the market date is less than 1/1/2014. |
| E95 | Multiple package size error – Labeler submitted different ACA Base AMPs across multiple package sizes of the same product | Error | ACA Base AMP was not weighted as required. Review/Correct. |
| E96 | ACA Base AMP submitted outside allowable timeframe | Error | The submission of ACA Base AMP is subject to requirements of CMS-2345-F. |
| E97 | ACA Base AMP change rejected | Error | The timeframe for reporting changes to the ACA Base AMP field has closed. |
| E98 | COD Status/Drug Category combination is invalid | Error | Only certain Drug Categories are allowed in conjunction with COD Status selections. Please review, correct and re-submit. For a list of allowable values for each COD Status, please refer to the COD Status lookup table, which can be accessed online via DDR under Documents-->Lookup Tables-->COD Status. |
| E99 | COD Status/Drug Type combination is invalid | Error | Only certain Drug Types are allowed in conjunction with COD Status selections. Please review, correct and re-submit. For a list of allowable values for each COD Status, please refer to the COD Status lookup table, which can be accessed online via DDR under Documents-->Lookup Tables-->COD Status. |
| E100 | Change to COD Status field not allowed. | Error | Changes to COD Status are not permitted. If you believe that the COD Status originally entered for this product is incorrect, please contact rxdrugpolicy@cms.hhs.gov. |
| E101 | Invalid value submitted. | Error | The COD Status field must contain one of the values in the COD Status lookup table, which can be accessed online via the DDR Documents tab. |
| E103 | AMP and Best Price must be greater than zero. | Error | This pricing record requires the submission of the quarterly AMP and Best Price values for [insert Base AMP quarter/year in q/yyyy format] in order to establish the NDC’s OBRA ’93 Base AMP value. Please provide the required quarterly AMP and Best Price values in order to submit this record. |
| E104 | Drug Category Change Requires Submission of an OBRA ’90 Base AMP. | Error | The submitted product record contained a Drug Category change from “Non-innovator” to “Innovator Multiple Source” or “Single Source.” Therefore, the submission of a value greater than zero is required in the OBRA ’90 Base AMP field. |
| E107 | BP must be a value greater than zero. | Error | The Drug Category of this NDC has been updated from “N” to “S/I”. Therefore, the BP for [insert OBRA ’93 Base AMP quarter/year in format of q/yyyy] is required. |
| E108 | AMP must be a value greater than zero. | Error | The Drug Category of this NDC has been updated from “N” to “S/I”. Therefore, the quarterly AMP for [insert OBRA ’93 Base AMP quarter/year in format of q/yyyy] is required and must be greater than zero in order to establish this product’s OBRA ’93 Base AMP. |
| E109 | The submitted BP and the AMP values must be greater than zero. | Error | The Drug Category of this NDC has been updated from “N to “S/I”. Therefore, the quarterly AMP and BP for [insert OBRA ’93 Base AMP quarter/year in format of q/yyyy] are required and must be greater than zero in order to establish this product’s OBRA ’93 Base AMP. |
| E112 | Removal of or change to existing termination date rejected. | Error | Termination Date cannot be removed or changed via file transfer. It can only be removed or changed online in DDR |
| E113 | Product Data Fields Must Be Submitted Before Monthly Pricing Can Be Reported  | Error | Monthly pricing data cannot be reported until the product data fields have been updated in the NDC’s product file and then certified. Refer to the Labeler Status screen for more information on these data fields. |
| E114 | Product Data Fields Must Be Submitted Before Quarterly Pricing Can Be Reported | Error | Quarterly pricing data cannot be reported until the product data fields have been updated in the NDC’s product file and then certified. Refer to the Labeler Status screen for more information on these data fields. |
| E115 | Change to COD Status Not Allowed | Error | Changes to a previously reported COD Status are not allowed without CMS permission. Please contact CMS at rxdrugpolicy@cms.hhs.gov to request a change. |
| E116 | Missing or Invalid FDA Application No./OTC Monograph No.  | Error | This record was submitted with a COD Status of ANDA, NDA, BLA, or Authorized Generic. Therefore, the FDA Application No./OTC Monograph No. field must contain the 6-digit number assigned by the FDA for approval to market the product in the U.S., preceded by a leading zero. |
| E117 | COD Status of “OTC Monograph Final” Requires an FDA Application No./OTC Monograph No. | Error | This record was submitted with a COD Status of OTC Monograph Final. Therefore, the FDA Application No./OTC Monograph No. field must contain the word “PART” followed by a 3-digit numeric value that identifies the FDA’s regulatory citation for the OTC. |
