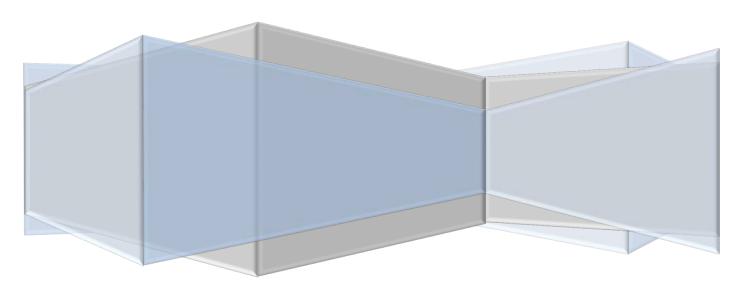# Part D Medication Therapy Management (MTM) Program Area PILOT
AUDIT PROCESS AND DATA REQUEST

Expires: TBD

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Audit Purpose and General Guidelines

1. **Purpose**: To evaluate the implementation of the sponsor's CMS approved Medicare Part D Medication Therapy Management (MTM) Program. The Centers for Medicare & Medicaid Services (CMS) will perform its audit activities using these instructions (unless otherwise noted).

2. **Review Period**: The review period for the MTM program area audit is described below. CMS reserves the right to expand the review period to ensure a sufficient universe size and/or to capture appropriate information according to the sponsor's CMS approved MTM program.

    2.1. **MTM Universe**

    - <u>All</u> beneficiaries who were enrolled in the sponsor's MTM program(s) as required under 42 CFR 423.153(d) (including members enrolled in employer plans and Medicare-Medicaid Plans (MMPs)). This includes all enrollees that were disenrolled from the MTM program during the contract year. Do not include beneficiaries that were offered MTM services, but do not meet the eligibility criteria under section 423.153(d). The audit review period for this universe covers January 1st through December 31st of the contract year <u>immediately prior</u> to the audit year. For example, for audits conducted in 2017, sponsors should populate this universe using the MTM data for the 2016 contract year.

    2.2. **Prescription Drug Event (PDE) Universe -** CMS will extract final action PDE data from the contract year immediately prior to the audit year for audited sponsors from the Integrated Data Repository (IDR). The PDE universe will be used to identify enrollees who were potentially eligible for auto-enrollment in a MTM program for the contract year of interest, but were not enrolled at any time during that year. Beneficiaries that were enrolled by the sponsor in an MTM program for the contract year of interest will be omitted from this universe.

3. **Responding to Documentation Requests**: The sponsor is expected to present its supporting documentation during the audit and take screen shots or otherwise upload the supporting documentation, as requested, to the secure site using the designated naming convention as provided and within the timeframe specified by the CMS Audit Team.

4. **Sponsor Disclosed Issues**: Sponsors will be asked to provide a list of all disclosed issues of non-compliance that are relevant to the program areas being audited and may be detected during the audit. A disclosed issue is one that has been reported to CMS <u>prior</u> to the receipt of the audit start notice (which is also known as the "engagement letter"). Issues identified by CMS through on-going monitoring or other account management/oversight activities during the plan year are not considered disclosed.

    Sponsors must provide a description of each disclosed issue as well as the status of correction and remediation using the Pre-Audit Issue Summary template. This template is due within 5 business days after the receipt of the audit start notice. The sponsor's Account Manager will review the summary to validate that "disclosed" issues were known to CMS prior to receipt of the audit start notice.

When CMS determines that a disclosed issue was promptly identified, corrected (or is actively undergoing correction), and the risk to beneficiaries has been mitigated, CMS will not apply the ICAR condition classification to that condition.

5. **Impact Analysis (IA)**: An impact analysis must be submitted as requested by CMS. The impact analysis must identify all beneficiaries subjected to or impacted by the issue of non-compliance. Sponsors will have up to 10 business days to complete the requested impact analysis templates. CMS may validate the accuracy of the impact analysis submission(s). In the event an impact analysis cannot be produced, CMS will report that the scope of non-compliance could not be fully measured and impacted an unknown number of beneficiaries across all contracts audited.

