This white paper provides the pharmaceutical industry with a guide to understanding dates associated with FDA-approved pharmaceutical products entering and leaving the market and how different stakeholders in the drug delivery industry utilize these dates.
Dates Associated with Pharmaceutical Products

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# Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disclaimer</td>
<td>4</td>
</tr>
<tr>
<td>1. Executive Summary</td>
<td>5</td>
</tr>
<tr>
<td>2. Purpose and Background</td>
<td>5</td>
</tr>
<tr>
<td>3. Defining the Stakeholders</td>
<td>6</td>
</tr>
<tr>
<td>4. Beginning Dates</td>
<td>7</td>
</tr>
<tr>
<td>4.1 What is the appropriate beginning date?</td>
<td>7</td>
</tr>
<tr>
<td>4.2 How are various beginning dates defined and used?</td>
<td>8</td>
</tr>
<tr>
<td>5. Ending Dates</td>
<td>10</td>
</tr>
<tr>
<td>5.1 How are various ending dates defined and used?</td>
<td>13</td>
</tr>
<tr>
<td>6. Improvement Recommendations</td>
<td>15</td>
</tr>
<tr>
<td>7. Frequently Asked Questions</td>
<td>15</td>
</tr>
<tr>
<td>8. Appendix A. Table of Beginning and Ending Definitions</td>
<td>18</td>
</tr>
<tr>
<td>9. Appendix B. History of Changes</td>
<td>24</td>
</tr>
</tbody>
</table>
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The writers of this paper will review and possibly update their recommendations should any significant changes occur.

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1. Executive Summary

This white paper provides the pharmaceutical industry with a guide to understanding dates associated with pharmaceutical products entering and leaving the market. This paper focuses on the FDA-approved products and the processes associated with them. Although non-FDA approved products may follow the same or similar processes, they are not addressed in this paper. The dates provided by a pharmaceutical manufacturer can affect product utilization, reimbursement, and rebates. This white paper provides guidance in the understanding of dates, date definitions, and how different stakeholders in the drug delivery industry utilize these dates. This paper does not intend to identify a universal beginning or end date in the drug delivery industry, rather it is intended to guide the reader in the definitions of dates that currently exist among the various stakeholders.

2. Purpose and Background

Organized under NCPDP Work Group 2 Product Identification, the Dates Associated with Pharmaceutical Product Task Group has identified differences of understanding within the drug delivery industry and in government agencies regarding pharmaceutical products’ beginning date of sale and ending date of sale in the marketplace.

The objectives of this white paper are to:

- Recognize that differences of terminology exist regarding the beginning and ending dates of sale
- Identify the terminology differences among the drug data compendia and government agencies, two of the biggest stakeholders that utilize dates associated with pharmaceutical products
- Ensure that the drug delivery industry, especially pharmaceutical manufacturers, understand the terminology and the impact of reporting the appropriate date(s) on distribution, reimbursement, and rebates in government programs (such as the Medicaid Drug Rebate Program (MDRP))
- Provide industry definitions of a beginning date of sale and an ending date of sale, to reflect how these dates are viewed by the drug delivery industry.

The complexity of today’s pharmaceutical market requires a guide for understanding beginning date of sale and ending date of sale as they pertain to pharmaceutical products within the drug delivery industry. The need for common understanding and definitions of these dates becomes even more important with the increase of drug launches, sale, and discontinuance of pharmaceutical products.

The following graphical timeline is an overview of potential trigger dates that occur during a pharmaceutical product lifecycle:
Product Lifecycle Milestones

Manufacturer Events Triggering Communication of Dates

Communicate to:
- CMS: Medicaid Drug Rebate Program (MDRP) ²
- FDA/SPL: marketing start date
  - National Library of Medicine (DailyMed)
  - SNOMED
- VA (if applicable)

Communicate to:
- Drug Data Compendia:
  - Ship date = effective date
- Obsolete date

Communicate to:
- CMS: termination date
  - Expiration date last lot produced

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3. Defining the Stakeholders

Stakeholders in the drug delivery industry who provide dates or request dates associated with pharmaceuticals products include, but are not limited to, the following:

**FDA** - The Food and Drug Administration (FDA or USFDA) is a federal agency of the United States Department of Health and Human Services (HHS), one of the United States federal executive departments. The FDA is responsible for protecting and promoting public health through the regulation and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), cosmetics, animal foods and feed, and veterinary products.

