



CENTERS FOR MEDICARE & MEDICAID SERVICES

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TO: All Part D Plans

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SUBJECT: Contract Year (CY) 2021 Part D Pricing Data Submission Guidance

Part D sponsors will use the Health Plan Management System (HPMS) Part D Pricing File Submission (PDPFS) module to submit their drug pricing and pharmacy data for posting on the Medicare Plan Finder (MPF). CMS will release the CY 2021 module to all Part D sponsors on **July 3, 2020** in preparation for the first official CY 2021 pricing file test window.

Designed as a “one-stop shop” for all aspects of the Part D drug pricing submission process, this module consolidates the upload, validation, and attestation functions into a single location. This solution:

- Enables users to resubmit continuously to address errors
- Provides validation results after each upload rather than at the end of the submission period
- Ensures that validations are being applied using the benefit and formulary data that resides natively inside HPMS
- Presents validation results immediately to users via online views and reports
- Allows users to perform attestations online in HPMS

The PDPFS module can be accessed using the following navigation path:

HPMS Home Page > Plan Formularies > Part D Pricing File Submission

For CY 2021, Part D sponsors also have the option to submit their Part D pricing files using an Application Programming Interface (API). CMS has been administering an API pilot comprised of organizations that expressed interest in response to the following memos: February 10, 2020 “Health Plan Management System Application Programming Interface Testing Opportunity - Responses Due by February 19, 2020” and May 11, 2020 “Application Programming Interface

(API) Testing Opportunity for the HPMS Part D Pricing File Submission Module.” Detailed information on the PDPFS API will be provided under separate cover.

New for CY 2021

CMS is implementing the following changes for CY 2021:

- **Appendix B** has been added to provide the dates on which HPMS will pull approved formularies and benefits and corresponding reference data in order to perform validations during each CY 2021 bi-weekly drug pricing submission window. This information is also available in the PDPFS module in HPMS. As a result, the letters that identify each of the remaining appendices have changed for CY 2021: validation inventory (C), pharmacy cost file layout (D), pricing file layout (E), and ceiling price file layout (F).
- Two validations are moving from informational to non-attestable suppressible errors: Pricing File with Duplicate NDC Records and PF Unit Cost Discrepancy.
- CMS will include the values for 6 months and 1 year in the refill frequency dropdown in MPF. When calculating the unit price of the drug, MPF will use the 90 day unit price submitted by the plan for the NDC and the selected pharmacy. When calculating the beneficiary cost sharing for the drug, MPF will use the 90 day cost sharing submitted by the plan for the tier of the drug, phase, and the pharmacy type.

Getting Access to the HPMS Part D Pricing File Submission Module

In order to access the new module, each user must have the following:

1. An active CMS user ID with the HPMS production job code assigned (HPMS_Prod_AWS);
2. One or more contract numbers assigned to the user ID in HPMS; and the
3. Following HPMS access types assigned to the user ID:
 - a. Part D Pricing Submission - Plan
 - b. Part D Pricing View/Reports - Plan

Consultants may also perform this work on behalf of Part D sponsors in HPMS. Please refer to the April 14, 2020 memo entitled “Instructions for Requesting Consultant Access to the Health Plan Management System (HPMS)” for detailed guidance on requesting this type of access.

Please note that there is **no limit** on the number of users permitted access to HPMS per organization.

General HPMS user access guidance is available at the following website:

<https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/UserIDProcess.html>

CY 2021 Drug Pricing Submission Schedule

HPMS uses a two week cycle for drug pricing submissions. The following calendar provides a sample **daily** view of the new two week submission schedule.

Week One						
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
	Submission period begins at 6:00 a.m. ET. Plans submit pricing files and receive validation results. Can resubmit continuously.	Plans submit pricing files and receive validation results. Can resubmit continuously.	Plans submit pricing files and receive validation results. Can resubmit continuously.	Plans submit pricing files and receive validation results. Can resubmit continuously. Submission period ends at 12:00 p.m. ET. HPMS runs outlier checks and notifies plans.	Resubmission period begins at 12:00 p.m. ET. Eligible plans submit pricing files and receive validation results. Can resubmit continuously.	Eligible plans submit pricing files and receive validation results. Can resubmit continuously.

Week Two						
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Eligible plans submit pricing files and receive validation results. Can resubmit continuously.	Eligible plans submit pricing files and receive validation results. Can resubmit continuously.	Eligible plans submit pricing files and receive validation results. Can resubmit continuously.	Eligible plans submit pricing files and receive validation results. Can resubmit continuously. Submission period ends at 12:00 p.m. ET. HPMS runs outlier checks and notifies plans.	Eligible plans complete attestations in HPMS.	Plan attestations due in HPMS by 2:00 p.m. ET.	

The complete CY 2021 drug pricing submission calendar is provided in **Appendix A**.

Appendix B includes the dates on which HPMS will pull approved formularies and benefits and corresponding reference data in order to perform validations during each CY 2021 bi-weekly drug pricing submission window.