6. **Calculation of Score:** CMS will determine if each condition cited is an Observation (0 points), Corrective Action Required (CAR) (1 point) or an Immediate Corrective Action Required (ICAR) (2 points). Invalid Data Submission (IDS) conditions will be cited when a sponsor is not able to produce an accurate universe within 3 attempts. IDS conditions will be worth one point.

   NOTE: During the pilot period, the MTM program area results will <u>not</u> be included in the overall audit score nor will they be displayed in the final audit report.

7. **Informing Sponsor of Results:** CMS will provide daily updates regarding conditions discovered that day (unless the case has been pended for further review). CMS will provide a preliminary summary of its findings at the pilot exit conference. The CMS Audit team will do its best to be as transparent and timely as possible in its communication of audit findings. Sponsors will also receive a draft audit report which they may formally comment on; however, during the pilot period the results of this pilot program area will <u>not</u> be included in the final report.

Universe Preparation & Submission

1. **Responding to Universe Requests**: The sponsor is expected to provide accurate and timely universe submissions within 15 business days of the engagement letter date. CMS may request a revised universe if data issues are identified. The resubmission request may occur before and/or after the entrance conference depending on when the issue was identified. Sponsors will have a maximum of 3 attempts to provide complete and accurate universes, whether these attempts all occur prior to the entrance conference or they include submissions prior to and after the entrance conference. However, 3 attempts may not always be feasible depending on when the data issues are identified and the potential for impact to the audit schedule. When multiple attempts are made, CMS will only use the last universe submitted.

   If the sponsor fails to provide accurate and timely universe submissions twice, CMS will document this as an observation in the sponsor's program audit report. After the third failed attempt or when the sponsor determines after fewer attempts that they are unable to provide an accurate universe within the timeframe specified during the audit, the sponsor will be cited an Invalid Data Submission (IDS) condition relative to each element that cannot be tested, grouped by the type of case.

2. **Pull Universe:** The universe collected for this program area tests whether sponsors are 1) accurately identifying and appropriately enrolling targeted beneficiaries in MTM programs, 2) appropriately disenrolling beneficiaries enrolled in MTM programs, and 3) offering and providing required MTM services to the MTM program enrollees. The universe should be compiled using the appropriate record layout as described in Appendix A. This record layout includes:

   - Medication Therapy Management Enrollee (MTME) Universe

   NOTE:
     - The sponsor should include all cases that match the description for this universe for all contracts in its organization as identified in the audit engagement letter (e.g., all beneficiaries, for all contracts in your organization, that were auto-enrolled in each MTM program for the contract year immediately prior to the audit year).

3. **Submit Universe to CMS:** Sponsors should submit the universe in the Microsoft Excel (.xlsx) or Comma Separated Values (.csv) file format <u>with</u> a header row (or Text (.txt) file format without a header row) following the record layout shown in Appendix A (Table 1). The sponsor should submit its universe in whole and not separately for each contract.

Audit Elements

I. Enrollment/Disenrollment

1. **Select Sample Cases:** CMS will select a total of 20 cases from the PDE and MTM universes to test the appropriateness of the sponsor's enrollment of eligible beneficiaries into a MTM program as well as disenrollment from a MTM program. These 20 cases will consist of:

   - 10 cases – non-enrolled members
   - 10 cases – disenrolled members

2. **Review Sample Case Documentation:** CMS will review all sample case file documentation to determine if the Part D sponsor has deficiencies related to the proper identification and processing of targeted beneficiaries for enrollment into an MTM program, and/or the appropriate disenrollment and processing of MTM program members.

   The sponsor will need access to the following documents during the live audit webinar and may be requested to produce screenshots of any of the following:
   - Beneficiary Name
   - Cardholder or member ID
   - CMS Contract ID
   - Effective date of eligibility determination
   - Documentation of targeted beneficiary's MTM program eligibility, including but not limited to drug and diagnosis information
   - Effective date of enrollment into the MTM program
   - Operational policies and procedures for implementing the MTM program
   - Documentation regarding the cognitive impairment determination of the enrollee
   - Effective date of opt-out
   - Documentation of beneficiary's/authorized representative's request to opt-out from the MTM program
   - Documentation of beneficiary's/authorized representative's declination of MTM program services

3. **Apply Compliance Standard:** At a minimum, CMS will evaluate cases against the following criteria. CMS may review factors not specifically addressed in these questions if it is determined that there are other related MTM program requirements not being met.