**CMS** - The Centers for Medicare and Medicaid Services (CMS), is a federal agency within HHS that administers the Medicare program and works in partnership with state governments to administer Medicaid, the Children’s Health Insurance Program (CHIP), and health insurance portability standards.

**Pharmaceutical Manufacturer** – Company that develops, produces, and markets drugs or pharmaceuticals licensed for use as medications. Pharmaceutical companies market generic, biosimilars, brand medications, and medical devices. They are subject to a variety of laws and regulations regarding the patenting, testing, assurance of safety and efficacy, and marketing of drugs. For the purposes of this paper, below is a sample of the internal departments within a pharmaceutical manufacturer that may be required to report dates throughout the product lifecycle:

- For reporting to CMS:
  - Government Pricing or Government Operations
  - Finance / Procurement

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¹ Product not expired, product still on shelves, depleting inventory
² A pharmaceutical manufacturer with a new product who has no MDRP agreement and wishes to participate in the MDRP may request and obtain a MDRP agreement from CMS. A request for a new MDRP agreement should only occur in the same calendar quarter that the product is commercially available. A pharmaceutical manufacturer with an existing MDRP agreement can report their new product to CMS upon commercial launch.
Outsourced vendors responsible for government pricing and commercial operations

- For reporting to drug data compendia:
  - Pricing and Institutional Operations
  - Pharma Channel Strategy and Commercial Operations
  - Strategic Pricing and Contracting Department
- For reporting to FDA (Structured Product Labeling (SPL) Listing):
  - U.S. Regulatory
- Other:
  - U.S. Channel Management or Trade Relations

**Drug Data Compendia** – Organizations that collect and maintain pharmaceutical product identification, pricing and clinical data in a database. This database resource provides the most current and historical information on pharmaceutical products and is integrated into medication ordering, pharmacy dispensing, and claims processing systems. The databases include:

- Drug name (brand, generic, and/or chemical names), strength and dosage form
- Various pricing (current and historical)
- National Drug Code (NDC)
- Package size quantity
- Unit of Measurement (UOM)
- Dates (FDA approval, commercial launch/marketing, termination)
- Product indications / clinical information

### 4. Beginning Dates

Identifying and providing the date when a pharmaceutical product becomes commercially available (i.e. beginning date of sale) presents challenges across the industry. Pharmaceutical manufacturers must coordinate with many internal departments (i.e. regulatory, quality assurance (QA), manufacturing, marketing, commercial operations) to determine the best launch date. The pharmaceutical manufacturer must be consistent in the reporting and communication provided to the industry stakeholders. Challenges result from a lack of understanding of whether the appropriate beginning date of sale should:

1. Be an actual date or an estimated date in the future
2. Reflect the first date the product is commercially available to wholesaler(s)/distributor(s) for which the pharmaceutical manufacturer can invoice and record the first product sale
3. Reflect the FDA approval date

Depending upon which date is used for beginning date of sale, the date can have widespread effects on claims adjudication, reimbursement, and rebate processing for both government and commercial entities.

#### 4.1 What is the appropriate beginning date?

The beginning date should be the day the pharmaceutical manufacturer can begin selling and shipping a pharmaceutical product. The best date to report is the first day the product is available and can be sold to the wholesalers, specialty distributor(s), pharmacies, including specialty, and the price is made available to the drug data compendia. This date is commonly referred to as a “Commercial launch date” in the industry. The beginning date reported will affect reimbursement, rebates, and price reporting to the government and commercial customers.
The following is a list of the dates currently used as beginning dates that are provided and/or requested upon a pharmaceutical manufacturer product introduction into the market:

- FDA Approval date\(^1\)
- FDA Marketing date
- CMS assigned MDRP Optional Effective date\(^2\)
- CMS assigned MDRP Mandatory Effective date\(^2\)
- Pharmaceutical manufacturer assigned Commercial Launch date
- CMS Market date
- Payer (including Medicaid) assigned Coverage Effective date
- Pharmaceutical manufacturer assigned Purchased Product date
- Pharmaceutical manufacturer assigned Reactivation date

### 4.2 How are various beginning dates defined and used?

One type of beginning date which has various definitions throughout the drug delivery industry is “Marketing date”. The variation is a result of the following reasons:

- Government agencies have differing definitions based on their roles and responsibilities.
- Pharmaceutical manufacturers have different interpretations of the meaning based on the role of the reporting individual within the pharmaceutical manufacturer’s organization.
- Drug data compendia definitions can be disparate based on the source of their information, which generally comes directly from the pharmaceutical manufacturer.
- Although the FDA defines the Marketing date one way, other entities may utilize an alternate date as the marketing date in their system (e.g. the product launch date).