CY 2021 Drug Pricing Validations

HPMS uses a multi-tiered approach when validating the in-bound drug pricing file submissions in regard to both format and content. The three distinct validation levels are described in the table below.

Validation Step	Description
Level One	Level One validation is performed when the user attempts to upload the zip file. This step performs basic checks (e.g., file format and file size) in real-time. If the zip file fails one or more checks in level one, it will not be uploaded to HPMS.
Level Two	<p>Level Two validation is performed after the zip file passes level one. The zip file goes into a queue where HPMS performs continuous processing. When the zip file is selected in the queue, HPMS executes two distinct sets of validation:</p> <p><u>Part One: Fatal Errors</u></p> <p>The upload will be automatically rejected if it fails one or more of these validations. Some examples include:</p> <ul style="list-style-type: none"> • Upload does not contain required files • Record format in each of the pharmacy cost/pricing/ceiling price files does not match the format specified in the guidelines • Pharmacy cost file has invalid plans or segments <p><u>Part Two: Comprehensive Validations</u></p> <p>When the upload passes part one, HPMS will perform a set of comprehensive checks (i.e., equivalent to the current Acumen validation routine excluding the universe outlier checks). Some examples include:</p> <ul style="list-style-type: none"> • Mail order pricing not indicated in the Plan Benefit Package (PBP) • Pharmacy cost and pricing file mismatch • Pharmacies marked as neither retail nor mail
Level Three	Level Three is performed one time after each of the first and second submission windows close. This step performs outlier checks that are based upon the entire set of drug pricing data submitted by Part D plans (i.e., high/low unit cost and high/low ceiling quantity).

Medicare beneficiaries depend on the display of accurate data on MPF. As such, Part D sponsors are required to perform their own quality assurance checks before submission to ensure that the files are complete and accurate.

The validations discussed in this memo are not statements of the levels of permissible error for Part D program compliance purposes. These validations are tools used by CMS to identify potential inaccuracies prior to display on MPF. They do not necessarily identify inaccurate drug pricing files; rather, they may prompt CMS to contact a sponsor for clarification of the accuracy of its submission.

Drug pricing submissions must be complete and accurate in all respects, and Part D sponsors are solely accountable for any errors in their data, regardless of how those errors come to CMS' attention. Because of MPF's critical role in providing beneficiaries with reliable information about their drug plan options, CMS will suppress the display of a sponsor's information when the sponsor fails to correct their data, confirm the accuracy of its data, or respond to a CMS inquiry. In addition, sponsors may be subject to Part D program compliance and enforcement actions as a result of MPF suppressions or inaccurate data submissions.

Please refer to **Appendix C** for a comprehensive inventory of the validations to be performed in CY 2021 across all three levels.

CMS recommends that Part D sponsors carefully review Appendix C as soon as possible to fully understand how validations have been updated for CY 2021.

Because of these changes, the results produced by HPMS for CY 2021 submissions may be different than the results received during CY 2020 for the same files. Failure to update drug pricing file generation processes to account for these differences for CY 2021 submissions could increase the likelihood of a suppression on MPF.

CY 2021 Drug Pricing Submission Rules

Only eligible Part D sponsors may resubmit pricing data during the second window of the two week submission period. The following table illustrates the circumstances under which a sponsor may resubmit in week two.

What happened in the first window?	Level One Results	Level Two Results	Level Three Results	Can the sponsor submit in the second window?
Sponsor does not submit any pricing data in HPMS.	N/A	N/A	N/A	No
Sponsor submits, but fails level one.	Fail	N/A	N/A	No

What happened in the first window?	Level One Results	Level Two Results	Level Three Results	Can the sponsor submit in the second window?
Sponsor submits and passes all levels.	Pass	Pass	Pass	No ¹
Sponsor submits, passes levels one and two, but triggers an outlier in level three.	Pass	Pass	Fail	Yes
Sponsor submits, passes level one, triggers an outlier in level two, but passes level three.	Pass	Fail	Pass	Yes
Sponsor submits, passes level one, but triggers outliers in levels two and three.	Pass	Fail	Fail	Yes

Please note the following:

- If a Part D sponsor submits multiple times during either the first or second window, HPMS will consider the last one to be the sponsor's official submission, regardless of its status.
- A submission will be included in the Level Three validation as long as it was processed through Level Two.

File Specifications

For CY 2021, Part D sponsors will use the same pharmacy cost file, pricing file, and ceiling price file layouts that are currently in use for CY 2020 submissions. These file layouts are provided in **Appendix D** (pharmacy cost), **Appendix E** (pricing file), and **Appendix F** (ceiling price).

Submissions must adhere to the following specifications:

- For each contract number, HPMS requires one pharmacy cost (PC) file, one pricing file (PF), and if applicable, one ceiling price (CP) file.