   3.1. Did the sponsor appropriately identify beneficiaries who met the targeting criteria of their CMS approved MTM program?

   3.2. Did the sponsor appropriately disenroll beneficiaries, when applicable?

4. **Sample Case Results**: CMS will test each of the 20 cases. If CMS requirements are not met, conditions (findings) are cited. If CMS requirements are met, no conditions (findings) are cited. **NOTE:** Cases and conditions may have a one-to-one or a one-to-many relationship. For example, one case may have a single condition or multiple conditions of non-compliance.

II. Comprehensive and Targeted Medication Review (CTMR)

1. **Select Sample Cases:** CMS will select a targeted sample of 20 cases from the MTM universe.

2. **Review Sample Case Documentation:** CMS will review all sample case file documentation to determine if MTM program enrollees were offered and/or provided appropriate, complete and accurate CMRs, including interventions for beneficiaries and/or prescribers, and written CMR summaries in CMS' standardized format. CMS will also review at least 10 cases to determine whether beneficiaries auto-enrolled in an MTM program received accurate, complete and at least quarterly TMRs with follow-up interventions when necessary. During the live review portion of the audit CMS will also verify the accuracy of the dates provided in the universe submission.

   The sponsor will need access to the following documents during the live audit webinar and may be requested to produce screenshots of any of the following, where applicable:

   - Effective date of eligibility determination
   - Documentation of targeted beneficiary's MTM program eligibility
   - Effective date of enrollment into the MTM program
   - Documentation regarding the cognitive impairment determination of the enrollee
   - Documentation regarding identification and outreach to authorized representative for cognitively impaired beneficiaries
   - Documentation of comprehensive medication review (CMR) offer
   - Documentation of beneficiary's/authorized representative's declination of individual MTM services (including CMRs)
   - Documentation including date that a required CMR was administered to the beneficiary as a part of the MTM process (e.g., copy of the comprehensive medication review report)
   - Documentation regarding provider's inability to administer CMR
   - Documentation of personnel involved in the comprehensive medication review
   - Copy of written summary of the comprehensive medication review or alternative documentation of the CMR
   - Documentation including date that a targeted medication review was performed (e.g., copy of the targeted medication review report)
   - Documentation of personnel involved in the targeted medication review
   - Documentation of any interventions taken as a result of the targeted review (or documentation that interventions were not necessary)
   - Effective date of opt-out
   - Documentation of beneficiary's/authorized representative's request to opt-out from the MTM program

3. **Apply Compliance Standard:** At a minimum, CMS will evaluate cases against the following criteria. CMS may review factors not specifically addressed in these questions if it is determined that there are other related MTM requirements not being met.

   3.1. Was a CMR offered at least annually? For newly targeted beneficiaries, was a CMR offered within 60 days of enrollment?

   3.2. For cognitively impaired members, did the sponsor perform appropriate outreach to the beneficiary's authorized representative to offer a CMR?

3.3. Did the sponsor perform an annual comprehensive medication review in accordance with CMS' professional service definition?

3.4. Did the sponsor provide the beneficiary or their authorized representative with a written summary of the comprehensive medication review?

   3.4.1. Was the written summary provided in the standardized format?
   3.4.2. Was the written summary provided within 14 days of the completed CMR?

3.5. Did the sponsor utilize the appropriate qualified staff when performing the CMR?

3.6. Were the required CMR services offered and provided consistent with the approved MTM description?

3.7. Did the sponsor provide TMRs at least quarterly or according to the timeframe as described in the CMS approved MTM description?

3.8. Were the TMRs performed consistent with the approved MTM description?

3.9. Did the sponsor implement beneficiary and/or prescriber interventions resulting from TMRs when necessary and/or as described in the CMS approved MTM description?

