

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 (Quarterly Pricing)

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 Manufacturers 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.

5i Threshold: This field only applies to those drugs classified as “5i drugs” and identifies whether the AMP calculation of such a drug was calculated using the alternate 5i AMP calculation. Labeler enters Y if the drug met the threshold requirement of sales to entities other than a retail community pharmacy and, therefore, calculated AMP using the alternate 5i AMP methodology; or Labeler enters N if the drug did not meet the threshold requirement of sales to entities other than retail community pharmacies and, therefore, calculated AMP using the traditional (non-5i) methodology. The Labeler enters an X if the drug is not a 5i drug.

Valid Values:

Y = Yes

N = No

X = Not a 5i drug

DATA FIELDS – CMS-367b (Monthly Pricing)

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 Manufacturers 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 Manufacturers Price (AMP) Unit: 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: This field only applies to those drugs classified as “5i drugs” and identifies whether the AMP calculation of such a drug was calculated using the alternate 5i AMP calculation. Labeler enters Y if the drug met the threshold requirement of sales to entities other than a retail community pharmacy and, therefore, calculated AMP using the alternate 5i AMP methodology; or Labeler enters N if the drug did not meet the threshold requirement of sales to entities other than retail community pharmacies and, therefore, calculated AMP using the traditional (non-5i) methodology. The Labeler enters an X if the drug is not a 5i drug.

Valid Values:

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

Filler:

DATA FIELDS – CMS-367c (Drug Product)

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 manufacturer (i.e., NDA holder). For N drugs, the date the drug was first marketed under the

manufacturer'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. (Note: This field is grayed-out and is viewable as historical data only. It has been replaced by the Rebate Eligibility Code field.)

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.

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 purchased the product from another company. Zero or blank fill if not applicable. Numeric values, 8-digit field, format: MMDDYYYY

ACA Baseline AMP (Optional): For active innovator drugs, the OBRA '90, OBRA '93 or DRA Baseline AMP revised in accordance with relevant regulations and 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.

5i Drug Indicator: Identifies whether a product is a 5i Drug.

Valid Values:

Y = Yes

N = No

5i Route of Administration: Identifies the method by which the 5i drug is administered to a patient.

Valid Values:

000 = Not Applicable	035 = Intraepidermal	070 = Intravascular
001 = Auricular (Otic)	036 = Intraesophageal	071 = Intravenous
002 = Conjunctival	037 = Intra gastric	072 = Intraventricular
003 = Endocervical	038 = Intra gingival	073 = Intravesical
004 = Endosinusal	039 = Intra hepatic	074 = Intravitreal
005 = Endotracheal	040 = Intra ileal	075 = Iontophoresis
006 = Epidural	041 = Intralesional	076 = Irrigation
007 = Extra-Amniotic	042 = Intra lingual	077 = Laryngeal
008 = Hemodialysis	043 = Intra luminal	078 = Nasal
009 = Infiltration	044 = Intra lymphatic	079 = Nasogastric
010 = Interstitial	045 = Intra mammary	080 = Ophthalmic
011 = Intra-Abdominal	046 = Intra medullary	081 = Parenteral
012 = Intra-Amniotic	047 = Intra meningeal	082 = Percutaneous
013 = Intra-Arterial	048 = Intra muscular	083 = Periarticular
014 = Intra-Articular	049 = Intra nodal	084 = Peridural
015 = Intra biliary	050 = Intra ocular	085 = Perineural
016 = Intra bronchial	051 = Intra omentum	086 = Periodontal
017 = Intra bursal	052 = Intra ovarian	087 = Rectal
018 = Intra cardiac	053 = Intra pericardial	088 = Respiratory (Inhalation)
019 = Intra cartilaginous	054 = Intra peritoneal	089 = Retrobulbar
020 = Intra caudal	055 = Intra pleural	090 = Soft Tissue
021 = Intra cavernous	056 = Intra prostatic	091 = Subarachnoid
022 = Intra cavitory	057 = Intra pulmonary	092 = Subconjunctival
023 = Intra cerebral	058 = Intra ruminal	093 = Subcutaneous
024 = Intra cisternal	059 = Intra sinal	094 = Subgingival
025 = Intra corneal	060 = Intra spinal	095 = Submucosal
026 = Intra coronal, Dental	061 = Intra synovial	096 = Subretinal
027 = Intra coronary	062 = Intra tendinous	097 = Transendocardial
028 = Intra corporus Cavernosum	063 = Intra testicular	098 = Transmucosal
029 = Intra dermal	064 = Intra thecal	099 = Transplacental
030 = Intra discal	065 = Intra thoracic	100 = Transtracheal
031 = Intra ductal	066 = Intra tubular	101 = Transtympanic
032 = Intra duodenal	067 = Intra tumor	102 = Ureteral
033 = Intra dural	068 = Intra tympanic	103 = Urethral
034 = Intra epicardial	069 = Intra uterine	104 = Vaginal