¹ Sponsors that subsequently identify an error in their data from the regular submission window (i.e., the first submission period of the two week cycle) may submit a request to planfinderqa@cms.hhs.gov to resubmit in the correction window. CMS will review these requests on a case-by-case basis. If a suppressible error is discovered during the correction window, the contract will be suppressed on MPF.

- All files must be prepared as fixed length, tab-delimited text (.txt) files.
- All files must follow these Float(12) and Currency(12) guidelines:
 - Do not include the decimal point
 - Format structure of \$\$\$\$\$\$cccc
 - \$\$\$\$\$\$ are the numbers to the left of the decimal point (with leading zeros)
 - cccc are the numbers to the right of the decimal point (with trailing zeros)

Examples:

\$1.50 = 0000000015000
 10% = 000000001000

- Each file must have a header record that includes:
 - Contract number (letter plus four numbers)
 - Contract year (YYYY)
 - Record count for the entire file (num (9) with leading zeros) (XXXXXXXXXX)
 - Create date (CCYYMMDD)

Sample Header Record – H9999202100000001020200710

(Contract number is H9999; contract year is 2021; record count is 000000010; and create date is 20200710)

- Each file must have a footer record that includes:
 - Contract number (letter plus four numbers)
 - EOF (for End of File)

Sample Footer Record – H9999EOF

- Each file must use the following naming convention: ContractIDXX.txt
 - Contract ID is the five position (one letter followed by four numbers) contract number issued by CMS
 - XX is the abbreviation for each of the three files (i.e., PC, PF, and CP)
 - Example: H9999PC.txt
- These files must be packaged in a single zip file that uses the following naming convention: ContractID.zip
 - Example: H9999.zip

Timeline for CY 2021 Data Submissions for October 1, 2020 MPF Launch

The CY 2021 pricing data is scheduled to be published on MPF on October 1, 2020. The following table outlines the key submission, preview, and release schedules leading up to the October 1, 2020 publication.

HPMS will administer each test submission window according to the typical two-week cycle as described in the “CY 2021 Drug Pricing Submission Schedule” section above. In other words, the system will follow the same daily schedule, apply the full set of validations and accept attestations during each test submission window as it would during a production window.

Start Date	End Date	Event	Comments
July 6, 2020 6:00 a.m. ET	July 9, 2020 12:00 p.m. ET	Part D sponsors perform test submission #1 of their CY 2021 pricing and pharmacy data in HPMS. Data from test submission #1 will <u>not</u> be publicly released.	Eligible sponsors can resubmit from July 10 (12:00 p.m. ET) through July 15 (12:00 p.m. ET).
July 27, 2020 6:00 a.m. ET	July 30, 2020 12:00 p.m. ET	Part D sponsors perform test submission #2 of their CY 2021 pricing and pharmacy data in HPMS. Data from test submission #2 will <u>not</u> be publicly released.	Eligible sponsors can resubmit from July 31 (12:00 p.m. ET) through August 5 (12:00 p.m. ET).
August 12, 2020	August 18, 2020	Part D sponsors participate in the first preview of their CY 2021 drug pricing data in HPMS.	This preview will be populated with data from test submission window #2.
August 17, 2020 6:00 a.m. ET	August 20, 2020 12:00 p.m. ET	Part D sponsors perform test submission #3 of their CY 2021 pricing and pharmacy data in HPMS. Data from test submission #3 will <u>not</u> be publicly released.	Eligible sponsors can resubmit from August 21 (12:00 p.m. ET) through August 26 (12:00 p.m. ET).
August 31, 2020 6:00 a.m. ET	September 3, 2020 12:00 p.m. ET	Part D sponsors perform their final CY 2020 pricing and pharmacy data submissions in HPMS before CY 2021 open enrollment begins.	Eligible sponsors can resubmit from September 4 (12:00 p.m. ET) through September 9 (12:00 p.m. ET).

Start Date	End Date	Event	Comments
September 8, 2020 6:00 a.m. ET	September 11, 2020 12:00 noon ET	Part D sponsors participate in the second preview of their CY 2021 drug pricing data in HPMS.	This preview will be populated with data from test submission window #3.
September 14, 2020 6:00 a.m. ET	September 17, 2020 12:00 noon ET	Part D sponsors perform their first CY 2021 production pricing and pharmacy data submission in HPMS. These data will be published on MPF on October 1, 2020.	Eligible sponsors can resubmit from September 18 (12:00 p.m. ET) through September 23 (12:00 p.m. ET).
October 1, 2020	October 1, 2020	CMS launches the CY 2021 drug pricing data on MPF.	MPF will use the drug pricing data from the September 14-17 submission cycle.

