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

The following data fields are required for the relevant collections:

DATA FIELDS – CMS-367a

Labeler Code: First segment of 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.

<u>DATA FIELDS – CMS-367b</u>

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 <u>per product code</u> 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) Unit: 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.

Filler: Spaces

<u>DATA FIELDS – CMS-367c</u>

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. Zero or blank fill if not present. Numeric values, 8-digit field, format: MMDDYYYY.

DESI Indicator: Drug Efficacy Study Implementation code. Numeric value, 1 digit.

Valid values:

2 = Safe and effective
3 = Drug under review (no NOOH issued)
4 = LTE/IRS drug for SOME indicators
5 = LTE/IRS drug for ALL indicators
6 = LTE/IRS drug withdrawn from market

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

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

	New Message	Type	Reason For Occurrence
E1	Product record contains a missing or invalid labeler code	Error	Labeler code (NDC1) on the product record is blank or does not exist in the database.
E2	Pricing record contains a missing or invalid labeler code	Error	Labeler code (NDC1) on the price record is blank or does not exist in the database.
E3	Missing or incorrect product code	Error	Product code (NDC2) is blank or incorrect format or value.
E4	Missing or incorrect package size	Error	Package size code (NDC3) is blank or incorrect format or value.
E5	Deleted product - rejected by CMS	Error	Product or package size has been deleted by CMS.
E6	Drug Category is blank or is not S, I or N	Error	Drug Category field may not be blank and must be S, I or N.
E7	Missing or invalid TEC	Error	TEC is blank or is invalid code.
E8	Missing Drug Type or drug type is not 1 or 2	Error	Drug Type cannot be blank and must be 1 or 2.
E9	OBRA '90 Base AMP required	Error	Base AMP cannot be blank or contains zero when the drug category is S or I and the market date is earlier than 10/01/1993.
E10	Base AMP change is rejected	Error	Pricing changes after 12 quarters are not allowed.
E11	Base AMP is less than 6 decimal places and/or is not numeric	Error	Base AMP must be both numeric and 6 decimal places.
E12	Reserved	Error	Reserved
E13	Term Date is invalid and/or earlier than the Market Date	Error	Termination Date must be a valid date and later than the Market Date, and should be zero or blank-filled if not present.
E14	Missing or invalid Unit Type	Error	Unit Type is blank or not a valid value.
E15	UPPS is less than 3 decimal places and/or is not numeric and/or is missing or invalid	Error	Units Per Package Size must be both numeric and 3 decimal places and cannot be blank.
E16	Future FDA Approval Date not allowed	Error	FDA Approval Date must be equal to current quarter or earlier.
E17	Missing or invalid Market Date	Error	Market Date cannot be blank and must be a valid date.
E18	Market Date not allowed	Error	Market Date cannot be greater than current quarter plus one.
E19	Invalid FDA Approval Date	Error	FDA Approval Date must be a valid date.
E20	Market Date is less than FDA Approval	Error	Market Date must be equal to or greater than the FDA Approval Date.

	New Message	Type	Reason For Occurrence
	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.

	New Message	Type	Reason For Occurrence
E45	Monthly pricing data submitted for monthly periods beyond Termination Date	Error	Labeler submitted monthly pricing data greater than Termination Date. Review for accuracy.
E46	Reserved	Error	Reserved
E47	Reserved	Error	Reserved
E48	Reserved	Error	Reserved
E49	Pricing change submitted after expiration date	Error	Labeler submitted change after specified date.
E50	Product code access denied	Error	User does not have access to this product code.
E51	Labeler code access denied	Error	User does not have access to this labeler code.
E52	Customary Prompt Pay Discount is missing, not numeric, and/or is not equal to a value of zero or greater	Error	Customary Prompt Pay Discount must be present, numeric and equal to a value of zero or greater.
E53	Nominal Price is missing, not numeric and/or is not equal to a value of zero or greater	Error	Nominal Price must be present, numeric and equal to a value of zero or greater.
E54	Reserved	Error	Reserved
E55	Reserved	Error	Reserved
E56	DRA Base AMP submitted outside allowable timeframe	Error	The submission of DRA Base AMP is subject to requirements of CMS-2238-FC.
E57	Multiple package size error – labeler submitted different DRA Base AMPs across multiple package sizes of the same product	Error	DRA Base AMP was not weighted as required. Review/Correct.
E58	Market Date change requires additional pricing	Error	Market Date change to earlier date results in additional pricing due from labeler. If Market Date change is correct, labeler must process the change online in DDR.
E59	Market Date change invalidates labeler pricing	Error	Market Date change to later date causes submitted pricing for earlier quarters to become invalid. If Market Date change is correct, labeler must process the change online in DDR.
E60	Purchased Product Date field not properly reported	Error	Purchased Product Date must be supplied. If Market Date is within current reporting period, or if the product is being reported late and there is no Purchased Product Date, then the Purchased Product Date should be blank or zero-filled.

	New Message	Type	Reason For Occurrence
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	Error	Market Date was not the same across all package sizes for the same

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

	New Message	Type	Reason For Occurrence
	Market Date		
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.

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