

Dates Associated with Pharmaceutical Products

Version 2.0

July 2025

A decorative graphic in the bottom left corner of the page. It consists of a cluster of overlapping hexagons in various shades of teal and blue. Some hexagons are solid, while others are outlined. Small white dots are scattered throughout the pattern, and thin white lines connect some of the dots, creating a network-like structure.

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

1. Executive Summary.....	4
2. Purpose and Background.....	4
3. Defining the Stakeholders.....	5
4. Beginning Dates.....	6
4.1 What Is The Appropriate Beginning Date?	6
4.2 How Are Various Beginning Dates Defined and Used?	7
5. FDA Product Maintenance and Certification	10
6. Ending Dates	10
6.1 What are the Manufacturer Reporting Responsibilities?	10
6.2 What are the Challenges to Reporting End Dates?	11
6.3 How Are Various Ending Dates Defined and Used?.....	12
7. Improvement Recommendations.....	14
8. Frequently Asked Questions.....	14
8.1 Why Are Begin and End Dates of Sale Important To Report In The Industry?	14
8.2 As A Pharmaceutical Manufacturer, What Dates Are We Responsible To Report?	14
8.3 What Dates Are Used In Medicaid or The Medicaid Drug Rebate Program?	14
8.4 How Is Reimbursement of A Product Associated With A Date (Beginning and End)?.....	15
8.5 Who Are The Drug Data Compendia and What Do They Do?	15
8.6 How Do The Drug Data Compendia Work With The Government and Other Payers?	15
8.7 What Happens if A Pharmaceutical Manufacturer Does Not Report A Beginning or End Date of Sale To The Drug Data Compendia?.....	15
8.8 As A Pharmaceutical Manufacturer, What if I Do Not Know a Beginning or End Date of Sale? Where Should I Go?	16
8.9 What Happens if An Inappropriate Beginning or End Date of Sale is Reported?	16
8.10 Where Should I Go for More Information About the FDA Regulation on Certifying NDC Numbers?	16
9. Appendix A. Table of Beginning and Ending Definitions	17
10. Appendix B. History of Changes	22
Version 1.0	22
Version 2.0	22

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 U.S. Food and Drug Administration (FDA)-approved products and the processes related to those products. 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 to understand 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:

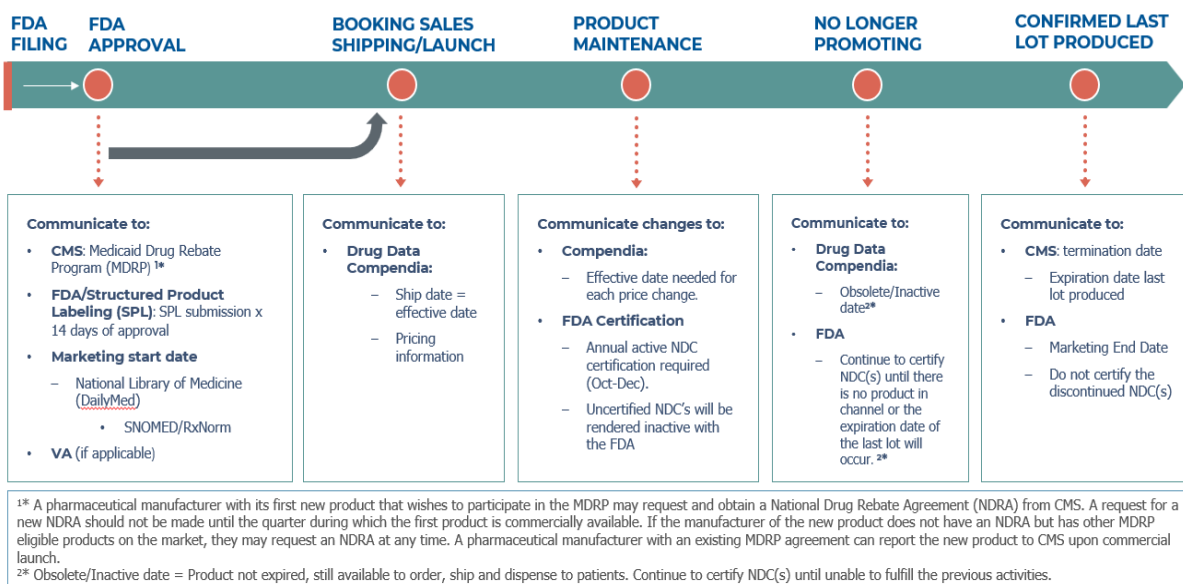
- Recognize differences of terminology exist regarding the beginning and ending dates of sale
- Identify the terminology differences among the drug data compendia and government agencies, two of the biggest stakeholders that utilize dates associated with pharmaceutical products
- Ensure the drug delivery 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, sales 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