#### Pharmaceutical Manufacturer

- Commercial Launch date - When the pharmaceutical manufacturer starts shipping the product into the marketplace for commercial distribution. This date is determined by the pharmaceutical manufacturer.
- Commercial Marketing date – When the pharmaceutical manufacturer may start speaking about and marketing/promoting the product in the marketplace. This date is provided by the pharmaceutical manufacturer to the FDA.
- Reactivation date\(^3\) – This is a date on which a previously terminated product is reintroduced to the market (i.e. reactivated).

#### Government Agencies

The beginning dates that are required with the Government Agencies, described below, are dependent upon an FDA approval date and a Pharmaceutical Manufacturer commercial actual date. The beginning dates are dependent upon how the government views their programs. For example, beginning dates may be determined on a full calendar quarter or the beginning of a year, based on when a product enters into the marketplace and or a contract with the Government Agency is signed.

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\(^1\) Please refer to the FDA website (www.fda.gov) for additional information on the FDA assigned dates.

\(^2\) Optional Effective and Mandatory Effective dates are assigned for new MDRP agreements. The MDRP is a voluntary program that pharmaceutical manufacturers may elect to participate. More information on the MDRP may be found at www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html.

**FDA (U.S. Food and Drug Administration)**

The FDA as defined in section 3 Defining the Stakeholders.

When a pharmaceutical product is commercially launched, there are two critical dates:

- Approval date
- Marketing Start date (FDA)*

*FDA considers the **Marketing Start date** to be the date the pharmaceutical manufacturer indicates when it started marketing the packaged product.  

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**CMS (Centers for Medicare and Medicaid Services)**

*Medicaid*

Medicaid is a health care program that assists low-income families or individuals in paying for long-term medical and custodial care costs. Medicaid is a joint program, funded primarily by the federal government and run at the state level, where coverage may vary. Source: [www.cms.gov](http://www.cms.gov)

The Center for Medicaid and CHIP Services (CMCS) oversees the Medicaid Drug Rebate Program (MDRP) created by the Omnibus Budget Reconciliation Act of 1990 (OBRA ’90). Pharmaceutical manufacturers who wish to have their products covered under Medicaid must participate in the MDRP.

CMS requires pharmaceutical manufacturers to enter into, and have in effect, a National Drug Rebate Agreement (NDRA) with the Secretary of HHS and provide data for all of their covered outpatient drugs. This data includes drug product information and pricing which is reported in the Drug Data Reporting system (DDR). The DDR is a secure website designed by CMS to standardize pharmaceutical manufacturer drug data reporting and provides pharmaceutical manufacturers with a fast and accurate tool for reporting drug data to CMS for purposes of the MDRP. The DDR provides an instructional guide to the participating pharmaceutical manufacturers within the system. Additionally, states may access DDR as a resource for viewing labeler contact information and current drug data reported by the pharmaceutical manufacturers, such as Unit Rebate Amounts (URAs) and various dates.

If a pharmaceutical manufacturer elects to participate and is new to the MDRP, their participation and coverage of their drug will be dependent on the FDA approval date and four additional dates assigned by CMS:

- **Optional effective date** – Date the NDRA is approved by CMS. States have the option of covering a manufacturer’s covered outpatient drugs on this date.
- **Mandatory effective date** - The date that states must begin coverage of a manufacturer’s covered outpatient drugs. The mandatory effective date is the 1\textsuperscript{st} day of the quarter that is at least 60 days after the optional effective date.
- **Coverage Effective date** – Reflects the date on which a product is first eligible for coverage under the MDRP.
- **Market Date** – For S, I, and N drugs (see Table 3 in Appendix A) marketed under an FDA-approved application (e.g. BLA, NDA, and ANDA), CMS defines Market date as the earliest date the drug was first marketed under the application number by any pharmaceutical manufacturer (labeler).

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\* From data element descriptions of the Comprehensive NDC SPL Data Elements File (NSDE) at [https://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm240580.htm](https://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm240580.htm)
Medicare
Medicare is the federal health insurance program for people who are 65 or older, certain younger people with disabilities, and people with End-Stage Renal Disease (permanent kidney failure requiring dialysis or a transplant, sometimes called ESRD).