Line Extension Indicator: Identifies whether a product is an initial brand name listed drug or a line extension of the initial brand name listed drug.

Valid Values:

- 1 = Initial Brand Name Listed Drug
- 2 = Line Extension
- 3 = Neither

Initial Brand Name Listed NDC: The 9-digit NDC of the initial brand name listed drug. Numeric values only, 9-digit field, right-justified. Zero-fill if the NDC is not an initial brand name listed drug.

COD Status: Covered outpatient drug (COD) status is the status of the drug provided by the labeler to demonstrate that the drug meets the statutory definition of a covered outpatient drug under section 1927(k)(2) to 1927(k)(4).

Valid Values:

- 01 = ANDA
- 02 = BLA
- 03 = Export Only
- 04 = NDA
- 05 = NDA Authorized Generic
- 06 = OTC drug product manufactured exclusively for private label distributor
- 07 = OTC monograph final
- 08 = OTC monograph not final
- 09 = Premarket notification
- 10 = Unapproved drug other
- 11 = Unapproved homeopathic
- 12 = Unapproved medical gas
- 13 = Unapproved other

FDA Approval Number: If a drug COD Status is an ANDA, BLA, NDA, or NDA Authorized Generic, then this a six-digit number is assigned by FDA to each application for approval to market a generic drug or new drug in the United States. Provide the Numeric 6-digit only value, left-justified and zero-fill remaining 24 positions.

If a drug COD Status is an OTC final monograph, then this is the regulation citation for the OTC. Provide the Alpha-numeric 30 character value, left justified, blank-fill unused positions.

If a drug COD Status is NOT an ANDA, BLA, NDA, NDA Authorized Generic, or OTC final monograph, zero-fill for 30 positions

Filler:

Labelers will have two data reporting options within DDR: first, they may key their data online on an 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 data error. Labelers that opt to transfer their data to DDR via a file can view or download status reports for files that have completed processing. Periodically throughout the day, DDR generates a status report for each file uploaded and processed through the file transfer function. The following File Transfer Edit Report includes the current errors and alerts and the instructions to the labeler to correct each data issue:

	New Message	Type	Reason For Occurrence
1	Missing or non-existent labeler code for product record	Error	NDC1 on the product record is blank or does not exist in the database.
2	Missing or non-existent labeler code for pricing record	Error	NDC1 on the price record is blank or does not exist in the database.
3	Missing or incorrect product code	Error	NDC2 is blank or incorrect format or value.
4	Missing or incorrect package size	Error	NDC3 is blank or incorrect format or value.
5	Deleted product - rejected by CMS	Error	Product or package size has been deleted by CMS.
6	Drug category is blank	Error	Drug category field may not be blank.
7	Drug category is not S, I, or N	Error	Drug category field must be S, I, or N.
8	Missing or invalid TEC	Error	TEC is blank or not a valid code.
9	Missing drug type	Error	Drug type is blank.
10	Drug type is not 1 or 2	Error	Drug type must be 1 or 2.
11	Base AMP required for OBRA '90 drugs	Error	Base AMP is blank or contains zero and drug category is S or I and the market date is earlier than 10/01/1993.
12	Base AMP change is rejected	Error	Pricing changes after 12 quarters are not allowed.
13	Base AMP is less than 6 decimal places and/or is not numeric	Error	Base AMP must be both numeric and 6 decimal places.
14	-Reserved-	Error	-Reserved-
15	Term date is invalid and/or earlier than the market date	Alert	Term Date must be later than the market date ...
16	Missing or invalid unit type	Error	Unit type is blank or not a valid value.
17	Missing or invalid UPPS	Error	UPPS is blank or not numeric.
18	UPPS is less than 3 decimal places and/or is not numeric	Error	UPPS must be both numeric and 3 decimal places.
19	Future FDA approval date not allowed	Error	FDA approval date must be equal to current quarter or earlier.
20	Missing or invalid market date	Error	Market date is invalid or blank.
21	Market date not allowed	Error	Market date cannot be greater than current quarter plus one.
22	Market date change rejected	Error	Market date changes are not allowed after 12 quarters.