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 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 – Any 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

Version 2.0

July 2025

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Dates Associated with Pharmaceutical Products White Paper

- 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 ([see Table 1 in Appendix A](#)). Pharmaceutical manufacturers must coordinate with many internal departments (e.g., 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, 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. In the industry, this date is commonly referred to as a Commercial Launch Date. The beginning date reported will affect reimbursement, rebates and price

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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 Date¹
- FDA Marketing Start Date
- CMS assigned MDRP Optional Effective Date²
- CMS assigned MDRP Mandatory Effective Date²
- 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 Start Date (or Start 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 anticipates marketing/promoting the product. This date is provided by the pharmaceutical manufacturer to the FDA via the SPL; the date is known as the Marketing Start Date.
- CMS Reactivation Date³ – 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 agencies define specific terms for 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

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 in which 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.

³ For additional information, please refer to *CMS Manufacturer Release No. 95 dated Dec 31, 2015* available at <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-095.pdf>

Dates Associated with Pharmaceutical Products White Paper

government agency is signed.

FDA (U.S. Food and Drug Administration)

The FDA developed the SPL process in which a manufacturer must report product dates and various other requirements. The following two dates need to be reported prior to commercializing the product. It is customary for these dates to be reported within 14 days of approval.

- Approval Date*
- Marketing Start Date (FDA)**

* The Approval Date is the Prescription Drug User Fee Act (PDUFA) date assigned to a product by the FDA. Other approval date types are Biological Drug User Fee Act (BDUFA) and Generic Drug User Fee Act (GDUFA).

**FDA considers the Marketing Start Date to be the date the pharmaceutical manufacturer indicates when it started marketing the packaged product.⁴

CMS (Centers for Medicare and Medicaid Services)

Medicaid

The Center for Medicaid and CHIP Services (CMCS) oversees the MDRP created by the Omnibus Budget Reconciliation Act of 1990 (OBRA '90). In general, pharmaceutical manufacturers that wish to have their products covered under Medicaid must participate in the MDRP.⁵

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 Medicaid Drug Program (MDP) System. The MDP 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 MDP provides an instructional guide to the participating pharmaceutical manufacturers within the system. Additionally, states may access MDP 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, its participation and coverage of their drug will be dependent on the FDA approval date and four additional dates assigned by CMS:

- Optional Effective Date – The date the signed and completed NDRA has been received and accepted by CMS via the MDP system. 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 first day of the quarter that is at least 60 days after the optional effective date.
- Coverage Effective Date – The date on which a product is first eligible for coverage under the MDRP.
- Market Date – for drugs marketed under an FDA-approved application (e.g., Biologics License Application (BLA), New Drug Application (NDA) and Abbreviated New Drug Application

⁴ From data element descriptions of the Comprehensive NDC SPL Data Elements File (NSDE) at <https://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm240580.htm>

⁵ For additional information on the MDRP, please refer to Medicaid.gov at <https://www.medicaid.gov/medicaid/prescription-drugs/index.html>

Dates Associated with Pharmaceutical Products White Paper

(ANDA)), CMS defines Market Date as the earliest date the drug was first marketed under the application number by any pharmaceutical manufacturer (labeler).

In September 2024, CMS released CMS-2434, Misclassification Of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program Final Rule which includes a definition for “Market Date” and other pricing date requirements for reporting to the MDRP. This final rule explains the expanded penalties that may be imposed for manufacturer reporting of inaccurate information. The final rule describes a range of actions that CMS may take against a manufacturer that does not correct misclassification after being notified, which includes the agency correcting the misclassification, suspension of the drug and/or its manufacturer from the MDRP, exclusion of the misclassified drug from Medicaid payment and imposition of civil monetary penalties (CMPs).