The different parts of Medicare (i.e. Part A, B, C and D) help cover specific services. For the purpose of this white paper we will concentrate on Medicare Part B, Part D, and the Part D Coverage Gap. Source: www.cms.gov

- Medicare Part B (Medical Insurance)
Part B is for drugs that need to be administered by a Health Care Professional. Part B covers certain doctors’ services, outpatient care, medical supplies, and preventive services. Pharmaceutical manufacturers that have physician administered drugs may need to calculate and report an Average Sales Prices (ASP) on a quarterly basis for those drugs. An FDA approval date and commercial launch date will need to be assigned when the ASP is reported. Source: www.cms.gov

- Medicare Part D (Prescription drug coverage)
Part D adds prescription drug coverage to some Medicare plans, these plans are offered by insurance companies and other private companies approved by Medicare. Pharmaceutical manufacturers may elect to contract with Medicare approved insurance and private companies in this space. Source: www.cms.gov

- Medicare Part D – Coverage Gap
Most Medicare drug plans have a coverage gap (also called the “donut hole”). This means there’s a temporary limit on what the drug plan will cover for drugs. Pharmaceutical manufacturers may elect to enter into a contract with CMS Medicare that assists patients that use their drugs who may enter this annual coverage gap. Source: www.cms.gov

Commercial Payer
The commercial payer defines a beginning date as when there is actual product on the market in sufficient quantity that a pharmacy can fill a prescription.

Drug Data Compendia
It is the responsibility of the pharmaceutical manufacturer to notify and provide product and pricing data, which includes beginning and end dates, to the drug data compendia. Since the drug data compendia are responsible for providing data to their customers (i.e. pharmacies and payers), beginning dates and product information not reported to the drug data compendia when a product is launched may result in denied claims and cause patients to not receive medication.

Appendix A will provide the data elements and beginning date definitions currently used by the drug data compendia.

5. Ending Dates
When a product is no longer promoted or marketed, the pharmaceutical manufacturer is faced with the challenge of how to proceed with the discontinuation/removal of the product. Products are removed from the market for many reasons. These reasons span from safety concerns to commercial issues including lack of demand or manufacturing problems.

The following provides some reasons a product may require an ending date:
• **Safety Concerns** – If a product has been deemed unsafe for patient use, the product is immediately withdrawn from the market.

• **Commercial Discontinuation** – There are many reasons a pharmaceutical manufacturer discontinues a product for commercial reasons. For example:
  o Patent has expired so generics have launched reducing the demand for branded product;
  o Individual product package size is no longer required by the marketplace;
  o Product has been sold to another pharmaceutical manufacturer and will no longer be produced under the selling pharmaceutical manufacturer’s labeler code/NDC;
  o Product is no longer profitable and therefore being discontinued;

**Manufacturer Reporting Responsibilities**

When the pharmaceutical manufacturer determines that a product will be removed from the marketplace, the reason for the removal determines the ending date to be reported.

- The removal may be immediate (e.g. recall) in which case the ending date is the date of removal.
- The removal may occur at a future date (e.g. commercial discontinuation) in which case the ending date is the end of the shelf life for the last manufactured lot of product, also known as last lot expiration date.

The ending date is reported to the appropriate government agencies and trading partners as soon as feasible based on the discontinuation/removal date to ensure the drug in question is no longer dispensed to patients. It is critical for pharmaceutical manufacturers to report the ending date in a timely manner to the following entities

- **Government agencies**
  o CMS
  o FDA
- **Trading Partners**
  o Drug data compendia
  o Wholesalers and Distributors

There are consequences if end dates are not reported timely, which we will further expand on below.

**CMS**

CMS defines “termination date” as the date on which a drug is withdrawn from the market or the drug’s last lot expiration date. CMS reminds pharmaceutical manufacturers that the termination date for a product should be reported timely (e.g., when the last lot of a product is shipped) to ensure that a product will not be dispensed or paid for after the termination date and to support timely and appropriate rebate invoicing.\(^5\)

The pharmaceutical manufacturer may be liable for any drug rebates invoiced by the State Medicaid programs under the MDRP for claims that states had inadvertently reimbursed providers because they were unaware the drug had terminated. CMS (under the MDRP) will not consider the failure to properly report termination dates in the DDR as grounds for a successful dispute of invoiced amounts.

CMS utilizes FDA (SPL) listing information in administration of the MDRP, therefore if the pharmaceutical

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\(^5\) For additional information, please refer to [https://www.medicaid.gov/medicaid/prescription-drugs](https://www.medicaid.gov/medicaid/prescription-drugs)
manufacturer fails to maintain the FDA information it may hinder dispute resolutions.