General Submission Guidance

In support of the MPF, Part D sponsors are required to:

- Ensure that there are a sufficient number of individuals with the HPMS access required to perform the CY 2021 drug pricing submissions.
- Participate in the scheduled test submission windows and plan previews, as outlined in this memo.
- Prepare and submit their drug pricing files in accordance with the technical specifications and timelines provided in this memo.
 - If multiple files are submitted for a given contract number, HPMS will consider the latest one that is received to be the official submission on record. If a prior submission is successful, but the last submission is not, HPMS will use the results from the last submission.
- Submit complete pricing files for each contract number during every two-week submission cycle.
 - When changes occur, submit updated pricing files.
 - When no changes have occurred, submit the same pricing files from the previous cycle.
- Monitor and review the submission status and validation results as presented in HPMS.
- Address validation errors, as needed, and resubmit pricing files to HPMS.

- Complete plan attestations in HPMS, where applicable.

CMS strongly recommends that plans submit their pricing files as early as possible in order to retrieve the validation results and resubmit accordingly.

Preparing the Pharmacy Cost File

Part D sponsors are required to adhere to the following guidance when preparing the pharmacy cost (PC) file:

- Pharmacy network submissions for MPF must be a full representation of the Part D sponsor's contracted retail and mail order network pharmacies. All pharmacies submitted for MPF display must be identified as either retail or mail order based on the sponsor's retail and mail order pharmacy network contracts.
 - Any contracted pharmacy that only serves as a long-term care (LTC), home infusion (HI), limited access (LA), or any other non-retail or non-mail pharmacy type **may not** be included in the PC file.
 - A pharmacy that serves both as retail and/or mail order and as LTC, HI, or LA organizations may be included in the PC file. In the PC file, sponsors must ensure that the retail and/or mail order pharmacy flag(s) are set to "1," in accordance with their network contracts.
 - If a Part D sponsor submits pharmacies that are not flagged as either retail or mail order (i.e., PHARMACY_RETAIL=0 and PHARMACY_MAIL=0), their pricing data will be suppressed in MPF. Conversely, an organization must not falsely flag pharmacies contracted to only serve as LTC, HI, or LA as a retail network or mail network order pharmacy, if not contracted as such, in their PC file.
- There must only be one record per network pharmacy/plan.
- All PRICE_IDs listed in the PC file must exist in the corresponding pricing file (PF).
- If a sponsor's network has Preferred Network pharmacies, then there must also be Standard Network pharmacies.
 - In other words, if a sponsor has indicated "1" (i.e., Preferred Network Pharmacy), the PC file must also have a "0" (i.e., Standard Network Pharmacy).
 - If a sponsor's network does not have Preferred Pharmacies, then all pharmacies must be indicated as "0" (i.e., Standard Network Pharmacy).
 - As defined in the regulation 42 CFR § 423.104, a *preferred pharmacy* is a network pharmacy that offers covered Part D drugs at negotiated prices to Part D enrollees at lower levels of cost sharing than would apply at a non-preferred pharmacy under its pharmacy network contract with a Part D sponsor.

- PHARMACY_RETAIL and PHARMACY_MAIL are present to indicate whether a particular contracted network retail or mail order pharmacy offers drug sales at either a standard retail supply or a mail order supply. If both services are offered, enter “1” for both fields. Otherwise, enter a “1” only for the applicable pharmacy type.

Example: If pharmacy #101234567890 offers 30, 60, and 90 day retail and 90 day mail order, the pharmacy cost file would be prepared as follows:

```
H9999 001 000 101234567890 100 000000030000 000000015000 000000200000 0 1 1 0
0 0 0 000000060000 000000030000 000000090000 000000045000
```

- Pharmacies that offer both retail and mail order pharmacies can designate different preferred network pharmacy statuses. Please note that the preferred status of both retail and mail order pharmacies as presented in the PC file must match the sponsor’s CY 2021 bid submission.
- For pharmacies that offer both retail and mail order pharmacies and have different dispensing fees for retail and mail order pharmacies, the highest dispensing fee must be entered (applies to BRAND_DISPENSING_FEE_30, GENERIC_DISPENSING_FEE_30, BRAND_DISPENSING_FEE_60, GENERIC_DISPENSING_FEE_60, BRAND_DISPENSING_FEE_90, and GENERIC_DISPENSING_FEE_90).
- The maximum cost of administering any covered vaccine under the respective price ID must be entered. If a vaccine requires a series of administrations, include the cost of one (1) dose.
- Floor pricing is used when a sponsor negotiates a minimum price that a given pharmacy will be paid for filling a prescription. Floor pricing is often used for very low cost generics. Please note that floor pricing is applied to drugs when the full cost is less than the floor price. This full cost includes the dispensing fee.

Example: A sponsor has a floor price of \$3 in price ID 101 at Pharmacy A. The sponsor would submit pharmacy records in the following format:

```
H9999 001 000 101234567890 101 000000015000 000000015000 000000000000
010000 0 000000030000 000000015000 000000015000 000000015000 000000015000
```

If drug Z has a full cost of \$4 at Pharmacy A, then MPF will display the standard full cost.

If drug Y has a full cost of \$2.50 at Pharmacy A, then MPF will display the floor price of \$3.

