

PBM Transparency in Coverage Reporting by Qualified Health Plan Issuers

Appendix C – QHP issuer Data Collection

Introduction

Pharmacy Benefit Managers (PBMs) and issuers of Qualified Health Plans (QHPs) will use the web form (Appendix A) and the template (Appendix B) to submit required information related to prescription benefits via a HIOS module on an annual basis. PBMs will use the attestation (Appendix D) to attest to the data's accuracy, completeness, and truthfulness, based on their best knowledge, information, and belief. PBMs must provide the completed template in an electronic format. The following document provides instructions for completing the data submission process and guidelines for complying with the data requirements.

HIOS Account Creation and Template Retrieval

Submitters must establish an account within the HIOS Pharmacy Benefits Managers Collection Module and designate a single point of contact to grant other users within their company access to perform PBM functions in HIOS. After creating an account and designating a point of contact, the submitter may download a copy of the template from HIOS.

Template File Submission Format

Submitters must submit their completed templates as a tab delimited text (.txt) file for submission in HIOS. Once the submitter has fully completed the required data elements on the Excel template, it must be converted to the tab delimited text (.txt) file to be uploaded to HIOS for submission. This can be done by first locating the "Save As" option in Excel. Submitters must save the template with the convention "[Calendar Year] - [Issuer Name] - [HIOS ID] - Template [X]". After naming the template, the submitter must select "Text (Tab delimited)" from the drop-down menu under the "Save as Type" on the popup window and then select "Save." Figure 1 below indicates the process by which this can be done.

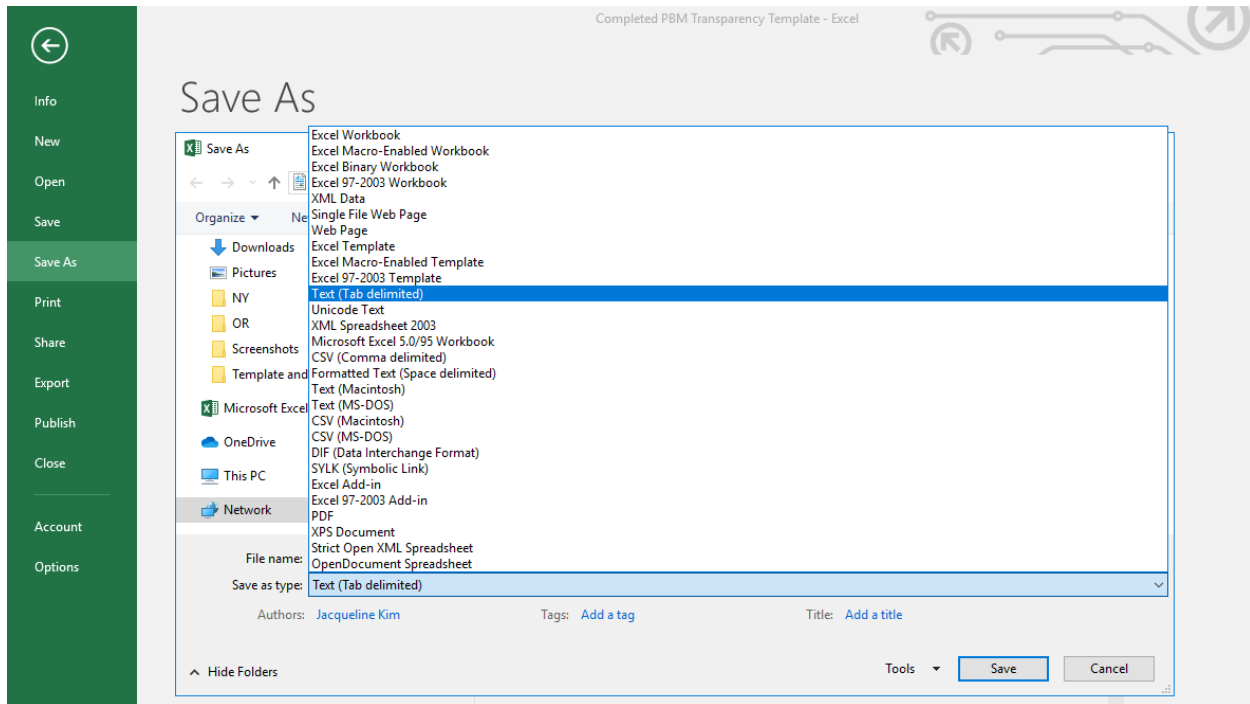


Figure 1. How to convert Excel templates to .txt files for submission

Allocation methodology

PBMs or issuers that do not contract with a PBM are required to report PBM financial and prescription data at the QHP issuer and 11-digit NDC level. We are aware, however, that some submitters may receive and/or record data at the product or plan level instead. To satisfy the reporting requirements, submitters must allocate data to the QHP issuer and 11-digit NDC level using reasonable allocation methodologies. A description of all allocation methodologies used to report data at the issuer and/or 11-digit NDC level must be submitted by the submitter in HIOS as part of the PBM Transparency Reporting.