**FDA**
Pharmaceutical manufacturers are required to maintain updated electronic FDA listings of all National Drug Codes (NDC’s) including the timely reporting of a “stop marketing date” for NDC’s no longer on the market.

Effective 10/1/2017, pharmaceutical manufacturers will be required to recertify all active NDC’s for the entire portfolio of products commercially available with the FDA the last calendar quarter each calendar year. The FDA SPL drug listing was updated to include the date through which the certification of the NDC is valid. This is a new regulation that is evolving at the time of this paper. More guidance from the FDA on this regulation may be found in the Frequently Asked Question section of this paper.

**Drug Data Compendia**
Pharmaceutical manufacturers are also responsible for ensuring the drug data compendia are prospectively notified when NDC’s are removed from the market.

**Challenges to reporting end dates:**
Pharmaceutical manufacturers often struggle to report their Drug Termination dates accurately and on a timely basis. This can be an issue for products terminated for commercial reasons which generally are the majority of a company’s product terminations. Many companies experience a breakdown in the communications across the pharmaceutical manufacturer’s internal departments involved in the manufacturing vs. those responsible for reporting the Drug Termination dates. Below is a typical schematic (titled: Pharmaceutical Manufacturer’s Dilemma – Internal Communications) which shows the parts of the company that may hold the details regarding the date the last production batch was manufactured and the product’s shelf life vs. the departments who need this information to submit accurate and timely Drug Termination dates to government and private agencies. It is important to note that pharmaceutical manufacturers often have production facilities in many countries and may or may not have integrated systems for tracking the dates necessary to accurately report the termination dates.
A best practice within a pharmaceutical manufacturer is to develop a cross departmental/shared Standard Operating Procedure (SOP) specific to the identification, communication, and reporting of discontinued drugs. The SOP should contain specific reporting guidelines to govern who within the pharmaceutical manufacturer is responsible for the accurate and timely reporting of the final manufacture date of the final lot and the product shelf life. The SOP should also include financial implications of late or inaccurate reporting of the drug termination date.

5.1 How are various ending dates defined and used?
When a product is discontinued/removed from the market, the following dates are essential for maintaining the integrity of pharmacy claims reimbursement, rebate invoicing, and the FDA NDC Directory.

**Pharmaceutical Manufacturer**
The following is a list of the dates currently used as ending dates that are requested from pharmaceutical manufacturers when products are discontinued/removed from the market:
- Marketing End date
- Obsolete date
- Inactive date
- CMS Drug Termination date
- NDC Directory Drop date

**Government Agencies**
**Dates Associated with Pharmaceutical Products White Paper**

**CMS**
CMS Drug Termination date: The CMS drug termination date as defined by CMS is the Date of the expiration of the Last Lot or the date in which the product has been withdrawn or recalled from the market.\(^6\)

**FDA**
Marketing End Date: This is the expiration date of the last lot distributed. Products that are actively being marketed will not have a marketing end date. Products that are no longer manufactured may have a future end marketing date for the expiration of the last lot distributed.

**Commercial Payers**
The commercial payer defines an end date as meeting at least one of the following conditions:
1. When no product is available in the market due to manufacturer withdrawal
2. When all product available in the market has reached the last lot’s expiration date
3. When the manufacturer has ceased production or distribution of the product
4. When significant time has passed since the drug data vendors posted an obsolete date on their transmissions, typically 1-3 years

**Drug Data Compendia**
The drug data compendia may utilize several end date fields, depending on the data provided by the pharmaceutical manufacturer. Below are examples of end dates in compendia’s drug databases. Appendix A provides a detailed date field description by drug data compendium.
- Marketing End date
- Obsolete date
- Date of Last Lot
- Inactive date
- Off-Market date

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\(^6\) For date definitions as defined by FDA and CMS please refer to their respective websites at [www.fda.gov](http://www.fda.gov) and [www.cms.gov](http://www.cms.gov).

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6. Improvement Recommendations

To improve efficiency and the understanding of beginning and end dates, it is recommended that:

- Within the pharmaceutical manufacturing organization there is an understanding of who is reporting these date(s) and ensuring there is communication among the different departments within the organization on what date is being reported, why that date is being reported, and who is responsible for the reporting of the date(s).
  - It is suggested in section 5 that, as a best practice, a Standard Operating Procedure (SOP) should be developed by the pharmaceutical manufacturer to ensure effective communication among internal departments on the reporting of dates.
- Dates should not be estimated as it is important that these dates are accurate and can be sourced and documented. Estimated dates may also be a compliance risk that a pharmaceutical manufacturer will want to avoid.
- Beginning Market date should be referred to as a Commercial Launch date, which indicates the first date of sale of a new product. This date establishes the start of product sales and reimbursement.
- Pharmaceutical manufacturers need to understand their products and the business around the product in the market place. Any changes to the product (i.e. price, indication, new formulation, and discontinuation) must be communicated to the industry and the dates on which these changes occurred.