Preparing the Pricing File

Part D sponsors are required to adhere to the following guidance when preparing the pricing file (PF):

- MPF displays one cost for all National Drug Codes (NDCs) for a given brand name, generic name, dosage form, route of administration, and strength combination. Sponsors must submit records, as described in this memo, with unit costs for all of the specific NDCs listed on the CMS Formulary Reference File (FRF) that are also present on the corresponding approved plan formulary.
- Enhanced alternative plans that submitted a supplemental excluded drug file in HPMS must also include the pricing for the related NDCs in this submission.
- Failure to submit pricing for an NDC/RXCUI on the plan's approved formulary will result in the display of a default drug price (to approximate cash pricing) on MPF.
- Submission of pricing for NDCs that are not included on the plan's approved formulary will also result in the display of default pricing.
- The pricing file determines the base unit cost of an NDC in the associated PRICE_ID.
- The PRICE_ID field is determined by the Part D sponsor using the following parameters:
 - The lowest available PRICE_ID is 001.
 - PRICE_IDs are assigned sequentially.
- Ranges of PRICE_IDs are no longer reserved for certain types of pharmacies. As long as the lowest available PRICE_ID is 001, and the PRICE_IDs are assigned sequentially, sponsors may associate a given PRICE_ID to any type of pharmacy (i.e., retail or mail order).
- The pricing file is associated with a plan through the pharmacy cost file.
- Every drug from the formulary must be covered under each PRICE_ID.
- Unit pricing can be provided for 30, 60, and 90-day supplies at either a retail or mail-order pharmacy. Pricing must not be included for any DAYS_SUPPLY that is other than 30, 60, or 90. For example, a 34-day supply is not supported and will produce a level 2 fatal error (i.e., invalid record format).

- Plans must review their pricing data prior to submission.
- HPMS will treat a value of **000000000000** in the Unit_Cost field of the pricing file as a “true” \$0 unit cost. This value will no longer trigger the display of default pricing on MPF.
- An NDC can be listed up to 6 times, as long as the DAYS_SUPPLY and IS_MAIL fields are unique (i.e., 30-Retail, 30-Mail Order, 60-Retail, 60-Mail Order, 90-Retail-90, or 90-Mail Order).
- Pricing must be included for all DAYS_SUPPLY and IS_MAIL types offered by the plan benefit package. If drug pricing is provided for a type that the plan has not defined as covered, those prices will be ignored.

Example: If a pharmacy offers 30, 60, and 90 day supply at retail and 90 day supply at mail order under PRICE_ID 100, the following records must be included in the pricing file:

```
S1234 100 12345678910 30 0 000000080000 0
S1234 100 12345678910 60 0 000000125000 0
S1234 100 12345678910 90 0 000000160000 0
S1234 100 12345678910 90 1 000000100000 0
```

The above structure indicates that NDC 12345678910 has a UNIT_COST of \$8.00 for a 30-day retail supply, \$12.50 for a 60-day retail supply, \$16.00 for a 90-day retail supply, and \$10.00 for a 90-day mail order supply. If the plan submitted a UNIT_COST for this drug at a 30- or 60-day mail order pharmacy, those unit costs would be ignored. If the plan did not provide a price for this drug at 30 day supply at retail, MPF would display a default price.

- Plans that have vaccines in their formulary are required to include pricing for vaccines in all PRICE_IDs, including those PRICE_IDs specifically designated for mail order. Please refer to the pharmacy cost file layout for more information.
- Related NDCs contained on the CY 2021 FRF must be used for the submission of Part D drug pricing files.

Example: Zocor 10 MG and Simvastatin 10 MG are represented on the CY 2021 FRF as follows:

RXCUI	TTY	RxNorm Description	Related NDC
314231	SCD	SIMVASTATIN 10 MG ORAL TABLET	16729000417
104490	SBD	SIMVASTATIN 10 MG ORAL TABLET [ZOCOR]	00006073531

- When submitting pricing for Zocor 10 MG and Simvastatin 10 MG, the sponsor must adhere to the following:

- For Simvastatin 10 MG, RXCUI 314231 is used for the HPMS formulary submission, while the related NDC 16729000417 is used for the pricing file submission.
- For Zocor 10 MG, RXCUI 104490 is used for the HPMS formulary submission, while the related NDC 00006073531 is used for the pricing file submission.