CMS has identified several reasonable allocation methodologies (see below) and requires that submitters select the applicable option from a dropdown menu when reporting the allocation methodology used. Submitters must make one selection from a dropdown menu specifying an allocation methodology for reporting data at the issuer level and one selection from a dropdown menu specifying an allocation methodology for reporting data at the 11-digit NDC level. If data was already received from the manufacturers at the issuer and/or 11-digit NDC level, submitters should make the “No allocation method needed” selection from the dropdown menu.

In the event that a submitter uses different allocation methodologies for different types of data, the must select the “Other” option and describe in a comment the allocation methodologies used and the data category for which each methodology was used. CMS may need to follow-up with submitters to better understand allocation methodologies. Submitters should keep internal documentation of all allocation methodologies used in anticipation of explaining them to CMS.

The options included in each dropdown menu are the following:

Allocation Methodology to the QHP issuer level

1. No allocation method needed to the QHP issuer level. Data was received from the manufacturer at the QHP issuer level.
2. Allocation to the QHP issuer level based on Actual Drug Utilization
3. Allocation to the QHP issuer level based on issuer's Total Drug Spend
4. Allocation to the QHP issuer level based on issuer's Brand Drug Spend
5. Allocation to the QHP issuer level based on Total Drug Spend for Drugs in Preferred Brand Tier
6. Allocation to the QHP issuer level based on Billed Rebate Amounts
7. Other allocation to the QHP issuer level (comments are required)

Allocation Methodology to the 11-digit NDC level

1. No allocation method needed to the 11-digit NDC level. Data was received from the manufacturer at the 11-digit NDC level.
2. Allocation to the 11-digit NDC level based on Actual Drug Utilization
3. Allocation to the 11-digit NDC level based on Plan's Total Drug Spend
4. Allocation to the 11-digit NDC level based on Plan's Brand Drug Spend
5. Allocation to the 11-digit NDC level based on Total Drug Spend for Drugs in Preferred Brand Tier
6. Allocation to the 11-digit level based on Billed Rebate Amounts
7. Other allocation to the 11-digit NDC level (comments are required)

Table 2 provides examples of the allocation methodologies listed above and indicates whether they are considered reasonable for allocating manufacturer rebate amounts to the QHP issuer and 11-digit NDC levels. Please note that our determination of the reasonableness of the various allocation methodologies presented in Table 2 below is specific to the allocation of manufacturer rebates, and that some of the methodologies determined to be unreasonable for rebate allocation may in fact be reasonable for allocating other categories of data to a QHP issuer or 11-digit NDC. For instance, allocation based on the number of claims, while unreasonable for use with manufacturer rebates, could be appropriate for use with per-claim administrative fees charged to pharmacies.

Submitters, when able, should allocate rebates for a specific drug to the QHP issuer and 11-digit NDC levels based on the actual utilization of that specific drug. Other allocation methodologies may be subject to additional validation. When selecting among the options allowed, submitters should consider the accuracy with which an allocation methodology applies rebate dollars to the applicable QHP issuer or 11-digit NDC.

Submitters selecting “Other allocation to the QHP issuer level” or “Other allocation to the 11-digit NDC level” must provide comments, which must identify the entity responsible for applying the allocation methodology *and* include a clear explanation of the methodology, as well as a specification of each category of data for which the methodology was used. The response “Not Applicable,” or any of its variations, is not an acceptable explanation and will be rejected.