7. Frequently Asked Questions

Q. Why are begin and end dates of sale important to report in the industry?
A. The beginning and end dates of sale of a pharmaceutical product are important to report and manage primarily as it relates to accurate reimbursement and rebate processing, both on the government and commercial spectrum.

Q. As a pharmaceutical manufacturer, what are we responsible to report as dates?
A. Pharmaceutical manufacturers are responsible to manage dates in a pharmaceutical product’s life cycle, which includes, but not limited to: FDA approval date, beginning marketing and commercial launch dates, price change dates, any temporary but extended unavailability or “stock out” dates, end dates when a product is no longer being marketed or made, expiration dates of last lot available in the marketplace, dates of recalled drugs, and dates that the product was sold to another company. These dates may need to be reported to the drug compendia, regulatory bodies, commercial companies, and government agencies with whom the pharmaceutical manufacturer may contract.

Q. How does the government (Medicaid) use the beginning date of sale?
A. When a pharmaceutical manufacturer voluntarily enters into the National Drug Rebate Agreement, which is managed by Medicaid, they submit an approved covered outpatient drug product and pricing information, with a beginning date the product is commercially available. Both the FDA approval date and the beginning commercial launch date are needed to request the National Drug Rebate Agreement. More information on requesting the National Drug Rebate Agreement may be found at: [https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html](https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html)

Q. How is reimbursement of a product associated with a date (beginning and end)?
A. Payers who reimburse providers leverage drug data compendia databases that contain product beginning and end dates of sale. A beginning date turns the “reimbursement on” for a product and
an end date may turn the “reimbursement off,” depending on whether a product was pulled or terminated from the market and is no longer available. Users of the drug data compendia databases must determine the appropriate use of the end date to account for situations when a product is no longer marketed but product remains in the distribution channel and can still be used for dispensing prescriptions.

Q. Who are the drug data compendia and what do they do?
A. The drug data compendia play an important role in the overall drug delivery industry. They manage and maintain data associated with the pricing of pharmaceutical products and the clinical components of these products. The drug data compendia provide an integrated resource primarily used in pharmacy dispensing systems to price prescriptions and payer claims processing systems to calculate reimbursement. The databases maintained by the drug data compendia are large and contain historical and current pricing. They also contain product National Drug Code(s) (NDC), description (product name, strength, and dosage form), packaging, images of the product, and Drug Enforcement Agency (DEA) status. They also provide clinical information, product indication, drug interactions, adverse events, contraindications, dosing, mechanism of action, and pharmacokinetics. The drug data compendia sell their data/content to pharmacies (retail, hospital, specialty, long term care, etc.), physicians, payers, federal, state and local government (including all CMS divisions), e-prescribing vendors and pharmaceutical manufacturers. The current drug data compendia consist of the following companies:
  • First Databank (Hearst Health)
  • Gold Standard (Elsevier, Inc.)
  • MediSpan (Wolters Kluwer Health, Inc.)
  • Multum (Cerner Multum, Inc.)
  • Red Book (Truven Health Analytics, an IBM Company)
  • ScriptPro

Q. How do the drug data compendia work with the government and other payers?
A. The drug data compendia sell their data/content to the government and other payers who use this data in their systems that have their own custom built interface application(s).

Q. What happens if a pharmaceutical manufacturer doesn’t report a beginning or end date of sale to the drug data compendia?
A. An incorrect date may be placed in a drug data compendia or payer system that could cause reimbursement and rebate challenges. It may also cause compliance challenges for the pharmaceutical manufacturer who needs to reconcile sales of a product that correlate to when the product was commercially launched and active in the market.

Q. As a pharmaceutical manufacturer, what if I don’t know a beginning or end date of sale? Where should I go?
A. It is best to begin researching the beginning and end date(s) within your organization. Begin with commercial operations, marketing (product management), and regulatory departments. If that is not possible, contact one or more of the drug data compendia and ask what date(s) they may have in their databases. If a product was acquired, you may ask the selling company for the dates they have on file.

