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.

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.)

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.

	New Message	Type	Reason For Occurrence
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.

	New Message	Type	Reason For Occurrence
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.

	New Message	Type	Reason For Occurrence
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.

	New Message	Type	Reason For Occurrence
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.

	New Message	Type	Reason For Occurrence
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.

	New Message	Type	Reason For Occurrence
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.

	New Message	Type	Reason For Occurrence
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.

	New Message	Type	Reason For Occurrence
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.

	New Message	Type	Reason For Occurrence
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.

	New Message	Type	Reason For Occurrence
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).

	New Message	Type	Reason For Occurrence
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.

	New Message	Type	Reason For Occurrence
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.

	New Message	Type	Reason For Occurrence
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.

	New Message	Type	Reason For Occurrence
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.