| E118 | COD Status of “OTC Monograph Tentative” Requires an FDA Application No./OTC Monograph No.  | Error | This record was submitted with a COD Status of OTC Monograph Tentative. Therefore, the FDA Application No./OTC Monograph No. field must contain the word “PART” followed by a 3-digit numeric value that identifies the FDA’s regulatory citation for the OTC. If a 3-digit numeric value is not available, enter “000” following “PART”. |
| E119 | The submitted COD Status requires the FDA Application No./OTC Monograph No. to be zero-filled. | Error | This record was submitted with a COD Status of something other than ANDA, NDA, BLA, NDA Authorized Generic, OTC Monograph Final, or OTC Monograph Tentative. Therefore, the FDA Application No./OTC Monograph No. field must be zero-filled. |
| E121 | Incorrect COD Status value of “ANDA” submitted. (*This message will only be received through 10/30/15.)* | Error | The selection of a COD Status category of “ANDA” requires a Drug Category of “N”; however, this NDC currently has a Drug Category of “S” or “I”. Please review, correct, and re-submit. |
| E122 | Incorrect COD Status value of “ANDA” submitted.  | Error | The selection of a COD Status category of “ANDA” requires a Drug Category of “N”; however, this NDC currently has a Drug Category of “S” or “I”. Please contact CMS at rxdrugpolicy@cms.hhs.gov for assistance in making the initial COD Status selection for this NDC, and to request the corresponding Drug Category change (if applicable). |
| E123 | Incorrect COD Status value of “NDA Authorized Generic” submitted. (*This message will only be received through 10/30/15.)* | Error | The selection of a COD Status category of “NDA Authorized Generic” requires a Drug Category of I; however, this NDC currently has a Drug Category of “N”. Please review, correct, and re-submit. Also note that a Drug Category of “S” or “I” requires a Base AMP pricing record. |
| E124 | Incorrect COD Status value of “NDA Authorized Generic” submitted.  | Error | The selection of a COD Status category of NDA Authorized Generic requires a Drug Category of “I”; however, this NDC currently has a Drug Category of “N”. Please contact CMS at rxdrugpolicy@cms.hhs.gov for assistance in making the initial COD Status selection for this NDC, and to request the corresponding Drug Category change (if applicable). |
| E125 | Incorrect COD Status value of “NDA” submitted. (*This message will only be received through 10/30/15.)* | Error | The selection of a COD Status category of "NDA" requires a Drug Category of S or I; however, this NDC currently has a Drug Category of "N". Please review, correct, and re-submit. |
| E126 | Incorrect COD Status value of "NDA" submitted. | Error | The selection of a COD Status category of "NDA" requires a Drug Category of S or I; however, this NDC currently has a Drug Category of "N". Please contact CMS at rxdrugpolicy@cms.hhs.gov for assistance in making the initial COD Status selection for this NDC, and to request the corresponding Drug Category change (if applicable). |
| E127 | Incorrect COD Status value of “BLA” submitted. (*This message will only be received through 10/30/15.)* | Error | The selection of a COD Status category of "BLA" requires a Drug Category of "S"; however, this NDC currently has a Drug Category of "N". Please review, correct, and re-submit. |
| E128 | Incorrect COD Status value of "BLA" submitted. | Error | The selection of a COD Status category of "BLA" requires a Drug Category of "S"; however, this NDC currently has a Drug Category of "N". Please contact CMS at rxdrugpolicy@cms.hhs.gov for assistance in making the initial COD Status selection for this NDC, and to request the corresponding Drug Category change (if applicable). |
| E129 | Incorrect COD Status value of “Prescription Dietary Supplement” submitted.  *(This message shall only be applicable through 10/30/2015.)* | Error | The selection of a COD Status category of “Prescription Dietary Supplement” requires a Drug Type of “Rx”; however, this NDC currently has a Drug Type of “OTC”. Please review, correct, and re-submit. |
| E130 | Incorrect COD Status value of “OTC Monograph Tentative” submitted. *(This message shall only be applicable through 10/30/2015.)* | Error | The selection of a COD Status category of “OTC Monograph Tentative” requires a Drug Type of “OTC”; however, this NDC currently has a Drug Type of “Rx”. Please review, correct, and re-submit. |