Q. What happens if an inappropriate beginning or end date of sale is reported?
A. Reporting an inappropriate beginning or end date of sale could affect the product’s reimbursement. For example: A beginning date is reported as a commercial launch of April 2, 2015;
however the Marketing date collected by the FDA is April 10, 2015. If the April 10, 2015 date is entered as a commercial launch date by the drug data compendia and the government, then reimbursement for the product is not expected to begin until April 10, 2015. Providers (physicians, pharmacists) that obtain and dispense the product April 2, 2015 and bill insurance (payers) that day will receive denials stating that the product isn’t covered until April 10, 2015. As a result, providers will not be reimbursed for this product dispensed ahead of the April 10, 2015 beginning date. If an incorrect end date is reported, the same reimbursement challenges may occur, as the payer will see this product as not available or discontinued and will not reimburse or provide coverage for any in-date product that may remain in distribution following the incorrect end date.

Q. Where should I go for more information about the 10/01/2017 FDA regulation on certifying NDC numbers?
A. Additional information may be found in the following resources:
   • Code of Federal Regulations for 21 CFR 207: https://www.ecfr.gov/cgi-bin/text-idx?SID=24bd12b55721210e31bb9921427d9390&mc=true&tpl=/ecfrbrowse/Title21/21cfr207_main_02.tpl
   • The SPL Implementation Guide on the FDA’s SPL website: https://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
   • For those with a CDER Direct Account, helpful tutorials and a user guide are available here: https://direct.fda.gov/apex/

Q. Will the FDA coordinate with any other organizations (CMS, Drug Compendia, Medicare Part D etc.) referencing these uncertified NDC’s for the purposes of tracking active/inactive status?
A. At the time of this paper, the FDA is actively working with CMS and DailyMed to figure out the best way to present the “expired” listings. While a final recommendation is not yet available, the FDA does plan to publish a separate download file of all listings that were not certified.
8. Appendix A. Table of Beginning and Ending Definitions

Table 1 Beginning Dates

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Date</td>
<td>The approval date is granted by the FDA to the Pharmaceutical Manufacturer in the form of an FDA Approval letter.</td>
<td>The FDA Approval Date reflects the date on which the drug is approved by the FDA.</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
</tr>
<tr>
<td>Market/Marketing Date</td>
<td>Start Marketing Date – This is the date that the labeler indicated was the start of its marketing of the drug product.</td>
<td>Market Date - For S and I drugs, the Market Date is the date the drug was first marketed by the original labeler. If the S/I drug was purchased or otherwise acquired from another labeler, the Market Date should be equal to the Market Date of the original product. For N drugs, the Market Date is the date the drug was first marketed under the labeler’s rebate agreement. If an N drug was purchased or otherwise acquired from</td>
<td>On Market Date - The date the drug company indicated they were shipping this package, version of the package, or product to the market.</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Date product approved for marketing/distribution</td>
<td>Start Marketing Date</td>
<td>Start Date-the pharmaceutical manufacturer’s “marketing date”</td>
</tr>
</tbody>
</table>

*Dark Gray Shaded areas with “Not Available” indicate the entity does not use the date terminology in the far left column and consequently definitions or descriptions were not available for them at the time this white paper was produced.*
another labeler, the Market Date should be equal to the Market Date of the original product, if that date is available. 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 this aspect of the program.

<table>
<thead>
<tr>
<th>Commercial Launch Date</th>
<th>Not Available</th>
<th>Not Available</th>
<th>Not Available</th>
<th>Not Available</th>
<th>Not Available</th>
<th>Not Available</th>
<th>Not Available</th>
<th>Not Available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coverage Effective Date</td>
<td>Not Available</td>
<td>The Coverage Effective Date field reflects the date on which a product is first eligible for coverage under the MDR program (i.e., the most recent of the product’s Market Date, Purchased Product Date (PPD), or rebate agreement optional effective</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
</tr>
</tbody>
</table>
### Purchased Product Date (PPD)

<table>
<thead>
<tr>
<th>Purchased Product Date (PPD)</th>
<th>Not Available</th>
</tr>
</thead>
</table>

The PPD is the date on which the company currently holding legal title to the NDC first marketed the drug under this NDC (e.g., due to the purchase of an NDC from one company by another company, the re-designation of an NDC from one labeler code to another within the same company, and cross-licensing arrangements).
### Table 2 Ending Dates