Table 1. Examples of Methodologies for Allocating Rebates to the QHP Issuer Level and 11-Digit NDC Levels

Allocation Methodology	Description	Considered Reasonable?	Explanation
Based on Actual Drug Utilization	Rebate amounts received for a specific drug are allocated to a QHP issuer and 11-digit NDC based on the number of units of the specific drug that were purchased under the QHP issuer as a percent of the total number of units purchased by the PBM.	Yes	Appropriately accounts for differences in a specific drug’s utilization across QHP issuers.
Based on Plan’s Total Drug Spend	Rebate amounts received for multiple drugs are allocated to a QHP issuer based on the total drug spend under the QHP issuer as a percent of the total drug spend under all of a PBM’s QHP issuers, and further to an 11-digit NDC based on the NDC-specific total drug spend under the QHP issuer as a percent of the total drug spending under the QHP issuer.	Yes	Approximates differences in utilization and spending on rebate eligible drugs across QHP issuers.

Allocation Methodology	Description	Considered Reasonable?	Explanation
Based on Plan's Brand Drug Spend	Rebate amounts received for multiple drugs are allocated to a QHP issuer based on the total drug spend for drugs under the QHP issuer as a percent of the total drug spend for brand drugs under all of the PBM's QHP issuers, and further to an 11-digit NDC based on the NDC-specific total drug spend under the QHP issuer as a percent of the total drug spend for brand drugs under the QHP issuer.	Yes, but only if the PBM receives rebates only for brand drugs.	Accounts for differences in utilization and spending on rebate eligible drugs across QHP issuers.
Based on Total Drug Spend for Drugs in Preferred Brand Tier	Rebates received for multiple drugs are allocated to a QHP issuer based on the total drug spend for drugs in the QHP issuer's preferred brand tier as a percent of the total drug spend for drugs in the preferred brand tier of all of the PBM's QHP issuers, and further to an 11-digit NDC based on the NDC-specific total drug spend under the QHP issuer as a percent of the total drug spend for drugs in the preferred brand tier under the QHP issuer.	Yes, but only if the PBM receives rebates only for drugs in the preferred brand tier.	Accounts for differences in utilization and spending on rebate eligible drugs across QHP issuers.
Based on Billed Rebate Amounts	Rebates received for a specific drug are allocated to a QHP issuer and 11-digit NDC based on the rebate amounts billed to the pharmaceutical manufacturer for the specific QHP issuer and drug as a percent of the total rebate amount billed to the pharmaceutical	Yes	Appropriately accounts for differences in a specific drug's utilization across QHP issuers.

Allocation Methodology	Description	Considered Reasonable?	Explanation
	manufacturer for all of the PBM's QHP issuers.		
Based on Enrollment	Rebates received for multiple drugs are allocated to a QHP issuer or 11-digit NDC based on the number of beneficiaries enrolled in the QHP issuer as a percent of the total number of beneficiaries enrolled in all of the PBM's QHP issuers.	No	Does not sufficiently approximate differences in utilization and spending on rebate eligible drugs across QHP issuers.
Based on Advanced Premium Tax Credit (APTC) Subsidy Enrollment	Rebates received for multiple drugs are allocated to a QHP issuer or 11-digit NDC based on the number of LIS beneficiaries enrolled in the QHP issuer as a percent of the total number of LIS beneficiaries enrolled in all of the PBM's QHP issuers.	No	Does not sufficiently approximate differences in utilization and spending on rebate eligible drugs across QHP issuers.
Based on Number of Claims	Rebates received for multiple drugs are allocated to a QHP issuer or 11-digit NDC based on the number of claims under the QHP issuer as a percent of the total number of claims received under all of the PBM's QHP issuers. Thus, allocation is based on the total number of claims for all of the drugs rather than the number of claims received for each drug.	No	Does not sufficiently approximate differences in utilization and spending on rebate eligible drugs across QHP issuers.

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CMS will evaluate the appropriateness of an allocation methodology we have not already identified as appropriate, on a case-by-case basis, using the information submitters provide on the methodology in the comment field.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is **0938-NEW (Expires XX/XX/2023)**. The time required to complete this information collection is estimated to average **203.64 hours per response**, including the time to review instructions, search existing data resources, and gather the data needed, and complete the template and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850. ******CMS Disclosure**** Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained. If you have questions or concerns regarding where to submit your documents, please contact Ken Buerger at Ken.Buerger@cms.hhs.gov, or LeAnn Brodhead at LeAnn.Brodhead@cms.hhs.gov.**