	New Message	Type	Reason For Occurrence
23	Market date less than FDA approval date	Error	Market date must be equal to or greater than the FDA approval date.
24	Missing FDA drug name	Error	FDA drug name is blank.
25	Missing or invalid DESI	Error	DESI is blank or not equal to 2, 3, 4, 5 or 6.
26	NDC2 does not exist	Error	Pricing rejected. NDC2 not found.
27	Missing year and/or quarter	Error	Period (QCCYY) is blank.
28	Quarter must be 1, 2, 3, or 4	Error	Quarter is not equal to 1, 2, 3 or 4.
29	Invalid year	Error	Year reported is not numeric or is greater than current year.
30	Year earlier than start of rebate program	Error	Year on the price record cannot be earlier than 1991.
31	Future period pricing not allowed	Error	Pricing quarter cannot be greater than current quarter.
32	Best price must contain 6 decimal places	Error	Best price is less than 6 decimal places.
33	Best price must be present, numeric and greater than zero	Error	Best price is blank, non-numeric, or zero.
34	AMP must contain 6 decimal places	Error	AMP is less than 6 decimal places.
35	AMP must be present, numeric, and greater than zero	Error	AMP is blank, non-numeric, or zero.
36	NDC3 does not exist	Error	Pricing rejected. NDC3 not found.
37	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.
38	Pricing change rejected	Error	Pricing changes not allowed after 12 quarters.
39	AMP change not approved by CMS	Error	Only best price change approved by CMS.
40	Best price change not approved by CMS	Error	Only AMP change approved by CMS.
41	Pricing change submitted after expiration date	Error	Labeler submitted changes after specified date.
42	Pricing submission equals current price	Error	Submitted pricing data equaled the pricing data already in the database.
43	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.
44	Warning: Unit type changed	Alert	Unit type change often requires UPPS and pricing changes. Review and adjust as needed
45	Base AMP must be zero-filled if market date greater than 9/30/1993 and for N drugs	Alert	Database uses AMP submitted for base AMP quarter. Base AMP not required for N drugs.
46	Market date changes are not allowed	Alert	Market date cannot be changed after 12 quarters without prior CMS approval.
47	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.

	New Message	Type	Reason For Occurrence
48	FDA approval date may not be after market date	Alert	Previous FDA approval date remains in database.
49	Multiple package size OBRA '90 base AMP error	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.
50	Multiple package size DRA '05 base AMP error	Alert	DRA '05 base AMP was not weighted as required. CMS used highest submitted base AMP which will result in highest possible AMP. Review/correct.
51	Multiple package size AMP error	Alert	AMP was not weighted as required. CMS used highest submitted base AMP which will result in highest possible AMP. Review/correct.
52	Multiple package size FDA approval date error	Alert	Initial FDA approval date does not change when new package size is added.
53	Multiple package size market date error	Alert	Initial market date does not change when new package size is added.
54	Drug category change made	Alert	Drug category changed from S to I or vice-versa.
55	Terminated drug pricing submitted	Alert	Pricing does not change during four quarters after termination.
56	Terminated package size latest active best price used	Alert	Pricing does not change during four quarters after termination.
57	Best price change not made	Alert	Best price change contains non-numeric characters or spaces.
58	WARNING: Best price greater than AMP	Alert	Best price cannot be greater than AMP. CMS changed best price to equal AMP. Review/correct
59	Multiple package size – Best price error	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.
60	Pricing data exists after termination date	Alert	Labeler submitted pricing data greater than new termination date. Review for accuracy.