4. **Sample Case Results:** CMS will test each of the 20 cases. If CMS requirements are not met, conditions (findings) are cited. If CMS requirements are met, no conditions (findings) are cited. **NOTE:** Cases and conditions may have a one-to-one or a one-to-many relationship. For example, one case may have a single condition or multiple conditions of non-compliance.

Appendix

Appendix A – Medication Therapy Management (MTM) Record Layout

The universe for the Medication Therapy Management program area must be submitted as a Microsoft Excel (.xlsx) or Comma Separated Values (.csv) file <u>with</u> a header row reflecting the field names (or Text (.txt) file without a header row). Do not include the Column ID variable which is shown in the record layout as a reference for a field's column location in an Excel or Comma Separated Values file. Do not include additional information outside of what is dictated in the record layout. Submissions that do not strictly adhere to the record layout will be rejected.

Note: There is a maximum of 4000 characters per record row. Therefore, should additional characters be needed for a response, enter this information on the next record at the appropriate start position.

Table 1. Medication Therapy Management Enrollee (MTME) Record Layout

- Include all beneficiaries auto-enrolled in the sponsor's MTM program as required under 42 CFR § 423.153(d) and the CMS approved MTM Description. If a beneficiary was auto-enrolled more than once in an MTM program during the contract year, include information related to the first effective enrollment in a MTM program during that year. This would include MTM information from the date of the first contract enrollment that offered an MTM program through the end of the year or through disenrollment from the MTM program (if applicable) – whichever comes first.
  - **When populating this universe, sponsors should use data from the contract year immediately prior to the audit year.** For example, for audits conducted in 2017, sponsors should populate this universe using the MTM data from contract year 2016.
- Exclude beneficiaries who did not meet the eligibility criteria under section 42 CFR § 423.153(d).

Column ID	Field Name	Field Type	Field Length	Description
A	HICN	CHAR Always Required	15	Health Insurance Claim Number assigned by the Social Security Administration to an individual for the purpose of identifying him/her as a Medicare beneficiary. The number is typically between seven and 11 digits long excluding hyphens or dashes (e.g., 123456789A) and should be submitted as it appears in MARx.
B	Beneficiary First Name	CHAR Always Required	50	First name of the beneficiary.
C	Beneficiary Last Name	CHAR Always Required	50	Last name of the beneficiary.
D	Date of Birth	CHAR Always Required	10	Date of birth of the beneficiary. Submit in CCYY/MM/DD format (e.g., 1940/01/01).
E	Enrollment Effective Date (Contract)	CHAR Always Required	10	Effective date of enrollment for the beneficiary into a contract. If the beneficiary was enrolled in multiple contracts during the year, enter the contract enrollment effective date for the first contract ID that offered an MTM program. Submit in CCYY/MM/DD format (e.g., 2016/01/01).

Column ID	Field Name	Field Type	Field Length	Description
F	Cardholder ID	CHAR Always Required	20	Cardholder identifier used to identify the beneficiary. This is assigned by the plan.
G	Contract ID	CHAR Always Required	5	The contract number (e.g., H1234) of the organization. If the beneficiary was enrolled in multiple contracts during the year, enter the first contract ID that offered an MTM program.
H	MTM Eligibility Date	CHAR Always Required	10	Date sponsor determined the beneficiary's eligibility for the MTM program. If the beneficiary was enrolled in multiple contracts during the year, enter the MTM program eligibility determination date for the first contract ID that offered an MTM program. Submit in CCYY/MM/DD format (e.g., 2016/02/01).
I	MTM Enrollment Date	CHAR Always Required	10	First effective date of auto-enrollment for the beneficiary into the MTM program. Submit in CCYY/MM/DD format (e.g., 2016/02/01).
J	Did beneficiary Opt-out of the MTM Program?	CHAR Always Required	1	Yes (Y) or No (N) indicator of whether the beneficiary opted-out of the first auto-enrollment in the MTM program. Opt-out includes a request from the beneficiary or authorized representative to be disenrolled from the MTM program, beneficiary changing to a different contract not covered by the existing MTM program, or death. Opt-out does not include a request to decline individual MTM services, such as CMRs.
K	MTM Opt-out Date	CHAR Always Required	10	Date beneficiary or authorized representative opted-out of the first MTM program. If the opt-out was due to death, please include the date the sponsor was made aware of the beneficiary's death if the actual date of death is not available. Submit in CCYY/MM/DD format (e.g., 2016/03/01). Answer NA if the beneficiary did not opt-out of the MTM program.
L	MTM Opt-out Reason	CHAR Always Required	2	Reason for opt-out of the first MTM program. Valid values are: 01 = Death 02 = Beneficiary disenrolled from contract 03 = Beneficiary requested opt-out 04 = Other (e.g., authorized representative requested opt-out) Enter NA if the beneficiary did not opt-out of the first MTM program into which they were auto-enrolled.