Appendix A, Summary PBM Transparency

Data Element Name	Data Element Description
Calendar Year	The calendar year for which the PBM is submitting data.
PBM Name	The name of the Pharmacy Benefit Manager (PBM).
Issuer Name	The name of the health insurance issuer offering Qualified Health Plans (QHP issuer) for which the PBM is submitting data.
Issuer State	The state where the issuer’s plans are sold.
Issuer HIOS ID	The QHP issuer’s 5-digit Health Insurance Oversight System (HIOS) ID.
PBM Retained Rebates	<p>Include all manufacturer rebates retained by the PBM and not passed through to the QHP issuer.</p> <p>Exclusions: Do not include any rebates expected but not yet received in this row, which must be reported in the “Rebates Expected But Not Yet Received” field. Do not include any rebate administration fees. Do not include any other types of information, even if retained by the PBM.</p>
PBM Retained Rebates (additional comments)	<p>Additional comments explaining why a negative amount was reported are required when the “PBM Retained Rebates” field is negative. This field is limited to 500 characters.</p>
Rebates Expected But Not Yet Received	<p>Include in this row good faith estimates of rebate amounts that are expected by the PBM for the applicable year but have not yet been received from a drug manufacturer, if applicable.</p> <p>All rebate guarantee amounts expected but not yet received from PBMs must also be reported in this row (see the “All Other Rebates” field for a definition of PBM rebate guarantee amounts). Similarly, all rebate amounts received by the PBM that are expected to be passed on to the QHP issuer but have not yet, as of the compilation of this Report, been passed to the QHP issuer must be reported in this row.</p> <p>This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal. This field must not be left blank.</p> <p>Exclusions: Do not include any manufacturer rebates reported in the “PBM Retained Rebates” row. Do not include any other types of remuneration.</p>
PBM Incentive Payments	<p>Include in this row any incentive or bonus payments paid by the QHP issuer to PBMs for performing administrative services for its QHPs, such as negotiating rebates and drug prices as well as increasing generic utilization.</p> <p>This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal. This field must not be left blank.</p>

Data Element Name	Data Element Description
All Other Rebates	<p>Exclusions: Do not include any manufacturer rebates reported in the “PBM Retained Rebates” or “Rebates Expected But Not Yet Received” fields. Do not include rebate guarantee amounts that are expected but not yet received; such amounts must be reported under the “Rebates Expected But Not Yet Received” field. Do not include any other types of remuneration from any other sources.</p> <p>Include all manufacturer rebates actually received from a manufacturer by the PBM and passed through to the QHP.</p> <p>PBM Rebate Guarantee Amounts. Also include any rebate guarantee amounts received from PBMs in connection with the QHP issuer. Rebate guarantee amounts, generally, are payments received by QHP issuers from PBMs to account for the difference between the rebate amount guaranteed by a PBM, as likely delineated in the contract between the two parties, and the actual rebate amount received from a drug manufacturer.</p> <p>Estimated Rebates at Point-of-Sale (POS). The actual manufacturer rebate amounts received for rebates that were estimated and applied to the negotiated price at the POS are also reported in this row.</p> <p>This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal. The value reported in this field may be negative. This field must not be blank.</p>
All Other Rebates (Additional Comments)	<p>Additional comments explaining why a negative amount was reported are required when the “All Other Rebates” field is negative.</p> <p>This field is limited to 500 characters.</p>
Price Concessions for Administrative Services from Manufacturers	<p>Exclusions: Do not include any rebate administration fees collected by the QHP issuer or the PBM. Do not include any pharmacy payments, fees, or adjustments, which are to be reported in the fields “Amounts Received From Pharmacies” and “Amounts Paid to Pharmacies” instead. Do not include any other types of price concessions.</p> <p>Include in this row all price concessions received by a PBM from drug manufacturers for administrative services. Price concessions that are reported here are received when the manufacturer provides administrative services to the PBM at a cost below market value.</p> <p>Also reported in this row are grants from pharmaceutical manufacturers for services and programs such as utilization management and medical education.</p> <p>Applicable price concessions for administrative services that are not associated with a specific drug must be reported in full in this row.</p> <p>Additional Details: This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal. This field must not be left blank.</p>

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Data Element Name	Data Element Description
All Other Price Concessions from Manufacturers	<p>Exclusions: Do not include any price concessions accounted for in the following fields: “PBM Retained Rebates,” “Rebates Expected But Not Yet Received,” “All Other Rebates.” Do not include price concessions from pharmacies, which are reported in the following fields: “Amounts Received from Pharmacies,” “Amounts Paid to Pharmacies.”</p> <p>Additional Details: All price concessions received by a PBM from pharmaceutical manufacturers for reasons not already captured by the previous rows are reported here. Include any amounts received and retained by PBMs. If all price concessions received from manufacturers are captured in the prior rows, the value reported here will be zero. This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal. This field must not be left blank.</p>
All Other Price Concessions from Manufacturers (Additional Comments)	<p>Additional comments are required when the field “All Other Price Concessions from Manufacturers” is a non-zero value. Describe the nature of all other price concessions reported in the “All Other Price Concessions from Manufacturers” field.</p> <p>This field is limited to 500 characters.</p>