Medicare⁶

Note: This white paper concentrates on Medicare Part B and Part D.

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.

- **Medicare Part B (Medical Insurance)**

Part B is generally for drugs that need to be administered by a healthcare 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.

- **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.

Commercial Payer

The commercial payer may utilize multiple beginning dates. The FDA Approval Date is the primary date utilized for execution of purchasing contracts. An NDC is required to have an effective date in order for prescription adjudication to occur.

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 a medication.

[Appendix A](#) will provide the data elements and beginning date definitions currently used by the drug data compendia.

⁶ Source: www.cms.gov

5. FDA Product Maintenance and Certification

All newly approved products within a calendar year must add their NDC numbers to the FDA database via SPL and certify annually thereafter. For information on drug listing certification, see the [Drug Listing Certification Quick Start Guide](#).

As part of the FDA NDC certification process, there are two dates created by the FDA for recertification which are Inactivation Date and Reactivation Date.

- **Inactivation Date:** The date on which registration or listing data was inactivated by FDA due to inaccuracies, incompleteness or noncompliance. Not to be confused with the Marketing End Date which is the date on which the manufacturer has decided to discontinue the NDC.
- **Reactivation Date:** The date on which a previously inactivated FDA registration or listing data is reactivated. This is a result of the manufacturer not certifying NDCs that are commercially available, resulting in the inactivation of those NDCs by the FDA.

6. 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 (see [Table 2 in Appendix A](#)). 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:
 - Patent has expired so generics have launched reducing the demand for branded product
 - Individual product package size is no longer required by the marketplace
 - Product has been sold to another pharmaceutical manufacturer and will no longer be produced under the selling pharmaceutical manufacturer's labeler code/NDC
 - Product is no longer profitable and therefore being discontinued

6.1 What are the Manufacturer Reporting Responsibilities?

When the pharmaceutical manufacturer determines 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 the 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 ensuring 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:

Dates Associated with Pharmaceutical Products White Paper

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

There are consequences if end dates are not reported timely, which are further detailed 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.⁷

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 MDP as grounds for a successful dispute of invoiced amounts.

CMS utilizes FDA (SPL) listing information in administration of the MDRP; therefore, if the pharmaceutical 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 NDCs. This includes the certification of all active NDCs within the FDA’s NDC Drug Listing database and the timely reporting of a “Marketing End Date” for NDCs no longer on the market. The Marketing End Date is the expiration date of the last lot distributed. Products that are no longer manufactured may have a future Marketing End Date for the expiration of the last lot distributed. These items can still be commercially available until inventory has been depleted or the expiration date of the product has come to pass.

Drug Data Compendia

Pharmaceutical manufacturers are also responsible for ensuring the drug data compendia are prospectively notified when NDCs are removed from the market or no longer being actively promoted.