Column ID	Field Name	Field Type	Field Length	Description
M	MTM Opt-out Reason Explanation	CHAR Always Required	750	Answer NA if the opt-out type was "01 (Death)," "02 (Disenrolled from contract)," or the beneficiary was not disenrolled by the organization from the first MTM program. If "03 (Beneficiary requested opt-out)" was selected for the MTM program opt-out reason, explain why the beneficiary requested to opt-out of the MTM program. Answer "no reason provided" if the beneficiary did not provide an explanation for their request to opt-out of the MTM program. If "04 (Other)" was selected, please further define this option and explain the reason it led to an opt-out.
N	Was the beneficiary residing in a long term care facility?	CHAR Always Required	2	Indicate whether the beneficiary was identified as being in long term care facility either at the time the first CMR was offered or administered during the year. Sponsors should use all available information to determine LTC status at the time the MTM services are offered and administered, such as the patient residence code on drug claims data and the Long Term Institutionalized (LTI) resident report. Valid values are: Y = Yes N = No U = Unknown Answer NA if no CMRs were offered or administered during the year.
O	Cognitively Impaired	CHAR Always Required	2	Indicate whether the beneficiary was identified as being cognitively impaired either at the time the first CMR was offered or administered? Valid values are: Y = Yes N = No U = Unknown Answer NA if no CMRs were offered or administered during the year.
P	Authorized Representative	CHAR Always Required	2	Indicate whether the beneficiary had an authorized representative (e.g., prescriber, caregiver, health care proxy or legal guardian) either at the time the first CMR was offered or administered during the year? Valid values are: Y = Yes N = No U = Unknown Answer NA if no CMRs were offered or administered during the year.

Column ID	Field Name	Field Type	Field Length	Description
Q	Number of CMRs offered	CHAR Always Required	2	Total number of distinct CMRs for which offers were delivered to the beneficiary, regardless of the number and type of delivery methods attempted for the CMR offer. Answer "0" (zero) if no CMRs were offered during the year. **NOTE:** In order to count as a CMR offer it must have been received by the MTM program member (e.g., returned mail or incorrect phone numbers do not count as an offer).
R	Number of CMRs administered	CHAR Always Required	2	Total number of CMRs administered during the year. Answer "0" (zero) if no CMRs were administered during the year.
S	Number of written CMR summaries	CHAR Always Required	2	Total number of written CMR summaries provided during the year. Answer "0" (zero) if no CMRs were administered or no written CMR summaries were provided during the year.
T	Date of 1st CMR offer	CHAR Always Required	10	Date the first CMR was offered. Submit in CCYY/MM/DD format (e.g., 2016/02/16). Answer NA if no CMRs were offered in during the year.
U	1st CMR offer declined?	CHAR Always Required	2	Yes (Y) or No (N) indicator of whether the first CMR offered was declined. Answer NA if no CMRs were offered during the year.
V	Who declined 1st CMR offer?	CHAR Always Required	2	Indicate who declined the first CMR offer. Valid values include: Beneficiary (B) and authorized representatives such as the Prescriber (P), Caregiver (C), or other Authorized Individual (AI) such as a beneficiary's health care proxy or legal guardian. Answer NA if no CMRs were offered during the year or the first CMR offer was not declined.
W	Date 1st CMR administered	CHAR Always Required	10	Date the first CMR was administered. Submit in CCYY/MM/DD format (e.g., 2016/03/01). Answer NA if no CMRs were administered during the year.
X	1st CMR Delivery Method	CHAR Always Required	2	Indicate the delivery method for the first CMR administered. Valid values include: Face-to-face (FF), Telephone (T), Telehealth Consultation (TH) (e.g., video-conference) or Other (O). Answer NA if no CMRs were administered during the year or the beneficiary/authorized representative declined CMR services.
Y	Qualified Provider of 1st CMR	CHAR Always Required	300	Indicate the type of qualified provider that administered the first CMR. Valid values include: Physician; Registered Nurse; Licensed Practical Nurse; Nurse Practitioner; Physician's Assistant; Local Pharmacist; LTC Consultant Pharmacist; Plan Sponsor Pharmacist; Plan Benefit Manager (PBM) Pharmacist; MTM Vendor Local Pharmacist; MTM Vendor In-house Pharmacist; Hospital Pharmacist; Pharmacist – Other; or Other. Answer NA if no CMRs were administered during the year or the beneficiary/authorized representative declined CMR services.