Data Element Name	Data Element Description
<p>Amounts Received from Pharmacies</p>	<p>Exclude any pharmacy payment adjustments applied at the POS and all post-POS incentive payments to pharmacies and positive adjustments to pharmacy payments, which must be reported in the “Amounts Paid to Pharmacy Field.” Do not include other types of remuneration.</p> <p>Additional Details: Reported in this row is any sum received by a PBM from a pharmacy after the POS that is not otherwise required to be included in the negotiated price. Include any amounts received and retained by PBMs (i.e., those not passed through to the QHP issuer).</p> <p>Specifically, if a PBM pays a pharmacy a specified amount for a prescription event but recoups some of the payment after the event, if, for instance, the pharmacy has failed to meet performance standards set under a performance-based payment arrangement, the amount recouped by the PBM must be reported in this row if it is not otherwise included in the negotiated price, as it reduces the drug costs of the PBM.</p> <p>Examples of adjustments to be reported in this field include any reconciliation amount that accounts for differences between the contracted rate and the higher adjudicated rate received by the pharmacy at the POS and contingent incentive fees related to, for instance, generic dispensing rates, audit performance/error rates, refill rates, preferred dispensing rates, and/or other performance metrics, including qualitative measures. Such adjustments must only be reported in this row if they reduce the PBM’s costs and are not otherwise included in the negotiated price.</p> <p>This row must also include per-claim administrative fees collected, not paid, by the PBM from pharmacies after the POS that are not included in the negotiated price. Examples of such fees include, but are not limited to, preferred pharmacy fees, fees related to extended supply rates, etc.</p> <p>This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal. This field must not be left blank.</p>
<p>Amounts Received From Pharmacies (Additional Comments)</p>	<p>This field is required when the field “Amounts Received From Pharmacies” is a non-zero value. Describe the types of pharmacy price concessions reported in the “Amounts Received From Pharmacies” field and detail the metrics by which pharmacy performance was assessed, if relevant to the price concession calculation.</p> <p>This field is limited to 500 characters.</p>
<p>Amounts Paid to Pharmacies</p>	<p>Exclusions: Do not include any payments to entities other than pharmacies. Exclude any remuneration received from pharmacies (which is reported in the “Amounts Received From Pharmacies” field). Do not include other types of data.</p> <p>Additional Details: Reported in this row is any sum paid by a PBM to a pharmacy after the POS that is not otherwise required to be included in the negotiated price.</p>

Data Element Name	Data Element Description
	<p>Specifically, if a PBM pays a pharmacy a bonus payment after the POS, the amount paid by the PBM must be reported in this row as a negative amount, if it is not otherwise included in the negotiated price, as it serves to increase the drug costs of the PBM.</p> <p>Examples of adjustments to be reported in this field include any reconciliation amount that accounts for differences between the contracted rate and the lower adjudicated rate achieved by the pharmacy at the POS and contingent incentive payments related to, for instance, generic dispensing rates, audit performance/error rates, refill rates, preferred dispensing rates, and/or other performance metrics, including qualitative measures. Such adjustments must only be reported in this row if they increase the PBM's costs and are not otherwise included in the negotiated price.</p> <p>This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal. The value reported in this field must be negative or zero. This field must not be left blank.</p>
<p>Amounts Paid to Pharmacies (Additional Comments)</p>	<p>Additional comments are required when the "Amounts Paid to Pharmacies" field is a non-zero value. Describe the types of pharmacy incentive payments reported in the "Amounts Paid to Pharmacies" field. Please detail the metrics by which pharmacy performance was assessed, if relevant to the incentive payment calculation.</p> <p>This field is limited to 500 characters.</p>
<p>PBM Spread Amounts for Retail Pharmacies</p>	<p>The aggregate amount of the difference between the amount paid by the QHP issuer to the PBM and the amount the PBM pays retail pharmacies, sometimes referred to as "PBM spread" or "risk premium," must be reported in this row.</p> <p>We emphasize that PBM's must report aggregate values for all PBM spread amounts, not the PBM spread for each retail pharmacy. The value reported here must be for all covered drugs.</p> <p>If issuers use pass-through pricing to pay PBMs, this value must be zero. Issuers that use lock-in pricing to pay PBMs must report in this row the difference between the lock-in price and the price ultimately received by the pharmacy.</p> <p>PBM Spread Amounts for Retail Pharmacies are confidential and shall not be disclosed by CMS, except in a form which does not disclose the identity of a specific PBM, plan, or prices charged for drugs for the purposes of carrying out Section 1150A of Social Security Act.</p> <p>This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal. For a negative value, enter a minus sign and the value for the field. This field must not be left blank.</p>