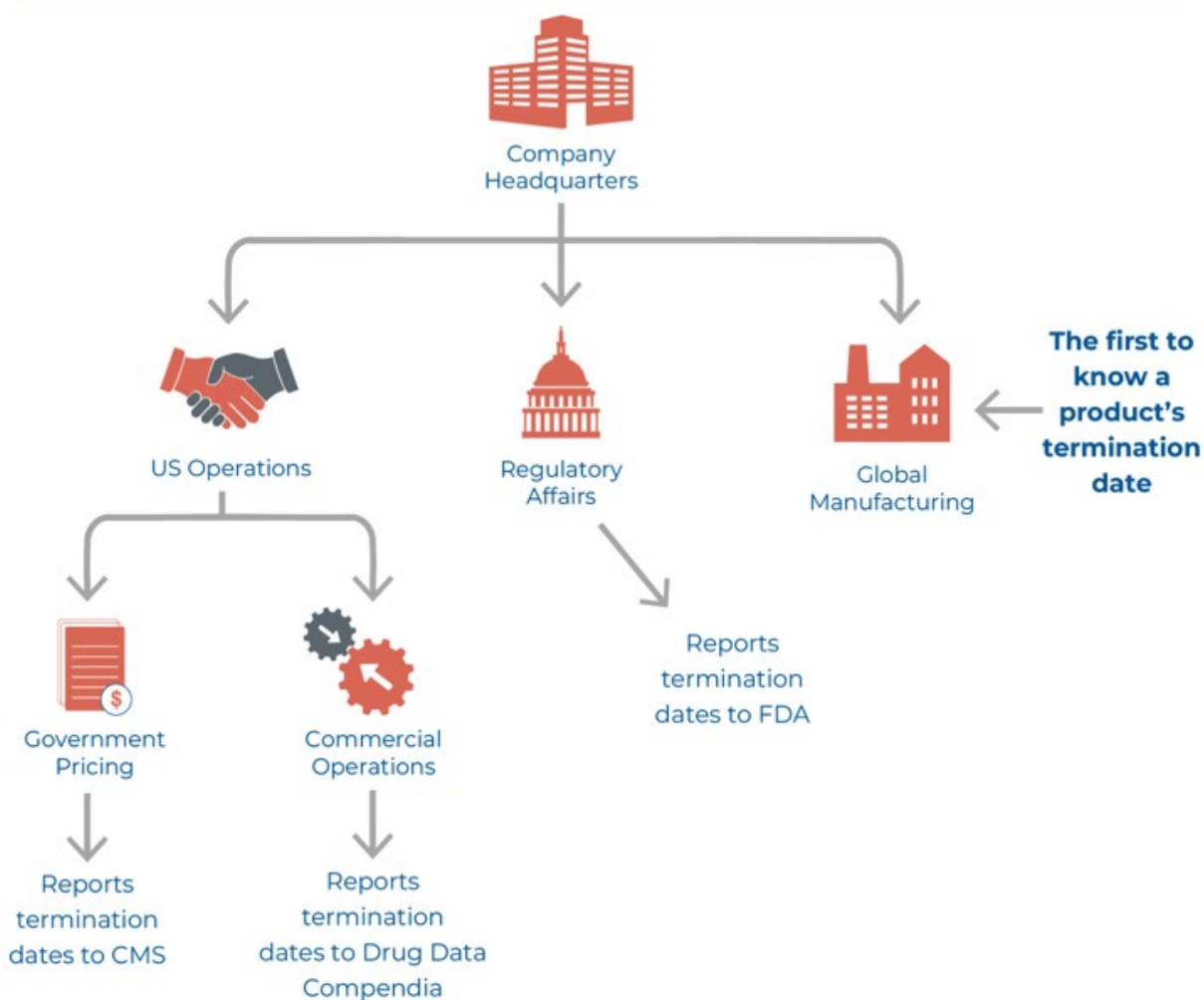
6.2 What are the Challenges to Reporting End Dates?

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 communications across the pharmaceutical manufacturer’s internal departments involved in the manufacturing versus those responsible for reporting the drug termination dates. Below is a typical schematic, titled *Manufacturer’s Dilemma – Internal Communications*, which shows the departments of the company that may hold the details regarding the date the last production batch was manufactured and the product’s shelf life versus the departments who need this information to submit accurate and timely drug termination dates to government and private agencies. It is important to note

⁷ For additional information, please refer to <https://www.medicaid.gov/medicaid/prescription-drugs/index.html>

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.

Manufacturer's Dilemma – Internal Communications



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 expiration date of the last lot and the product shelf life. The SOP should also include financial implications of late or inaccurate reporting of the drug termination date.

6.3 How Are Various Ending Dates Defined and Used?

When a product is discontinued/removed from the market, the following dates are essential for

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Dates Associated with Pharmaceutical Products White Paper

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/Inactive Date
- CMS Drug Termination Date

Government Agencies

CMS

CMS Drug Termination Date: The CMS Drug Termination Date as defined by CMS is the date of the expiration of the last lot sold or the date on which the product has been withdrawn or recalled from the market.⁸

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 Marketing End 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:

- When no product is available in the market due to manufacturer withdrawal
- When all product available in the market has reached the last lot's expiration date
- When the manufacturer has ceased production or distribution of the product
- When significant time has passed since the drug data vendors posted an obsolete/inactive date on their transmissions allowing a drug to flow through the distribution channels

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/Inactive Date
- Date of Last Lot
- Off-Market Date

⁸ For date definitions as defined by FDA and CMS please refer to their respective websites at www.fda.gov and www.cms.gov.