Example: The sponsor would use the following format when submitting pricing data for these two drugs, assuming 30-day retail supply and no ceiling price:

```
H1001 101 16729000417 30 0 000000000846 0
H1001 101 00006073531 30 0 000000053128 0
```

- CMS may update the related NDCs associated with RXCUIs due to factors such as changes in the marketing status of the FRF NDCs. These changes will be included in CMS' updates to the CY 2021 FRF. Sponsors will be required to submit updated pricing files that reflect the new related NDCs for RXCUIs on their last approved HPMS formulary file.
- The RXCUIs for supplies associated with the administration of insulin, prenatal vitamins, and fluoride preparations do not have related NDCs and are not displayed on MPF. Therefore, sponsors are prohibited from submitting pricing for insulin supplies, prenatal vitamins, and fluoride preparations.
- If the sponsor is unable to provide pricing data for a particular related NDC, they must submit pricing based on the most comparable drug product. Regardless, the pricing file must contain the related NDC from the FRF. Each NDC pricing must be based on the cost at the point of sale (POS). Sponsors must not submit pricing based on the assumption that a generic NDC will be substituted for a brand NDC.

Common examples of a “unit” for formulations are:

- **Solid Oral Dosage Forms** - For oral tablets with a unit of “EACH” (i.e., one unit of Simvastatin 20 mg is one tablet of Simvastatin 20 mg).
- **Liquid** - For liquid, a unit can be defined in several ways, such as one “vial,” “syringe,” or as “1MG,” depending upon the availability of packaging for the drug. For example, one unit of Fortaz INJ (All strengths) or Protonix INJ (40MG) is represented by a vial, while one unit of Aralast 500MG vial is represented by 1MG.
- **Nebulizers** - For inhalers or nebulizers, similarly to liquid, a unit can be defined in several ways. For example, one unit of albuterol is represented by per “ML,” while one unit of Proair HFA is represented by “GM” instead of bottle of vial.
- For pharmacies that offer different price structures at the point-of-sale for different pharmacy services (i.e., retail versus mail versus LTC), the unit cost field must reflect the applicable retail cost for retail pricing or the mail order price for mail order pricing (this applies to both brand and generic drugs and the UNIT_COST field).

Example: If a pharmacy is marked as retail and HI, the cost must reflect the price to be paid by the beneficiary at retail. If the pharmacy is marked as mail order and HI, the cost must reflect the price to be paid by the beneficiary at mail order. Similarly, if a pharmacy is marked as retail, mail, and HI, the cost submitted must be the applicable retail or mail order cost per the pricing file.

Sponsors must indicate if the pharmacy dispenses retail, mail, or both in the pharmacy cost file as well as use the IS_MAIL indicator to ensure the display of the proper unit cost on MPF. MPF is not designed to display the LTC, HI, or LA pharmacy drug costs, so only retail or mail order costs may be provided.

- Ceiling pricing is used when a sponsor negotiates a maximum price that a given pharmacy will be paid for a specific NDC. Ceiling pricing is often used for high cost generics. If ceiling pricing is provided in the ceiling price file for an NDC, the sponsor must enter “1” in the HAS_CEILING_COST field.

Example: H1001 101 00001234567 30 0 000000050000 1

In this example, the plan will provide the ceiling cost for a 30-day retail supply of this drug in price ID 101 at this pharmacy.

Preparing the Ceiling Cost File

Part D sponsors are required to adhere to the following guidance when preparing the ceiling cost file (CF):

- This file determines the ceiling cost of an NDC in the associated PRICE_ID within a certain range of quantity.
- The ceiling price file is associated with a plan through the pricing file.
- Every drug from the pricing file that has indicated “1” in the HAS_CEILING_PRICE field must be priced within the ceiling price file.
- Ceiling pricing is used when a sponsor negotiates a maximum price that a given pharmacy will be paid for a specific NDC. It is often used for high cost generics.
 - A plan has a ceiling price of \$100 for a 30-day retail supply of a drug in price ID 101 at this pharmacy with a dispensing fee of \$2. The plan would use the following format when submitting a pricing file record:

H1001 101 00001234567 30 0 030000 000001000000

Since this drug has a UNIT_COST of \$5 (defined in the PF file), it would cost \$152 for a quantity of 30 tablets ($\$5 * 30 \text{ quantity} + \2 dispensing fee). Because

there is a ceiling price of \$100 for a 30-day supply, MPF will display \$100 as the full drug cost of this particular drug.

- Ceiling price can be provided at varying quantity ranges for an NDC.
 - Example: A pharmacy offers ceiling prices for a 30-day supply at retail for a given drug. The ceiling price is \$4 at quantity 180 and \$6 at quantity 360. The sponsor would use the following format in the ceiling price file:

S1234 100 12345678910 30 0 180000 000000040000
S1234 100 12345678910 30 0 360000 000000060000

End User Support Resources

Support Resource	Contact Information
Technical support for the Part D drug pricing submission process in HPMS	HPMS Help Desk 1-800-220-2028 hpms@cms.hhs.gov
Questions regarding drug pricing file validations	PlanFinderQA@cms.hhs.gov
General HPMS user access questions	hpms_access@cms.hhs.gov
HPMS consultant user access requests	HPMSConsultantAccess@cms.hhs.gov
General MPF Questions	MPF@cms.hhs.gov

Frequently Asked Questions

1. How do I get access to the Part D Pricing File Submission module in HPMS?

In order to access the new Part D Pricing File Submission module in HPMS, a user requires a CMS user ID, the HPMS production job code to be assigned to that user ID, and the module's plan access types assigned to that user ID. Details are provided in the "Getting Access to the HPMS Part D Pricing File Submission Module" section of this memo.