Data Element Name	Data Element Description
PBM Spread Amounts for Mail Order Pharmacies	<p>The aggregate amount of the difference between the amount paid to the PBM and the amount the PBM pays mail order pharmacies, sometimes referred to as “PBM spread” or “risk premium,” must be reported in this row. We emphasize that PBM’s must report aggregate values for all PBM spread amounts, not the PBM spread for each mail order pharmacy.</p> <p>The value reported here must be for all covered drug costs under EHB, excluding spreads for drugs not covered under EHB.</p> <p>If issuers use pass-through pricing to pay PBMs, this value must be zero. Issuers that use lock-in pricing to pay PBMs must report in this row the difference between the lock-in price and the price ultimately received by the pharmacy.</p> <p>PBM Spread Amounts for Mail Order Pharmacies are confidential and shall not be disclosed by CMS, except in a form which does not disclose the identity of a specific PBM, plan, or prices charged for drugs for purposes of carrying out Section 1150A of Social Security Act.</p> <p>This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal. For a negative value, enter a minus sign and the value for the field. This field must not be left blank.</p>
Allocation Methodology for Issuer Level Data	<p>Dropdown menu with the following options:</p> <ol style="list-style-type: none"> 1. No allocation method needed to the QHP issuer level. Data was received from the manufacturer at the QHP issuer level. 2. Allocation to the QHP issuer level based on Actual Drug Utilization 3. Allocation to the QHP issuer level based on issuer’s Total Drug Spend 4. Allocation to the QHP issuer level based on issuer’s Brand Drug Spend 5. Allocation to the QHP issuer level based on Total Drug Spend for Drugs in Preferred Brand Tier 6. Allocation to the QHP issuer level based on Billed Rebate Amounts 7. Other allocation to the QHP issuer level (comments are required)
Allocation Methodology for Issuer Level Data Comments	<p>Required field if “Other allocation to the QHP issuer level” is selected. This field is limited to 500 characters.</p>
Allocation Methodology for 11-digit NDC Level Data	<p>Dropdown menu with the following options:</p> <ol style="list-style-type: none"> 1. No allocation method needed to the 11-digit NDC level. Data was received from the manufacturer at the 11-digit NDC level. 2. Allocation to the 11-digit NDC level based on Actual Drug Utilization 3. Allocation to the 11-digit NDC level based on Plan’s Total Drug Spend 4. Allocation to the 11-digit NDC level based on Plan’s Brand Drug Spend 5. Allocation to the 11-digit NDC level based on Total Drug Spend for Drugs in Preferred Brand Tier 6. Allocation to the 11-digit level based on Billed Rebate Amounts 7. Other allocation to the 11-digit NDC level (comments are required)
Allocation Methodology for 11-digit NDC Level Data Comments	<p>Required field if “Other allocation to the 11-digit NDC level” is selected. This field is limited to 500 characters.</p>

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Appendix B, Detailed PBM Transparency Template

Data Element Name	Data Element Description
Issuer HIOS Plan ID	The QHP issuer's 14-digit HIOS Plan ID. This number must be entered as exactly 14 digits and letters with no dashes (e.g., 11111MD0002222).
11-digit NDC	PBMs will enter the 11-digit National Drug Code (NDC) in this column. This number must be entered as exactly 11 digits with no dashes (e.g., 55555000102).
Total Number of Prescriptions Dispensed	PBMs will provide the total number of prescriptions dispensed for the associated of NDC.
Total Number of Prescription Drugs Dispensed at Retail Pharmacies	PBMs will provide the total number of prescription drugs dispensed through retail pharmacies.
Total Number of Prescription Drugs Dispensed at Mail Order Pharmacies	PBMs will provide the total number of prescription drugs dispensed through mail order pharmacies.
Total Rebate Amount	PBMs will provide the total rebate amount received.