7. 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 6.2](#) 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 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.
- Pharmaceutical manufacturers need to understand their products and the business around the product in the marketplace. Any changes to a product (e.g., price, indication, new formulation and discontinuation) and the dates on which these changes occurred must be communicated to the industry including the drug data compendia.

8. Frequently Asked Questions

8.1 Why Are Begin and End Dates of Sale Important To Report In The Industry?

The beginning and end dates of sale for 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.

8.2 As A Pharmaceutical Manufacturer, What Dates Are We Responsible To Report?

Pharmaceutical manufacturers are responsible to manage dates in a pharmaceutical product's life cycle which includes, but is not limited to, FDA Approval Date, Begin Marketing and Commercial Launch Dates, Inactivation Date, Reactivation Date, 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 on which a drug is recalled and dates the product was sold to another company. These dates may need to be reported to the drug data compendia, regulatory bodies, commercial companies and government agencies with whom the pharmaceutical manufacturer may contract.

8.3 What Dates Are Used In Medicaid or The Medicaid Drug Rebate Program?

A pharmaceutical manufacturer will not be issued a NDRA unless and until the manufacturer has a drug available for sale. The manufacturer must provide several dates to Medicaid for each of its covered outpatient drugs. Some dates that appear in the Medicaid databases are self-reported by the manufacturer, and others are assigned by the reporting system based on information provided by the manufacturer. The manufacturer must report the FDA Approval Date and Market Date⁹, and, if

⁹ The Market Date for Medicaid purposes is frequently not the date on which the NDC is first marketed. See definition of Market Date provided earlier in this document.

applicable, a Purchased Product Date, Termination Date, Reactivation Date and package size intro date. Dates that are populated in the reporting system by CMS are the Coverage Effective Date, the base Average Manufacturer Price (AMP) quarter, optional effective date of the NDRA and Mandatory Effective Date of the NDRA¹⁰.

8.4 How Is Reimbursement of A Product Associated With A Date (Beginning and End)?

Payers who reimburse providers leverage drug data compendia databases that contain product beginning and end dates of sale. Please refer to [Appendix A](#) for compendia-specific field names and definitions. 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 dispensed.

8.5 Who Are The Drug Data Compendia and What Do They Do?

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 databases maintained by the drug data compendia are large and contain historical and current pricing. They also contain product NDC, description (product name, strength and dosage form), packaging, images of the product and Drug Enforcement Agency (DEA) status. They also provide clinical decision support information. The current drug data compendia consist of the following companies:

- First Databank (Hearst Health) (FDB)
- Gold Standard Drug Database (Elsevier, Inc.)
- Medi-Span (Wolters Kluwer)
- Oracle Health Multum (formerly Cerner Multum)
- RED BOOK (Merative)
- ScriptPro

8.6 How Do The Drug Data Compendia Work With The Government and Other Payers?

The drug data compendia sell their data/content to the government and other payer organizations who utilize this data within their systems.

8.7 What Happens if A Pharmaceutical Manufacturer Does Not Report A Beginning or End Date of Sale To The Drug Data Compendia?

If a specific beginning or end date of sale is not reported, 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, active in the marketplace and has reached the end of its lifecycle.

¹⁰ More information on requesting the NDRA may be found at: <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html>

8.8 As A Pharmaceutical Manufacturer, What if I Do Not Know a Beginning or End Date of Sale? Where Should I Go?

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.

8.9 What Happens if An Inappropriate Beginning or End Date of Sale is Reported?

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, 2024; however, the marketing date collected by the FDA is April 10, 2024. If the April 10, 2024, 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, 2024. Providers (physicians, pharmacists) that obtain and dispense the product April 2, 2024, and bill insurance (payers) for that date of service will receive denials stating that the product is not covered until April 10, 2024. As a result, providers will not be reimbursed for this product dispensed ahead of the April 10, 2024, 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 end-date product that may remain in distribution following the incorrect end date.