Column ID	Field Name	Field Type	Field Length	Description
Z	1st CMR Recipient	CHAR Always Required	10	Indicate who received the first CMR. Valid values include: Beneficiary (B) and authorized representative such as the Prescriber (P), Caregiver (C), or other Authorized Individual (AI) such as a beneficiary's health care proxy or legal guardian. If there were multiple recipients, separate entries by forward slashes (/). Answer NA if no CMRs were offered during the year or the beneficiary/authorized representative declined CMR services.
AA	Date 1st Written CMR Summary Provided	CHAR Always Required	10	Date the first written CMR summary was provided in. Submit in CCYY/MM/DD format (e.g., 2016/03/15). If the CMR summary is not given to the beneficiary immediately after the CMR, enter the date the CMR summary leaves the sender's establishment by US mail, fax, or electronic communication. Answer NA if no written CMR summaries were provided during the year.
AB	Number of TMRs performed	CHAR Always Required	3	Total number of TMRs performed during the year. Answer "0" (zero) if no TMRs were performed.
AC	Date of 1st TMR performed	CHAR Always Required	10	Date of the first TMR performed during the year. Submit in CCYY/MM/DD (e.g., 2016/02/05). Answer NA if no TMRs were performed.
AD	Were interventions necessary for any TMRs?	CHAR Always Required	2	Yes (Y) or No (N) indicator of whether follow-up interventions were deemed necessary based on the results of any TMRs conducted during the year. Answer NA if no TMRs were performed.
AE	Date of 1st TMR requiring intervention(s)	CHAR Always Required	10	Date of the first TMR <u>requiring</u> follow-up intervention(s). This may be different than the date of the first TMR performed as some TMRs may not result in the need for an intervention. Submit in CCYY/MM/DD (e.g., 2016/03/01). Answer NA if no TMRs were performed during the year or interventions were not necessary for any TMRs.
AF	TMR Intervention Recipient(s)	CHAR Always Required	20	Indicate who was targeted to receive the first TMR follow-up intervention(s). Valid values include: Beneficiary (B) only, Prescriber (P) only, or both Beneficiary and Prescriber (BP). Answer NA if no TMRs were performed during the year or interventions were not necessary for any TMRs.

Column ID	Field Name	Field Type	Field Length	Description
AG	TMR Intervention(s) Delivered?	CHAR Always Required	2	Yes (Y), No (N), or Some (S) indicator of whether the first TMR drug therapy problem (DTP) recommendation intervention(s) were delivered. Answer "Y" if every DTP intervention was delivered. Answer "N" when no attempt was made to deliver an intervention or an attempt was unsuccessful (e.g., returned mail or wrong number). Answer "S" if some, but not all of the first TMR DTP interventions were delivered. Answer NA if no TMR interventions were delivered, no TMRs were performed during the year, or interventions were not necessary for any TMRs.
AH	TMR Intervention(s) Delivery Date	CHAR Always Required	10	Date the first TMR DTP recommendation intervention was delivered to the targeted recipient. When there are multiple DTP recommendation interventions for the TMR, submit the date that the last one was delivered. Submit in CCYY/MM/DD. Answer NA if no TMR interventions were delivered, no TMRs were performed during the year, or interventions were not necessary for any TMRs.