General HPMS user access guidance is also available at the following website:

<https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/UserIDProcess.html>

2. I have an active CMS user ID with access to HPMS. How do I request access to the new module for my existing account?

To request access to the Part D Pricing File Submission module, a request must be sent to the HPMS User Access mailbox (hpms_access@cms.hhs.gov) with the name, CMS user ID, organization name, contract number(s), and specific access types required:

Part D Pricing Submission - Plan
Part D Pricing View/Reports - Plan

3. Can a third party, such as a pharmacy benefit manager (PBM), submit pricing files on our behalf in HPMS?

Yes. Pricing files can be submitted in HPMS by both plan users and designated PBM or consultant users. Please refer to the April 14, 2020 memo entitled “Instructions for Requesting Consultant Access to the Health Plan Management System (HPMS)” (<https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/UserIDProcess.html>) for detailed guidance on requesting this type of access for a third party user.

4. Is there a limit on the number of users that can access HPMS for a given organization?

No. There is no limit on the number of users that can be registered in HPMS for a given organization.

5. Is there an alternative method to transmit my pricing files to CMS?

Yes. Beginning with CY 2021, Part D sponsors have the option to submit their Part D pricing files via an HPMS API. Further details will be provided under separate cover.

6. Can I submit pricing files for multiple contracts at one time in HPMS?

Yes. HPMS allows a user to select and upload multiple contract-level zip files at one time.

7. There are no changes to my drug pricing files for the upcoming submission cycle. Am I still required to submit files to HPMS?

Yes. Sponsors are required to submit pricing files for every two-week submission cycle, even if there are no changes to the data. If there are no changes, then sponsors are required to submit the same files for the upcoming submission cycle. Conversely, if there are changes, then sponsors are required to submit updated files for the upcoming submission cycle.

8. What data needs to be submitted by sponsors during each test submission period?

Sponsors must upload a complete submission. A complete submission for a given contract number includes one pharmacy cost file, one pricing file, and if applicable, one ceiling price file.

9. Which drug pricing data will be used for the initial launch of the CY 2021 Medicare Plan Finder?

CMS will use the CY 2021 data submitted by Part D plans during the September 14-23, 2020 cycle (i.e., September 14-17 for initial submissions and September 18-23 for eligible resubmissions) for the October 1, 2020 launch of the CY 2021 MPF.

10. Who do I contact for technical support with this process?

The HPMS Help Desk can be reached at either hpms@cms.hhs.gov or 1-800-220-2028.

11. Are all Part D plans required to submit drug pricing to CMS?

All Part D sponsors are required to submit drug pricing to CMS, with the exception of the following plans: employer-only; PACE; and 1876 and 1833 cost.

12. If my plan offers over-the-counter (OTC) drugs as part of a supplemental benefit, should I include them in my pricing file submission?

No. OTC drugs (where a plan has indicated OTC coverage in their Part D PBP submission) are provided to the beneficiary without any direct cost sharing at the point of sale. As such, they should not be included in the pricing file submission.

13. Can I submit pricing for drugs that are not included on my plan's approved formulary?

No. Sponsors may only submit pricing for drugs on the approved formulary, and in the case of enhanced alternative plans, the approved supplemental excluded drug file, that are associated with a related NDC and/or NDCs.

14. If my plan does not submit files during a regular submission, is there another opportunity to submit files?

No. If a plan does not submit files during a regular submission (i.e., the first submission period of a two-week cycle), they will be suppressed in the next MPF update.

15. Can we submit data for non-existent Plan IDs or Segment IDs?

No. Sponsors may only submit data for valid plan IDs and segment IDs that are offered by a given contract number. Sponsors that attempt to submit pricing data for invalid plan IDs and segment IDs will be suppressed on MPF and may face a compliance action.

16. Can a plan submit pricing data for pharmacies that are contracted as LTC, HI, or LA pharmacies?

Sponsors may only submit pricing data for LTC, HI, and LA pharmacies when they are also contracted with the sponsor as network retail or mail order pharmacies. To reflect this type of arrangement in the pharmacy cost file, sponsors must accurately set the retail and/or mail order pharmacy flag to “1” per their network contracts and set the flags for the LTC, HI, and LA pharmacies to “1,” as applicable.

If these pharmacies are only contracted with the sponsor as LTC, HI, LA, or as another non-retail or non-mail pharmacy type, the sponsor is prohibited from including them in their drug pricing submission. Moreover, sponsors may not falsely flag pharmacies that are only contracted as LTC, HI, or LA in the pharmacy cost file as network retail or mail order pharmacies.