8.10 Where Should I Go for More Information About the FDA Regulation on Certifying NDC Numbers?

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 Center for Drug Evaluation and Research (CDER) Direct Account, helpful tutorials and a user guide are available here: https://direct.fda.gov/apex/f?p=100:LOGIN_DESKTOP

9. Appendix A. Table of Beginning and Ending Definitions

Table 1 Beginning Dates¹¹

Defining Entities	FDA	Medicaid	Gold Standard Drug Database (Elsevier, Inc.)	First Databank (Hearst Health) (FDB)	Oracle Health Multum (formerly Cerner Multum)	ScriptPro	Medi-Span (Wolters Kluwer)	RED BOOK (Merative)
Approval Date	The approval date is granted by the FDA to the pharmaceutical manufacturer in the form of an FDA Approval letter	The FDA Approval Date reflects the date on which the drug is approved by the FDA.	Not Available	FDB outputs the FDA Approval Date	Not Available	Not Available	Not Available	Not Available
Market/Marketing Date	Start Marketing Date – This is the date the labeler indicated was the start of its marketing of the drug product.	Market Date – The date the drug was first marketed by the original labeler. If the drug was purchased or otherwise acquired from another labeler, the market date should be equal to the Market date of the original product. If a Market Date falls on a date that is earlier than 9/30/1990, CMS will change it to 9/30/1990 since dates earlier than the start of the Drug Rebate Program have no bearing on this	On Market Date – The date the drug company indicated they were shipping this package, version of the package or product to the market.	Not Available	Not Available	Date product approved for marketing/distribution	Start Marketing Date – The date the labeler indicates as the start of its marketing of the drug product. End Marketing Date – The date the product will no longer be available on the market.	Start Date – The pharmaceutical manufacturer's "marketing date"

¹¹ 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 at the time this white paper was produced.

Dates Associated with Pharmaceutical Products White Paper

Defining Entities	FDA	Medicaid	Gold Standard Drug Database (Elsevier, Inc.)	First Databank (Hearst Health) (FDB)	Oracle Health Multum (formerly Cerner Multum)	ScriptPro	Medi-Span (Wolters Kluwer)	RED BOOK (Merative)
		aspect of the program.						
Commercial Launch Date	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available
Coverage Effective Date	Not Available	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 date). This field is automatically populated by CMS.	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available
Purchased Product Date (PPD)	Not Available	The PPD is the date on which the company currently holding legal title to the NDC first marketed the drug under this NDC (i.e., 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).	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available

Version 2.0

July 2025

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Dates Associated with Pharmaceutical Products White Paper

Table 2 Ending Dates¹²

Defining Entities	FDA	CMS Medicaid	Gold Standard Drug Database (Elsevier, Inc.)	First Databank (Hearst Health) (FDB)	Oracle Health Multum (formerly Cerner Multum, Inc.)	ScriptPro	Medi-Span (Wolters Kluwer)	RED BOOK (Merative)
Package Size Introduction Date (PSID)	Not Available	The PSID is the date the package size was first available on the market.	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available
Last Lot Expiration Date	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available
NDC Directory Drop Date	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available
Expiration Date	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available
Obsolete/Inactive Date	Not Available	Not Available	Off-market Date – The date representing the last shipment of this version by the pharmaceutical manufacturer. Inventory may still be available in the marketplace.	The date or estimated date (per pharmaceutical manufacturer or FDA notification) on which an NDC is discontinued, no longer marketed, no longer produced, no longer distributed or otherwise made unavailable to the marketplace.	The expiration date of the last lot of product that was shipped by the pharmaceutical manufacturer.	Date product was discontinued by pharmaceutical Manufacturer/Distributor.	Inactive (last date pharmaceutical manufacture ships product).	The date or estimated date (per pharmaceutical manufacturer, FDA or RxNorm notification) on which an NDC is discontinued, no longer marketed or otherwise made unavailable to the marketplace.
Marketing End Date	<u>Marketing End Date</u> – This is the date the product will no longer be available on the market. If a product is no longer being	Not Available	Not Available	Not Available	The date that the product ceased to be marketed by the pharmaceutical manufacturer.	Not Available	<u>Marketing End Date</u> – The date the product will no longer be available on the market.	Not Available

¹² 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 at the time this white paper was produced.