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Package Size Introduction Date (PSID)</td>
<td>Not Available</td>
<td>The PSID is the date the package size was first available on the market.</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
</tr>
<tr>
<td>Last Lot Expiration Date</td>
<td>Not Available</td>
<td>Not Available For CMS, this is more like part of the definition of termination date, and not really a term defined on its own.</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
</tr>
<tr>
<td>NDC Directory Drop Date</td>
<td>Not Available</td>
<td></td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
</tr>
<tr>
<td>Expiration Date</td>
<td>Not Available</td>
<td></td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
</tr>
<tr>
<td>Obsolete Date</td>
<td>Not Available</td>
<td>Off-market Date – The date representing the last shipment of this version by the pharmaceutical manufacturer. Inventory may still be available in the marketplace.</td>
<td>Off-market Date – The date representing the last shipment of this version by the pharmaceutical manufacturer. Inventory may still be available in the marketplace.</td>
<td>Off-market Date – The date representing the last shipment of this version by the pharmaceutical manufacturer. Inventory may still be available in the marketplace.</td>
<td>Off-market Date – The date representing the last shipment of this version by the pharmaceutical manufacturer. Inventory may still be available in the marketplace.</td>
<td>Off-market Date – The date representing the last shipment of this version by the pharmaceutical manufacturer. Inventory may still be available in the marketplace.</td>
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<td>Off-market Date – The date representing the last shipment of this version by the pharmaceutical manufacturer. Inventory may still be available in the marketplace.</td>
</tr>
<tr>
<td>EndMarketing Date</td>
<td>End Marketing Date – This is the date the product will no longer be available on the market. If a</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
<td>The date that the product ceased to be marketed by the</td>
<td>Not Available</td>
<td>The End Marketing Date is the date the product will no longer be available on the market.</td>
</tr>
</tbody>
</table>

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8 Dark Gray Shaded areas with “Not Available” indicate the entity does not use the date terminology in the far left column and consequently definitions or descriptions were not available for them at the time this white paper was produced.
<table>
<thead>
<tr>
<th>Dates Associated with Pharmaceutical Products White Paper</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CMS Termination Date</strong></td>
</tr>
<tr>
<td>product is no longer being manufactured, in most cases, the FDA recommends firms use the expiration date of the last lot produced as the End Marketing Date, to reflect the potential for drug products to remain available after manufacturing has ceased.</td>
</tr>
</tbody>
</table>
Table 3 - Defining Drug Category Used by CMS:

Drug Category (i.e., Single Source/Innovator Multiple Source/Non-Innovator) for each 11-digit NDC (this value should be the same for every package size of a 9-digit NDC). Definitions of these terms may be found in Federal Regulations (42 CFR §447.502).

<table>
<thead>
<tr>
<th>Drug Category</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single Source (S)</td>
<td>“…a covered outpatient drug that is produced or distributed under an original NDA approved by FDA and has an approved NDA number issued by FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the NDA. It also includes a covered outpatient drug approved under a biologics license application (BLA), product license application (PLA), establishment license application (ELA), or antibiotic drug application (ADA). For purposes of this definition and the MDR program, an original NDA means an NDA, other than an ANDA, approved by the FDA for marketing, unless CMS determines that a narrow exception applies.”</td>
</tr>
<tr>
<td>Innovator multiple source drug (I)</td>
<td>“…a multiple source drug that was originally marketed under an original new drug application (NDA) approved by FDA, including an authorized generic drug. It also includes a drug product marketed by any cross-licensed producers, labelers, or distributors operating under the NDA and a covered outpatient drug approved under a biologics license application (BLA), product license application (PLA), establishment license application (ELA) or antibiotic drug application (ADA). For purposes of this definition and the Medicaid drug rebates (MDR) program, an original NDA means an NDA, other than an Abbreviated New Drug Application (ANDA), approved by the FDA for marketing, unless CMS determines that a narrow exception applies.”</td>
</tr>
</tbody>
</table>
| Noninnovator multiple source drug (N) |“(1) A multiple source drug that is not an innovator multiple source drug or a single source drug;  
(2) A multiple source drug that is marketed under an ANDA or an abbreviated antibiotic drug application;  
(3) A covered outpatient drug that entered the market before 1962 that was not originally marketed under an NDA;  
(4) Any drug that has not gone through an FDA approval process, but otherwise meets the definition of covered outpatient drug; or  
(5) If any of the drug products listed in this definition of a noninnovator multiple source drug subsequently receives an NDA or ANDA approval from FDA, the product’s drug category changes to correlate with the new product application type.” |
9. Appendix B. History of Changes