17. What determines a plan’s eligibility to submit during a correction submission window?

Sponsors that received an error in their last upload during the first submission period of the two cycle are eligible to resubmit during the correction window (i.e., the second submission period of the two-week cycle). Please refer to the “CY 2021 Drug Pricing Submission Rules” section of this memo for detailed guidance.

Sponsors that subsequently identify an error in their data from the regular submission window (i.e., the first submission period of the two-week cycle) may submit a request to planfinderqa@cms.hhs.gov to resubmit in the correction window. CMS will review these requests on a case-by-case basis. If a suppressible error is discovered during the correction window, the contract will be suppressed on MPF.

18. If in my plan’s uploaded PBP we have indicated that preferred mail order pharmacies are offered as a benefit, must there be preferred mail order pharmacies in the bi-weekly pricing files submitted to display on the Medicare Plan Finder?

Yes. Drug pricing submissions must be consistent with the corresponding plan’s approved plan benefit package submission. If the plan’s benefit package indicates that preferred mail order pharmacies are offered as a benefit, then the drug pricing submission must contain at least one mail order pharmacy that is marked as preferred. Conversely, if the plan’s benefit package indicates that preferred mail order pharmacies are not offered as a benefit, then the drug pricing submission may not contain mail order pharmacies that are marked as preferred.

Where a drug pricing submission differs from the corresponding approved plan benefit package, the contract will be suppressed on MPF.

Point-of-Sale Rebates

Current Part D rules allow sponsors to apply rebates at the point of sale. Below we address questions about MPF pricing file submissions from Part D plan sponsors that must apply (in the case of pharmacy price concessions that can reasonably be determined at the point of sale) or that wish to apply rebates or other price concessions, which we will collectively refer to as “rebates” for the purposes of this guidance, to the price at the point of sale.

19. Can Part D sponsors submit point-of-sale rebate data separately on the drug pricing files? Will the point-of-sale rebate be displayed on MPF?

No. For CY 2021, Part D sponsors will use the same pharmacy cost file, pricing file, and ceiling cost file layouts that are currently in use for CY 2020 submissions. Point-of-sale rebate information will not be reported separately in the pricing files nor displayed separately on MPF. Part D sponsors that apply rebates to the point-of-sale price of a drug must continue to submit the drug's negotiated price in their pricing files, which would be net of the rebates the sponsor applies at the point of sale. For example, if the unit cost for a drug is **\$20**, and the sponsor applies a **\$10** point-of-sale rebate to the unit cost for that drug, then the Part D plan must enter **\$10** into the unit cost field in the pricing file.

20. Which field(s) of the drug pricing files should any point-of-sale rebates be applied to – unit cost, dispensing fee, or both? What should be reported in instances where the point-of-sale rebate exceeds the unit cost?

Part D sponsors that apply rebates at the point of sale must apply the point-of-sale rebate only to the drug's unit cost reported in the pricing file, up to the full value of the unit cost, and not the dispensing fee. In the event that the point-of-sale rebate is greater than the drug's unit cost, the sponsor must submit a \$0 unit cost for that drug. HPMS will treat a value of **0000000000** in the unit cost field of the pricing file as a \$0 unit cost, and this value will no longer trigger the display of default pricing on Medicare Plan Finder (MPF). We cannot accept a negative unit cost at this time. Please note that default pricing will still be calculated and displayed when a formulary drug is not submitted by the plan sponsor, and also will be displayed for non-formulary drugs and out-of-network pharmacies.

Additionally, while point-of-sale rebate amounts might vary at the NDC level, the sponsor must continue to price the related NDC specified by CMS and include in the reported price only the point-of-sale rebates for that related NDC. If a plan is unable to provide pricing data for a related NDC, the plan should submit pricing for the most comparable drug product. The pricing files must still contain the related NDC.

If the point-of-sale rebate amount is not dependent on the number of units dispensed, the sponsor must allocate the flat or bundled rebate amount to the unit level. Pricing of each NDC should be based on the cost at the point of sale. Sponsors may determine how to allocate the rebate amount to the unit level in the most representative manner, and may opt to use the average or most frequently dispensed quantity.

In a similar fashion, if the point-of-sale rebate amount is based on a "bundled" arrangement, sponsors may use the allocation methodology determined to yield the most representative price that the member will encounter at point of sale for the various NDCs and unit amounts included under each bundled arrangement.

21. If the application of rebates at the point of sale creates a need for additional price file IDs, will CMS expand the number of price file IDs available to plans?

Beginning in CY 2021, ranges of PRICE_IDs are no longer reserved for certain types of pharmacies. As long as the lowest available PRICE_ID is 001, and the PRICE_IDs are

assigned sequentially, plans may associate a given PRICE_ID to any type of pharmacy (i.e., retail or mail order).

22. Will Part D sponsors applying rebates to the point of sale be given more time to update their drug pricing files?

No. All Part D sponsors will be required to update their drug pricing data on a biweekly schedule, regardless of whether they apply rebates to the point-of-sale price.