Dates Associated with Pharmaceutical Products White Paper

Defining Entities	FDA	CMS Medicaid	Gold Standard Drug Database (Elsevier, Inc.)	First Databank (Hearst Health) (FDB)	Oracle Health Multum (formerly Cerner Multum, Inc.)	ScriptPro	Medi-Span (Wolters Kluwer)	RED BOOK (Merative)
	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.							
Inactivation Date	The date on which registration or listing data was inactivated by FDA due to inaccuracies, incompleteness or noncompliance	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available
Reactivation Date	The date on which a previously FDA inactivated registration or listing data is reactivated	The date on which a previously terminated product is reintroduced to the market (i.e., reactivated).	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available
CMS Termination Date	Not Available	Expiration date of the last lot shipped or the date on which all product was withdrawn from the market.	Not Available	FDB provides CMS Termination Date	Not Available	Date product should be reviewed for discontinuation in ScriptPro's database.	Not Available	End Date – The date CMS is notified by pharmaceutical manufacturer that the product has been

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July 2025

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Dates Associated with Pharmaceutical Products White Paper

Defining Entities	FDA	CMS Medicaid	Gold Standard Drug Database (Elsevier, Inc.)	First Databank (Hearst Health) (FDB)	Oracle Health Multum (formerly Cerner Multum, Inc.)	ScriptPro	Medi-Span (Wolters Kluwer)	RED BOOK (Merative)
								discontinued/re moved.

Version 2.0
July 2025

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10. Appendix B. History of Changes

Version 1.0

- Original publication

Version 2.0

- Updated, added or edited content in the following sections:
 - Section 1 Executive Summary
 - Section 2 Purpose and Background
 - Updated marketplace to marketplace throughout paper
 - Updated Lifecycle Milestones graphic
 - Added Product Maintenance
 - Section 4 Beginning Dates
 - 4.1
 - Updated FDA Marketing date to FDA Marketing Start date
 - 4.2
 - Updated FDA Marketing date to FDA Marketing Start date
 - Updated definitions for:
 - Pharmaceutical Manufacturer
 - Government Agencies
 - FDA
 - CMS
 - Commercial Payer
 - Added Section 5 FDA Product Maintenance and Certification
 - Section 6 Ending Dates
 - Updated FDA
 - Updated Drug Data Compendia
 - Updated Manufacturer's Dilemma – Internal Communications schema
 - Section 6.1 What are the Manufacturer Reporting Responsibilities?
 - Updated Pharmaceutical Manufacturer
 - Updated CMS
 - Updated FDA
 - Updated Commercial Payers
 - Updated Drug Data Compendia 6.2 What are the Challenges to reporting end dates?
 - Updated Graphic
 - 6.3 How Are Various Ending Dates Defined and Used?
 - Updated Pharmaceutical Manufacturer
 - Updated Government Agencies
 - Drug Data Compendia
 - Section 7 Improvement Recommendations
 - Updated, added or edited content
 - Section 8 Frequently Asked Questions
 - Added sub-sections to FAQs
 - Section 8.3 What dates are used in Medicaid for the Medicaid Drug Rebate Program?
 - Updated content
 - Section 8.4 How is reimbursement of a product associated with a date (beginning and end)?

Version 2.0

July 2025

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Dates Associated with Pharmaceutical Products White Paper

- Added reference to Appendix A
- Section 8.5 Who are the drug data compendia and what do they do?
 - Updated content
- Section 8.6 How do the drug data compendia work with the government and other payers?
 - Updated content
- Section 8.7 What happens if a pharmaceutical manufacturer does not report a beginning or end date of sale to the drug data compendia?
 - Updated content
- Section 9 Appendix A. Table of Beginning and Ending Definitions
 - Updated, added or edited content in the following tables
 - Updated Table 1 definitions
 - Updated Table 2
 - Added Inactivation Date
 - Added Reactivation Date
 - Removed Table 3

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