| E131 | Incorrect COD Status value of “OTC Monograph Final” submitted. *(This message shall only be applicable through 10/30/2015.)* | Error | The selection of a COD Status category of “OTC Monograph Final” requires a Drug Type of “OTC”; however, this NDC currently has a Drug Type of “Rx”. Please review, correct, and re-submit. |
| E132 | Incorrect COD Status value of “Unapproved Drug – Drug Shortage” submitted. *(This message shall only be applicable through 10/30/2015.)* | Error | The selection of a COD Status category of “Unapproved Drug – Drug Shortage” requires a Drug Type of “Rx”; however, this NDC currently has a Drug Type of “OTC”. Please review, correct, and re-submit. |
| E133 | Incorrect COD Status value of “Prescription Prenatal Vitamin or Fluoride” submitted. *(This message shall only be applicable through 10/30/2015.)* | Error | The selection of a COD Status category of “Prescription Prenatal Vitamin or Fluoride” requires a Drug Type of “Rx”; however, this NDC currently has a Drug Type of “OTC”. Please review, correct, and re-submit. |
| E134 | Incorrect COD Status value of "Unapproved Drug – Per 1927(k)(2)(A)(ii)" submitted. (*This message will only be received through 4/30/15.)* | Error | The selection of a COD Status category of "Unapproved Drug – Per 1927(k)(2)(A)(ii)" requires a Drug Category of "N"; however, this NDC currently has a Drug Category of "S" or "I". Please review, correct, and re-submit. |
| E135 | Incorrect COD Status value of "Unapproved Drug – Per 1927(k)(2)(A)(ii)" submitted. | Error | The selection of a COD Status category of "Unapproved Drug – Per 1927(k)(2)(A)(ii)" requires a Drug Category of "N"; however, this NDC currently has a Drug Category of "S" or "I". Please contact CMS at rxdrugpolicy@cms.hhs.gov for assistance in making the initial COD Status selection for this NDC, and to request the corresponding Drug Category change (if applicable). |
| E136 | Incorrect COD Status value of "Unapproved Drug – Per 1927(k)(2)(A)(iii)" submitted. | Error | The selection of a COD Status category of "Unapproved Drug – Per 1927(k)(2)(A)(iii)" requires a Drug Category of "N"; however, this NDC currently has a Drug Category of "S" or "I". Please review, correct, and re-submit. |
| E137 | Incorrect COD Status value of "Unapproved Drug – Per 1927(k)(2)(A)(iii)" submitted. | Error | The selection of a COD Status category of "Unapproved Drug – Per 1927(k)(2)(A)(iii)" requires a Drug Category of "N"; however, this NDC currently has a Drug Category of "S" or "I". Please contact CMS at rxdrugpolicy@cms.hhs.gov for assistance in making the initial COD Status selection for this NDC, and to request the corresponding Drug Category change (if applicable). |
| 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. |
| 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 |
| 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 | Monthly AMP increased/decreased by 40% from last month. | Alert | Monthly AMP increased/decreased by 40% from last month, please review/correct. |
| 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. |
| A37 | ACA Base AMP is invalid | Alert | For N drugs, the ACA Base AMP must be zero-filled with no blanks or special characters. |
| A38 | ACA Base AMP must be zero-filled if Market Date is on or after 1/1/2014 or when drug category is N | Alert | ACA Base AMP is not required for NDCs with Market Dates on or after 1/1/2014 or for N drugs. |
| A39 | ACA Base AMP must be a valid numeric value with no blanks or special characters | Alert | ACA Base AMP, if supplied, must be numeric; 5 whole positive numbers and 6 decimals or must be zero-filled. |
| A40 | Change to 5i Indicator Results in Monthly 5i Threshold Changes | Alert | Changing the 5i Indicator from a value of “Y” to “N” results in the monthly 5i Threshold value changing to a value of “X” (i.e., not a 5i drug) for all previously reported monthly pricing records back to April 2014. These changes to the monthly 5i Threshold require certification in DDR. |
| A43 | OBRA ’93 Base AMP quarterly pricing record accepted. Submitted Best Price not stored since a Purchased Product Date was provided. | Alert | Because a Purchased Product Date was reported for this NDC, the submission of a BP for this quarter (i.e., the OBRA ’93 Base AMP Quarter) is not needed. Therefore, the submitted Best Price value will be blanked out. |
| A44 | Base AMP quarter AMP and BP are required. | Alert | The Drug Category of this NDC has been updated from “N” to “S/I”. Therefore, a pricing record containing the quarterly AMP and BP for [insert OBRA ’93 Base AMP quarter/year in format of q/yyyy] is required in order to establish this product’s OBRA ’93 Base AMP. |

**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 128.6 hours per response (CMS-367a = 34.8 hours, CMS-367b = 44.8 hours, CMS-367c = 43.5 hours, and CMS-367d = 1.0 hour), 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.